Draft Rule Comments

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Comments

Dear State Officials and Advisory Committee Members:
As the trade association for Ohio’s new cannabis industry, we act as the central voice to bring Ohio businesses, patients, advocates, leaders and consumers together to promote a safe cannabis marketplace that improves the economy and ultimately the quality of life for all residents.

We have conducted a review of the proposed regulations for physicians and believe there are key areas that need to be addressed and improved:

1. Definition of Licensed Physician
   a. Current definition suggests that only MD/DO who are also surgeons would be able to recommend. Not all physicians are licensed to do surgeries and that was certainly not the intent of the legislation.
   Our Recommendation: This is likely an oversight that must be corrected. Authorization should be given to any licensed professional who has the authority to prescribe.

2. New Qualifying Conditions.
   a. New studies are being conducted all the time and requirements that impose a 1-year wait are too long, especially for patients who are suffering.
   b. 4731-32-05 (C) 5 imposes an unrealistic requirement of proof making it impossible cannabis to be an alternative option to treat potentially new conditions. Under this restriction it will be nearly impossible to add new qualifying conditions.
   Our Recommendation: Window should be every 6-months or twice a year rather than just annually. 4731-32-05 (C) 5 must be removed.

Ohio Families CANN – In Pursuit of Promising Cannabis Therapy
We are a statewide organization of parents of significantly ill children, who have already been prescribed many failed pharmaceutical medications. We appreciate the opportunity to share our perspective as citizens who will be utilizing this program, and as Ohioans who have become quite familiar with many other parents and patients around our country whose state policies allow for various levels of access to a better, safer medicine for their loved ones.

First and foremost, we expect our government officials will create policies that afford us ease of access and regulations that support low cost cannabis therapy.

OSMB Proposed RULE: (7) Documented review that that standard medical treatment has been attempted or considered, and one of the following is met:
(a) The patient had inadequate treatment response to standard medical treatment;
(b) The patient was unable to tolerate the standard medical treatment;
(c) Standard medical approaches are

OFC response: Patients and parents should be afforded the civil right and patient autonomy to trial cannabis therapy as a first option. The above rule seems based in the false notion that non-cannabis therapies are a safer first therapy. It is a false notion that barbiturates, benzodiazepines and/or opiates are known to be safer for babies and young children. Our experience with years of failed pharmaceuticals tells us that traditional therapies come with significant detriment themselves and that cannabis therapy can be positive choice of harm reduction from traditional pharmaceuticals. The long term effects of the former medications have never been tested on children, yet they run the risk of death, need for oxygen, and greater distress from withdrawal, to name a few negative side effects of the failed pharmaceuticals our children have endured.

I hope we can agree that while there is more to know about cannabis therapy. What IS known is that cannabis therapy cannot cause a lethal overdose, withdrawal is considered far less significant than barbiturates, benzodiazepines and/or opiates. And while there is early evidence pointing to necessary risk assessments for developing brains, one cannot state definitively that other heavy hitting epilepsy, cancer, and pain medications that are currently being prescribed, come with less risk for young children.

To therefor require a parent or patient to first fail a barbiturates, benzodiazepines and/or opiates is not acceptable. Parents should be allowed the civil right to choose a promising new option.

The statute suggests that in order to obtain a Medical Marijuana Certification, “a patient must access the risks and benefits of cannabis therapy.” This means, “as compared to other existing therapies” and is a sufficient rule.

OSMB Proposed RULE: (f) Any instructions for use of medication marijuana, as determined by the physician.
The National Association of Social Workers, Ohio Chapter (NASW-OH) holds the position that as medical marijuana is made available in the state, consideration should be given to the accessibility of the medication to all Ohioans. This includes low-income patients, the elderly, and persons with disabilities. The current proposed rules could limit accessibility in the following ways.

- **Recommendation frequency limited to every 90 days.**
  - NASW-OH recommendation: With a commonly abused substance such as marijuana, it is reasonable to have more frequent visits early in a patient’s treatment plan. However, the Advisory Committee could consider some allowance for an extension of time between visits after set goals are met. As an example, a patient could be limited to one recommendation every 90 days for the first year, and in consideration of their compliance and the treatment plan, the patient could then be eligible to receive a recommendation every 180 days.

- **Restrictions on delivery of medication.**
  - NASW-OH recommendation: Homebound Ohioans and those without transportation are currently able to take advantage of delivery services. While security is certainly a concern, NASW-OH encourages the Advisory Committee to consider delivery options under some conditions such as limited mobility and transportation limitations.

As public comments are considered, NASW-OH would like to propose extensive consideration of cost accessibility during rule revision processes. Because marijuana is illegal under federal law, it is unlikely that Ohio patients will have medical marijuana covered through any available health insurance. As in most other legal states, the cost of medical marijuana will likely be paid for out of pocket by patients, presenting a significant cost barrier for some Ohioans. Many patients qualifying for medical marijuana may often be incapacitated by their illness, making it difficult for them to maintain full-time jobs. Discounts or insurance type programs for low-income patients may be necessary to guarantee access for Ohioans who are eligible for the alternative treatment.

The cost of medical marijuana treatment can quickly add up, as we’ve learned from the experiences of other legal states. Often, patients are required to register with the state, purchase a license or ID card, and attend multiple initial visits with a doctor.

**Sir, Ma'am,**

With many thanks I first acknowledge an appreciation of your open ears and minds in accepting public input to your decision making process.

About myself in brief, USAF Veteran, retired Law Enforcement 20yrs, private investigator 5yrs, retail management safety/security 15yrs, 28yrs total in the safety/security disciplines and 40yrs personal/professional experience in the cannabis industry. Involved with HB523 development from inception to date.

I have addressed and submitted issues of concern to the Medical Board, Pharmacy Board and various government bodies involved with the promulgation of rules/regulations, growth of success and those in enforcement of HB523. My inquiry of concern now is that of safety and security. As an Ohio based company and citizen I have seen or heard of very minimal standards to be applied in the safety and security sectors of this emerging valued industry being introduced to Ohio. As this discipline to the medicinal cannabis industry seems to be of least concern, I strongly encourage the factors of safety and security become one of utmost importance. As we see across the nation issues in this sector need to be addressed via best practices from States employing such successful programs. From exterior to interior barriers, employee training, vaults, safe glass, security systems (audio, visual, tracking, scan recognition, cloud based systems, and physical security) and a cash based business all present questions of need and use.

Furthermore questions of reporting an incident to law enforcement authorities brings alarm to all grow, process, research and dispensary employees as result of federal schedule 1 classification.

Access to cctv systems by governing bodies may be an issue of concern for all involved as well. Presenting both positive and pejorative view points this can be a valuable tool in the ethical operation via monitoring these facilities. Inspections play a vital role as well in the safety, security, and peace of mind to these facilities. What is expected per inspecions is a concern of utmost importance.

Hello, attached are comments from the Ohio Pharmacists Association in regards to the proposed rules for Physician Certificate to Recommend Medical Marijuana and Petition for Added Qualifying Condition.

Thank you for the opportunity to provide our feedback, and we look forward to working with you on refining these rules to ensure patient safety in Ohio.
Documented review of prior treatment and the patient’s response to the treatment

Hello,

my name is Karen Pilarski, D.O.,

With Ohio being one of the first states to want to understand the effectiveness and potential burdens of medical marijuana as well as the requirements to conduct MM testing for potency, homogeneity and contamination and prepare lab result an unique opportunity is created to capture data based results showing effectiveness, safety, and issues.

• We need a system to: Determine and communicate to doctors, patients, and patient advocates the most effective strains and dosages of medical marijuana as they relate to various diseases and pain levels.
• We need a concept to use a web based system available through any browser that patients can input information as they are utilizing the treatments. Utilizing biometric and patient response system that assess the effectiveness of the patient’s treatment.

Some examples of Additional Data could be requested pinpointing points of the body impacted such as: Sleepy, Hungry or Anxious

Intervals of time that can be suggested or customized – information will be requested by the system. Prompt such a buzz or vibration.

Advances in wireless technologies, low-power electronics, the internet of things, and in the domain of connected health are driving innovations in wearable medical devices.

- Single-Lead ECG
- Heart Rate
- RR Interval
- Heart Rate Variability
- Respiratory Rate
- Skin Temperature
- Body Posture
- Fall Detection

With information the Doctors can adjust plans based on each unique experience of the patient utilizing real data.

They system should include:

Attached please find Cleveland Clinic’s comments on the referenced draft rules. Thank you for the opportunity to participate in this important policy process.

I would like to specifically address the section of the Medical Marijuana Control Program’s section and the summary provided by the State Medical Board of Ohio that discusses the Petition to Request Additional Qualifying Conditions. It is irresponsible to not include the treatment of opiate addictions as a covered condition. There is sufficient medical evidence to support the use of marijuana in the process of opiate detoxification and ongoing management. For decades the medical profession has used opiate derivatives like methadone and buprenorphine for the treatment of opiate addiction. Many of these individuals initially become dependent upon opiates due to pain conditions but under our current standards of practice, prescription options have most frequently included opiates, almost exclusively.

While it is reassuring to see that pain and other pain-related conditions were included in the list of qualifying conditions, it seems only responsible, in the midst of an opiate crisis, that we take the next step to allow medical marijuana to be used to help those dependent upon opiates. The use of marijuana to assist patients in tapering off of opiates, while also then, receiving the desired benefit of managing pain with a much less dangerous medication is a safe and intelligent patient-centered intervention. Certainly there may be other protocols that doctors may wish to add to this strategy, like the addition of oral dose naltrexone or the injectable form, Vivatrol.

I am sending this prepared letter written by DFAA... I agree with these concerns. I am grandmother to 16 beautiful, vulnerable children & I am very concerned about where Ohio is headed. I am also mother to a kind, handsome 39 yr old, who happens to be a Heroin addict. He first used marijuana when he was 14. There are ways to obtain the benefits of this drug medically but Physicians need longer than two hours of education to realize the RISKS of prescribing medical marijuana. Prescribing medical marijuana should be RARE! I know people who live in other states with medical marijuana, and some say it is very easy to get a medical marijuana card. For the sake of our citizens, especially our youth, please limit the prescribing of medical
Attached, please find MPP’s comments on the proposed rules for physicians operating in the state medical marijuana program.

The authors of the research noted the important finding that substance abuse rates for patients with ADHD are significantly more likely to have substance abuse issues and to smoke cigarettes, compared with their peers without a history of the disorder. The authors of the research also noted that teenagers with ADHD, anxiety, depression, and childhood trauma are more likely to have a alcohol use disorder within 3 years; marijuana users who already had an alcohol use disorder at the outset were at greater risk of their alcohol use disorder worsening. Marijuana use is also linked to other substance use disorders including nicotine addiction.

Research indicates that for some people, a combination of risk factors including biological and environmental conditions create the opportunity for the development of substance use disorders when exposed to drugs, including marijuana. For example, the National Institute on Drug Abuse documents that "a study using longitudinal data from the National Epidemiological Study of Alcohol Use and Related Disorders found that adults who reported marijuana use during the first wave of the survey were more likely than non-users to develop an alcohol use disorder within 3 years; marijuana users who already had an alcohol use disorder at the outset were at greater risk of their alcohol use disorder worsening. Marijuana use is also linked to other substance use disorders including nicotine addiction."

It is also important for us to take into account the research on conditions that create increased risk for the development of substance use disorders and to reflect such science in Ohio’s policies and practices. For example, Ohio did this in 2014 when we passed a law that increased the informed consent requirements for the prescribing of opioids to minors so that parents would have a better opportunity to understand the risk of consuming medications that research indicates can lead to substance abuse, dependency, or addiction.

Sometimes marijuana can be a gateway drug for adolescents and teens, particularly those with conditions identified as connected to early onset of substance use and dependency and addiction later in life. For example, there is a significant body of research that indicates a link between substance use disorders and conditions such as ADHD, anxiety, depression, impulsivity disorder, and childhood trauma. A study published in the Journal of the American Academy of Child & Adolescent Psychiatry (March 2013 Volume 52, Issue 3, Pages 250–263) documented that teenagers with attention deficit hyperactivity disorder (ADHD) are significantly more likely to have substance abuse issues and to smoke cigarettes, compared with their peers without a history of the disorder. The authors of the research noted the important finding that substance abuse rates

| §4731-32-03(A) | Consider telemedicine technology to satisfy the “in-person” requirement. |
| §4731-32-03(A)(5) | The dispensary rules seem to talk about providing medical marijuana to adults only and here it talks about minors. Consistency, please. Both should read from minors with the consent of parent or guardian. |
| §4731-32-03(A)(5)(ii) | Where is the database housed? With the Board of Pharmacy? |
| §4731-32-03 (B)(7) | Creating a medical marijuana program in Ohio means that marijuana is medicine. Ohio has created a list of qualifying conditions for the state of Ohio. Patients should only have to have a diagnosis from their physician, based on a bona fide physician-patient relationship that the patient has one of the qualified conditions in order to make a recommendation for medical marijuana. What is the “standard medical treatment”? Opioids? Other pharmaceuticals? Patients and doctors should not have to demonstrate that other treatments did not elicit a certain response, or that the treatments were not “tolerable.” If medical marijuana is to be a viable medicine for patients with qualifying conditions, the patients should not have to suffer through these hoops. If the patient determines, with their bona fide physician’s physical examination, that medical marijuana is the appropriate treatment, which should be sufficient. |
| DISCUSSION and RATIONALE: | The requirements for physician recommendations should model Colorado’s more closely. The rule in Ohio, as written, will providers of healthcare and other supports including prevention, treatment, and recovery services for individuals with mental or substance use disorders and for their family members. We are grateful for the thoughtful work that is reflected in these draft rules and believe that they go a long way in establishing conditions that promote the health and safety of all Ohioans. To further this goal and to make the practice of recommending medical marijuana consistent with that of prescribed medications in Ohio, the Ohio Council recommends the following changes to the proposed rules for the regulation of medical marijuana through the State Medical Board of Ohio. |

The Ohio Council of Behavioral Health & Family Services Providers is a non-profit organization representing over 150 providers of healthcare and other supports including prevention, treatment, and recovery services for individuals with mental or substance use disorders and for their family members. We are grateful for the thoughtful work that is reflected in these draft rules and believe that they go a long way in establishing conditions that promote the health and safety of all Ohioans. To further this goal and to make the practice of recommending medical marijuana consistent with that of prescribed medications in Ohio, the Ohio Council recommends the following changes to the proposed rules for the regulation of medical marijuana through the State Medical Board of Ohio.

To recommend medical marijuana, a physician must:
1. Have an active MD or DO license in good standing with the state of Colorado.
2. Submit a copy of your current DEA Certificate to the Registry. If a copy of the DEA certificate is not already on file, please email it to: medical.marijuana@state.co.us
3. Have a bona fide physician-patient relationship with the patient.
4. Conduct a physical examination each year and review patient’s medical history to certify the patient has a qualifying debilitating medical condition.
5. Complete a physician certification for the patient. A new physician certification is required each year as part of the patient’s renewal process.
6. Provide a copy of the physician certification to the patient for their application packet.
7. Keep a copy of the completed physician certification in the patient’s medical record.”

The requirements for physician recommendations should model Colorado’s more closely. The rule in Ohio, as written, will providers of healthcare and other supports including prevention, treatment, and recovery services for individuals with mental or substance use disorders and for their family members. We are grateful for the thoughtful work that is reflected in these draft rules and believe that they go a long way in establishing conditions that promote the health and safety of all Ohioans. To further this goal and to make the practice of recommending medical marijuana consistent with that of prescribed medications in Ohio, the Ohio Council recommends the following changes to the proposed rules for the regulation of medical marijuana through the State Medical Board of Ohio.

DISCUSSION and RATIONALE:

Research indicates that for some people, a combination of risk factors including biological and environmental conditions create the opportunity for the development of substance use disorders when exposed to drugs, including marijuana. For example, the National Institute on Drug Abuse documents that “a study using longitudinal data from the National Epidemiological Study of Alcohol Use and Related Disorders found that adults who reported marijuana use during the first wave of the survey were more likely than non-users to develop an alcohol use disorder within 3 years; marijuana users who already had an alcohol use disorder at the outset were at greater risk of their alcohol use disorder worsening. Marijuana use is also linked to other substance use disorders including nicotine addiction.”

It is also important for us to take into account the research on conditions that create increased risk for the development of substance use disorders and to reflect such science in Ohio’s policies and practices. For example, Ohio did this in 2014 when we passed a law that increased the informed consent requirements for the prescribing of opioids to minors so that parents would have a better opportunity to understand the risk of consuming medications that research indicates can lead to substance abuse, dependency, or addiction.

Sometimes marijuana can be a gateway drug for adolescents and teens, particularly those with conditions identified as connected to early onset of substance use and dependency and addiction later in life. For example, there is a significant body of research that indicates a link between substance use disorders and conditions such as ADHD, anxiety, depression, impulsivity disorder, and childhood trauma. A study published in the Journal of the American Academy of Child & Adolescent Psychiatry (March 2013 Volume 52, Issue 3, Pages 250–263) documented that teenagers with attention deficit hyperactivity disorder (ADHD) are significantly more likely to have substance abuse issues and to smoke cigarettes, compared with their peers without a history of the disorder. The authors of the research noted the important finding that substance abuse rates

| Word attachment pdf attachment | Attached, please find MPP’s comments on the proposed rules for physicians operating in the state medical marijuana program. |
certified to recommend Medical Marijuana. As a parent of a child with several debilitating disorders that show promise of improvement with the opportunity to trial medical cannabis, our family anxiously awaits the start of this program. We would like to provide comment on OSMB Proposed Rule 4731-32-03 Standard of Care, Section B. Item 7 which requires the Physician to include 'Documented review that standard medical treatment has been attempted or considered and one of the following is met: (a). The patient had inadequate treatment response to standard medical treatment (b). The patient was unable to tolerate the standard medical treatment (c). Standard medical approaches are not appropriate in this patient for other documented reasons.' Due to our son’s complicated medical needs, we are forced to continuously weigh the risks associated with many of his prescribed medications, and this effort often takes not days, not weeks, but months/years before we understand if 1). the medication is effective 2). he is at the proper therapeutic dose and 3). what the long term negative effects will be (which we have discovered, unfortunately, to be far greater than we were told to expect when he began these medications at age 8). This rule suggests that cannabis cannot be used as a first-line medication, but instead is recommended as a last resort. It is known and validated that the toxicity levels of many pharmaceuticals is substantially higher than cannabis. Patients should not be expected to first trial and fail the use of opiates, barbiturates, benzodiazepines or atypical antipsychotics before a medical cannabis recommendation is allowed. Currently, in pain clinics there is a statement required by physicians to disclose to patients that there is "no exit" off of narcotic therapy for chronic pain treatment. Narcotics, which are highly addictive, can instigate severe, sometimes life threatening withdrawal symptoms. There is substantiated evidence that Medical marijuana does not run these same risks. It feels morally abhorrent to place regulations that require a physician to exhaust narcotic options before recommending medical marijuana to their patients. Patients should be afforded the right to trial cannabis therapy as a first option, or at the very least as an immediate option in conjunction with 'standard medical treatment'. A second concern involves the same Proposed Rule, section (H): The physician shall submit to the board an annual report describing the physician’s observations regarding the effectiveness of medical marijuana in treating patients: While we are very encouraged and dedicated to the need for data to be collected and reported regarding the use of medical cannabis, we are concerned that if left as vague, Physicians will face an undue burden in determining what is appropriate to submit. Our request would be that a specific form/report is provided to ensure recommending Physicians have reasonable guidelines to follow, so as to ensure they are not risking loss of certificate for providing inadequate or insufficient information. And finally, regarding 4731-32-05 Petition to Request Additional Qualifying Condition or Disease, Any petition for a condition that has been previously reviewed by the board and rejected will not be considered by the board unless new scientific hours for every renewal of their license. Those CMEs should include training on addiction and the mental and physical health risks. Doctors should recommend dosage and strength when they recommend marijuana, just like with any other medicine. Pregnant women should not receive a recommendation. Doctors should not be allowed to advertise that they will or can recommend marijuana. Instead, it should come up during I don’t feel the training requirement for initial certificates to recommend are sufficient. I feel that 8 hours would be more appropriate, and that it should contain information on addiction, as well as mental and physical risks involved with marijuana use. Also, to renew a certificate, a refresher course should be mandatory, as with many other licenses. A minimum of 2 hours per renewal period, if not annually. Doctors should be required to give a recommended dosage and TCH content level when they recommend, which dispensaries should have to see when filling the “recommendation”. Pregnant women should not be allowed to use medical marijuana. Doctors should not be allowed to advertise their certificates to recommend, as this will lead to doctor shopping and potentially to a patient not receiving adequate care standards. While many people feel marijuana is harmless, there are many respected studies that show it can indeed be addictive and harmful. Please take into account not only those who may benefit from some medicinal properties, but also the community as a whole that will be exposed to the industry
In reviewing the proposed rules for physician certificate requirements, I was struck by the relative lack of training requirements for the educational component on medical marijuana, a drug with more than 60 chemicals, most of which we know very little about, that can be recommended to treat a wide variety of medical conditions. Further, the products themselves, which I recognize have not been defined as of yet by the committee, can be manufactured into a seemingly endless variety of dosage forms and concentrations. Currently, this educational requirements stands at 2 hours. While we want to avoid making this educational component time-prohibitive, it is certainly in stark contrast to the requirement of 8 hours to obtain a certificate to prescribe buprenorphine-containing products which contain up to 2 active compounds for managing the disease of addiction. Secondly, the Federation of State Medical Boards (FSMB) have published the Model guidelines for the recommendation of marijuana in patient care in April 2016 in which the following recommendations were made that physicians address the potential risks of the medical use of marijuana with the patient to include

- The variability of quality and concentration of marijuana;
- The risk of cannabis use disorder;
- Use of marijuana during pregnancy or breastfeeding;
- The need to safeguard all marijuana and marijuana-infused products from children and pets or domestic animals; and
- The need to notify the patient that the marijuana is for the patient’s use only and the marijuana should not be donated or otherwise supplied to another individual.

Thus, I would urge the board to add language that would make the educational requirements address the (potential) variability of quality and concentration of medical marijuana products that will be available, cannabis use disorder, side effects or adverse events that may be associated with medical marijuana, the use of marijuana during pregnancy or breastfeeding and the potential risks for infants and children who may come into contact with these products so that physicians can meet the requirements set forth by the FSMB. I would also add like to recommend that the board consider requiring a component that teaches signs of drug diversion or potential abuse/addiction as the wording of the bill currently calls for the physician to making process.

About myself in brief, USAF Veteran, retired Law Enforcement 20yrs, private investigator 5yrs, retail management safety/security 15yrs, 28yrs total in the safety/security disciplines and 40yrs personal/professional experience in the cannabis industry. Involved with HB523 development from inception to date.

My input comes from direct contact, personal/professional, with those in the medical disciplines. Regulatory guidelines discourage participation for many Physicians by adding unwarranted documentation cycles creating a financial and workload burdensome on the office staff. Requirements of background drug abuse issues, 90 day evaluation cycles, biases toward cannabis in relationship to other RX meds, restrictions of use with other RX meds, waiting periods while sampling other RX meds to treat an ailment, biased toward qualifying conditions, time frames to add potential new ailments, physicians personal biases via morals/values to participate in the program......etc. For physicians I recognize “to cause no harm”. Would it then be fair to say by not providing the use of a known medicinal valued plant, to which many of our medicines today were derived from.

With an understanding to a course of certifying physicians to recommend in compliance of law is perfectly acceptable and in doing so the, private, relationship between a patient and physician should be honored and respected as it is with any other medication or ailment. It is clear Ohio physicians have been left behind in the scientific studies of the endocannabinoid system

I strongly suggest modifying the dispensary requirements as found in 3796:6-5-01. A total revision of oppressive Medical marijuana dispensary fee structure to be in line with current pharmacy fees

For the following reasons

From a business owner’s perspective: The expense of such fees is a grossly over inflated when comparing these cost to other like businesses. These fees should be the same as any other pharmaceutical business. Excessive fees will deter potential businesses from establishing in the state and that will result in a loss of income for the state.

From an economic viewpoint: The extra financial burden will most likely be passed on to the patient and raise the cost of the medicine. This will deter patient use of the program and result in a loss of revenue for the state.

From a law enforcement Viewpoint: Increased cost of medical marijuana serves to only maintain the black market.

Thank you for your time and consideration in this matter. I am a small business owner and I have lost my parents to cancer.
From a patients view point: This rule should be a warning similar to the one found on the pharmaceutical drug Marinol. Caution should be advised but the effects of cannabis varies and not all users will respond the same. Cannabis strains and strengths will also vary and some strains will have little or no affect on motor skills. This puts the patient in unnecessary risk for OVI or driving under the influence charges. This risk may deter potential patients from using the system and result in a loss of revenue for the state.

From an economic viewpoint: The extra risk of criminal charges will keep patients from using the system as being a medical marijuana patient could subject you to police profiling and harassment. This will deter patient use of the program and result in a loss of revenue for the state.

From a law enforcement Viewpoint: Increased cost and burden of policing medical marijuana patients serves to only alienate a already strained police/citizen relationship and subtract from other areas where the police are needed. Small towns and some

**3796:6-3-06 Medical marijuana dispensary clinical director**

A. A dispensary shall appoint a key employee who is a pharmacist licensed under Chapter 4729. of the Revised Code, or any of the following licensed health professionals authorized to prescribe drugs under division (I) of section 4729.01 of the Revised Code, if also authorized by the provider’s licensing agency:

For the following reasons

From a business owner's perspective: The expense of hiring a license pharmacist will greatly increase the cost of operation which will place a unnecessary burden on any business. Cannabis is not a pharmaceutical and therefore does not need a license pharmacist.

From an economic viewpoint: The extra financial burden will most likely be passed on to the patient and raise the cost of the medicine. This will deter patient use of the program and result in a loss of revenue for the state.

From a law enforcement Viewpoint: Increased cost of medical marijuana serves to maintain the black market.

Thank you for your time and consideration in this matter. I am a small business owner and I have lost my parents to cancer.

Good comments, Jennifer! (in response to OSMA's comments)

many adults already think that marijuana is harmless and more and more kids are smoking marijuana daily. Kids also believe it is medicine and have to be educated that only FDA approves medicine. Many think that marijuana cures cancer and have to be educated that it any treats symptoms. Smoking marijuana damages your lungs worse than cigarettes, kids forget that and need to be educated. I am thankful that smoking medicinally is not legal, but am very concerned that youth and young kids are going to get ahold of the substance because it can be so appealing (gummies, oils, etc). Kids will get their hands on it even more if the access to it increases. There are so many misconceptions of marijuana already in Ohio. As states legalize for medicinal and even recreational use, more and more kids and even adults, change their view of this drug. We already have a terrible opiate and prescription drug problem in Ohio and across the nation. This is only going to expand with the prescriptions of marijuana. We all know that it is a gateway drug. As a former AOD counselor as well, I never met with a heroin addict that first didn’t use marijuana. And most even admitted that marijuana opened up the door to many more drugs.

If there is no way to make this “medical” issue go away in Ohio, my suggestion would be do make the restrictions very strict. Only a few medical conditions, only conditions that can be proven through science and not made up. NOT chronic pain.

These are my personal concerns and do not represent Akron Children’s Hospital. Having recently moved from Illinois there are a number of parts of the rules that do not improve patient care and add unnecessary burden. The regulations should be focused on confirming patient relationship and the confirmation of a qualifying diagnosis under the law. Reviewing the active registration in the patient registry Should not be physician responsibility but rather the dispensary responsibility. Currently there are no proven dosing schedules for Marijuana and the products in the dispensaries vary greatly form batch to batch in

**The Ohio State Medical Association’s comment letter regarding the State Medical Board of Ohio’s initial draft of the medical marijuana provider rules**

To Whom It May Concern:

Please see attached letter and share it with your committee. Thank you in advance.

In an attempt to make the MMJ program successful the list of conditions needs to be expanded immediately. The process to add conditions should be continual. No more than quarterly submission and decisions dates for both. The amount of conditions and supporting evidence as specified by HB 523 is more than sufficient to begin this process STAT and crucial to the programs success. The US GOVERNMENT has over 80 patents and patent pending applications on CBD, THC used for a plethora of conditions and EACH ONE should be added IMMEDIATELY. Addressing the opiate crisis is of utmost importance to the cannabis community. Putting in place a voluntary program for patients who want their pain to be treated with only Cannabis. Subjecting these participants to urinalysis proving no opiates are being used. Pain Management Physicians should stop disqualifying patients from prescriptions of opiates based on the presence of THC in a pt's blood stream. Instead use this opportunity to enroll them in a Cannabis only treatment plan or in a plan to reduce their use of opiates with a Cannabis substitute. This will add volumes to the research on Cannabis use for chronic pain condition. Physicians wanting to recommend MMJ need to form a coalition to help in bridging the gap between their office and the healthcare institutions in which they have rights to practice. Ohio physicians that are part of large hospital groups must be allowed to recommend without fear of retribution. A physician should have the right to continue a patients plan of care throughout a hospital visit, especially when
To the State Medical Board of Ohio,

In reference to the proposed physician rules regarding medical marijuana in Ohio, I ask that the State Medical Board of Ohio require doctors to attend eight hours of continuing medical education to begin recommending marijuana and four hours for every renewal of their license. Those CME hours should include training on addiction and the mental and physical health risks. Two hours of education is insufficient for doctors to truly learn about the risks associated with marijuana. Renewal requirements will help doctors stay informed as further studies are conducted on its effects on patients.

“Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study,” published in The Lancet Psychiatry in 2015, found a disturbing link between higher frequency use of high-potency marijuana and an increased risk of psychosis.

“Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015,” published in the Journal of the American Medical Association Pediatrics in 2016, found that marijuana poisonings of young children, many of them toddlers, have almost doubled at one hospital since Colorado began its legalization program. The study also suggested that legalization increased the rate of these exposures.

“Effect of Marijuana Use in Pregnancy on Fetal Growth,” published in 1986 by the American Journal of Epidemiology found that use of marijuana during pregnancy correlated with a significant decrease in birth weight and number of pre-term births in white women. More recently, “Birth outcomes associated with cannabis use before and during pregnancy” published in 2012 by Pediatric Research found an increase in the occurrence of low birth weights and faced a number of other adverse birth outcomes compared to babies born to mother who did not use marijuana. The latter study even adjusted for confounding factors found in the women who reported to be marijuana users but found that it did not materially change the findings.

The above research demonstrates that the potential negative health effects of marijuana are still being researched. For doctors to do more good than harm, they must remain up to date on marijuana research. Increasing the number of CME hours doctors who recommend marijuana must attend will help foster that education.

Additionally, in a recent survey conducted by the board (http://www.medicalmarijuana.ohio.gov/Documents/advisory-committee/December%202016/Physician%20Survey%20-%20Handout.pdf), more than 40 percent of doctors said they would (in response to another email) Some great points!
We commend the State for doing a thorough job in the creation of the rules that will regulate the issuance of certificates to physicians wishing to recommend Medical Marijuana. We are in agreement with the majority of the proposed rules, however we are concerned that some of the proposed conditions may limit the number of physicians who will participate in this program and ultimately affect the success of this new law. We propose the following comments to be considered:

1. 4731-32-02 Certificate to Recommend Medical Marijuana (A)(7)
   We highly support the need for physicians to be the gatekeeper of this new treatment. We recognize that physicians will have little knowledge on the effects of Medical Marijuana, and, there is a need for education on diagnosing qualifying medical conditions as defined by the law. We have great faith in the Medical community that they will research the proper dosing for each particular individual with qualifying conditions before they begin to recommend this new treatment. We recommend the State Medical Board publish guidelines that physicians can follow as they determine the proper strain and dosing for their individual patients. Therefore we feel the two hour continuing medical education requirement in advance of the application process is an added burden, and may limit the number of physicians who will participate in this new treatment option. We recommend the two hours of continuing medical education be a requirement within 12 months of their approved application.
2. 4731-32-02 Certificate to Recommend Medical Marijuana (B)(2)(a):
   To limit the number of hurdles, we recommend that once a physician completes their application and provides all the required documentation to the State, they be issued a temporary “Certificate to Recommend” where they can begin to recommend immediately. The Temporary license would be valid for eight weeks. This will allow the Ohio State Medical Board time to review the application and approve or deny, or if necessary, request additional documentation. If a physician does not provide the requested information with in an eight week period their Temporary license will be suspended.
3. 4731-32-03 Standards of Care (B)(7)(a-c):
   In the Standard of Care requirements it states physicians may only recommend Medical Marijuana only after other treatments have been utilized. We highly support the need for physicians to be the gatekeeper of this new treatment. We recognize that physicians will have little knowledge on the effects of Medical Marijuana, and, there is a need for education on diagnosing qualifying medical conditions as defined by the law. We have great faith in the Medical community that they will research the proper dosing for each particular individual with qualifying conditions before they begin to recommend this new treatment. We recommend the State Medical Board publish guidelines that physicians can follow as they determine the proper strain and dosing for their individual patients. Therefore we feel the two hour continuing medical education requirement in advance of the application process is an added burden, and may limit the number of physicians who will participate in this new treatment option. We recommend the two hours of continuing medical education be a requirement within 12 months of their approved application.

The link doesn’t work on my phone but I suppose that means my comments are mostly meaningless for this committee. Oh well. It will get sorted out over time. (from Sallie: Thank you for submitting comments on the proposed rules. They will be reviewed as part of the rulemaking process. Please be aware that proposed rule 4731-32-05 sets forth the proposed
Hello State Medical board re: Medical Marijuana:

This is my opinion, and not that of any organization, though I am copying our legislative committee chair of the Ohio Dermatological Association so he is aware of my note. I am not an expert on medical marijuana, but I have seen the dramatic effect it can have on the reduction in pain and suffering in a patient (a relative) who had radiation to the perineum.

When I look at the list of diagnoses approved (Under Ohio law, all of the following are qualifying medical conditions: AIDS, amyotrophic lateral sclerosis, Alzheimer’s disease, cancer, chronic traumatic encephalopathy, Crohn’s disease, epilepsy or another seizure disorder, fibromyalgia, glaucoma, hepatitis C, inflammatory bowel disease, multiple sclerosis, pain that is either chronic and severe or intractable, Parkinson’s disease, positive status for HIV, post-traumatic stress disorder, sickle cell anemia, spinal cord disease or injury, Tourette’s syndrome, traumatic brain injury, and ulcerative colitis. The Medical Board is charged with developing rules to regulate the issuance of certificates to doctors who want to be able to recommend medical marijuana for their patients. The Board is also responsible for establishing the procedure for adding conditions which may qualify patients for the state’s Medical Marijuana Control Program. ), I see pain and cancer, so I suppose radiation dermatitis secondary to cancer would be something that would make sense for me to try in a similar situation. As dermatologists we see a number of patients with treatment related skin problems. That being said, I’d also like to propose that

| Perfect. Sounds like that covers it anyway then, and certainly would make sense for restricting only to Ohio. Thanks for clarifying that, I wasn’t sure how expansive of a restriction it was going to encompass. By the way, I am happy to help out with any of the process, building the program, recommendations, etc. as needed since I do have a strong interest in this emerging new therapeutic field and have researched it quite extensively. (from Sallie: Thank you for submitting comments on the proposed rules. They will be reviewed as part of the rulemaking process. Please be aware that the restriction is as follows: “no ownership or investment interest in or compensation agreement with any medical marijuana entity licensed or applicant seeking licensure under Chapter 3796. of the Revised Code.” The restriction, |
| Hello, I am a headache specialist and neurologist at Cleveland Clinic. I have a strong interest in the quickly growing field of cannabis science based on existing research, evidence, and clinical observations of what many patients have told me in their self-treatment of medically refractory headache and pain disorders. Under eligibility for a certificate to recommend medical cannabis, I have a comment. I feel that investment ownership in a medical cannabis entity should in no way prevent the ability to obtain certification. I can understand if the company would in some way be related to the Ohio cannabis industry/program/market, which would make sense. However, if the company is completely unassociated with OH, or even based out of the country, this should in no way prevent ability to obtain certification. The cannabis industry is beginning to boom and is expected to be a multi-billion dollar industry that everyone should be able to have the opportunity to be a part of. This has been extensively covered by Forbes and all of the top financial networks. This would be no different than a physician invested in healthcare related stocks, who simply has to provide full disclosure of this. As I mentioned, if the stock ownership is tied to Ohio’s program in some way, I think this would be an acceptable restriction to certification. However, if the stock ownership is based in a company outside of Ohio, and especially if it is based out of the country, this restriction should be removed from the rules completely. Please remove and revise this clause, as above. |
| My name is Andrea Smith M.Ed. and I am the Executive Director of Swanton Area Community Coalition, a rural coalition west of Toledo. In our community, with the support of our 2016 Youth Survey, our youth are increasing their use of marijuana and the parental perception of harm is low. With medical marijuana regulations being developed, the outcomes are going to directly affect our community. In reference to the proposed physician rules regarding medical marijuana in Ohio, I ask that the State Medical Board of Ohio require a sufficient amount of education to physicians seeking to recommend marijuana or renew their license. At present, only two hours of education are identified in the proposed rules. This is insufficient for doctors to truly learn about the risks associated with marijuana. In order for a physician to recommend marijuana or apply for renewal, I ask that the number of required continuing medical education hours be increased to a total of eight hours. Those CME hours should include training on addiction, substance misuse prevention, and the mental and physical health risks associated with marijuana. Renewal requirements will help doctors stay informed as further studies are conducted on its effects on patients. Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study,” published in The Lancet Psychiatry in 2015, found a disturbing link between higher frequency use of high-potency marijuana and an increased risk of psychosis. Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015,” published in the Journal of the American Medical Association Pediatrics in 2016, found that marijuana poisonings of young children, many of them toddlers, have almost doubled at one hospital since Colorado began its legalization program. The study also suggested that legalization increased the rate of these exposures. Effect of Marijuana Use in Pregnancy on Fetal Growth,” published in 1986 by the American Journal of Epidemiology found that use of marijuana during pregnancy correlated with a significant decrease in birth weight and number of pre-term births in white women. More recently, “Birth outcomes associated with cannabis use before and during pregnancy” published in 2012 by Pediatric Research found an increase in the occurrence of low birth weights and faced a number of other adverse birth outcomes compared to babies born to mother who did not use marijuana. The latter study even adjusted for confounding variables, and the increase held even after adjusting for confounding variables. |
To the State Medical Board of Ohio,

In reference to the proposed physician rules regarding medical marijuana in Ohio, I ask that the State Medical Board of Ohio require doctors to attend eight hours of continuing medical education to begin recommending marijuana and four hours for every renewal of their license. Those CME hours should include training on addiction and the mental and physical health risks. Two hours of education is insufficient for doctors to truly learn about the risks associated with marijuana. Renewal requirements will help doctors stay informed as further studies are conducted on its effects on patients.

“Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study,” published in The Lancet Psychiatry in 2015, found a disturbing link between higher frequency use of high-potency marijuana and an increased risk of psychosis.

“Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015,” published in the Journal of the American Medical Association Pediatrics in 2016, found that marijuana poisonings of young children, many of them toddlers, have almost doubled at one hospital since Colorado began its legalization program. The study also suggested that legalization increased the rate of these exposures.

“Effect of Marijuana Use in Pregnancy on Fetal Growth,” published in 1986 by the American Journal of Epidemiology found that use of marijuana during pregnancy correlated with a significant decrease in birth weight and number of pre-term births in white women. More recently, “Birth outcomes associated with cannabis use before and during pregnancy” published in 2012 by Pediatric Research found an increase in the occurrence of low birth weights and faced a number of other adverse birth outcomes compared to babies born to mother who did not use marijuana. The latter study even adjusted for confounding factors found in the women who reported to be marijuana users but found that it did not materially change the findings.

The above research demonstrates that the potential negative health effects of marijuana are still being researched. For doctors to do more good than harm, they must remain up to date on marijuana research. Increasing the number of CME hours doctors attend will help them stay informed about these effects.

Here is what needs to happen with Medical Marijuana laws in Ohio. I have been an active and dedicated advocate for substance abuse prevention in Ohio for almost 35 years. I sit on the Board of Directors for the Alcohol and Drug Prevention Association of Ohio and am a Certified Ohio Prevention Specialist II. I am not in favor of medical marijuana at all, but we are stuck with it for now so lets do it right with integrity, safety, and the optimal health of all as our priorities….especially for our youth. Mary Marvel

Doctors should be required to attend eight hours of continuing medical education to begin recommending marijuana and four hours for every renewal of their license.

Those CMEs should include training on addiction and the mental and physical health risks.

One more item.
Considering the probable risk of marijuana use on the developing fetus.

I suggest that a pregnancy test be done on every female, and that it would be prohibited to dispense THC to a pregnant female.

In reference to the proposed physician rules regarding medical marijuana in Ohio, I support the following recommendations:

Doctors should be required to attend eight hours of continuing medical education (“CMEs”) to begin recommending marijuana and four hours for every renewal of their license.

Those CMEs should include training on addiction and the mental and physical health risks.

Doctors should recommend dosage and strength when they recommend marijuana, just like with any other medicine. Pregnant women should not receive a recommendation.

Apologies for a second email.

I would like to address the issue of costs, quickly.

Costs, of course, mean financial. For example, catastrophically ill children medicine and hospital stays cost an enormous amount of Medicaid dollars.

The other meaning of costs, is the human cost. By not educating our healthcare professionals in the Endocannabinoid System, the human costs to generations could be detrimental.

According to international experts, the Endocannabinoid System maybe key in Epilepsy, and many other neurological disorders. (CB1 receptors in the brain) It maybe key in Crohn’s disease.(CB2 receptors in the digestive tract.) It would be interesting to see the numbers as to how many with these disorders are on Medicaid, and the cost of their treatment. We should be looking at whole system cost.
I have been involved with drug policy reform on a national level for six years. During my time in drug policy, I have advised multiple state decision makers. While traveling the country with national organizations, my expertise has been the lack of healthcare professional education in the cannabis industry.

When I began in the industry in 2011, there were no educational requirements for Physicians making recommendations. With a hard push by a few of us, we were able to get basic requirements for healthcare professionals implemented into regulatory programs. These basic requirements in New York, Florida, Minnesota, and other states, are focusing on dosing, varieties of cannabis, and very basic information.

FACT: Not one medical cannabis state has focused on educating their healthcare professionals in the Endocannabinoid System, before, during or after a medical cannabis program was implemented. This is a biological system discovered in the late 1980's. There is much research and studies about this biological system. It is illogical that not one state has focused on educating their healthcare professionals this innate biological system with receptors in the brain, and throughout the body. This is not an assumption, as I have attached a study reflecting the lack of Endocannabinoid System education in Medical Schools. Again, this is illogical for a biological system discovered 30 years ago. Physicians cannot ignore the digestive system or the immune system in making their diagnoses. They need the ECS System information.

As for the burden, benefits, and costs - Not educating our healthcare professionals in the ECS System creates a burden on the physician, and is absolutely not in the best interest of the patient. The benefit to educating Ohio’s healthcare professionals in the ECS System is that our OHIO physicians, nurses, and other healthcare professionals will be on the forefront of the industry with accredited information about a biological system that other states are currently lacking - thus creating a great benefit for Ohio patients, physicians and other healthcare workers.

As for the cost of this proposal – Governor Kasich has already implemented programs connecting medical schools and hospital systems educational technology. TDCANN Institute can help facilitate curriculum and classes, with internationally recognized experts, at a relatively low cost. This will be extremely beneficial to our patients.

Because the State Medical Board oversees licensing, I recommend they become involved to help facilitate required Endocannabinoid System education in the ECS for all healthcare professionals in Ohio, including medical schools.

As for the amount of CMEs for recommending physicians - 2 CMEs are a great start to get our program moving quickly.

Thank you for taking public comment on the physician draft rules. I applaud the effort to ensure that all physicians who recommend marijuana consider standard treatments, and I further applaud the effort to ensure that complementary use is considered. I do think that one area is a bit restrictive, however, and that an item is missing. Specifically, I believe that subsections (a)-(c) of rule (B)(7) within Standards of Care section are unnecessary and overly restrictive, and I believe physicians should be taking into consideration any results reported by the patient of marijuana use as a medical treatment (including previously illicit use) when recommending. My explanations are listed in your requested format below.

1. Removal or changes to subsections (a)-(c) of rule (B)(7) within Standards of Care section

*Explain your views as clearly as possible-

It appears to me as though the required consideration of standard medicine and complimentary use outlined elsewhere within the rules are sufficient. Adding the need to fulfill one of the requirements created by (a)-(c) would appear to deem medical marijuana as a last course of treatment, which may not be appropriate in many cases. It might, however, be appropriate in the consideration of recommending to a minor suffering from epilepsy or other situations.

*Describe any assumptions used-

My assumptions are that legislature, and those fighting for this law, did not intend for medical marijuana to be used only as a last resort of treatment. Also, I am obviously assuming that this requirement will result in most physicians believing medical marijuana must be a last resort.

*Provide any technical information and/or data used to support your views-

None, other than the knowledge that many physicians in other parts of the country believe in the immediate use of marijuana as a complementary medicine very early on for some patients.

*Explain how you arrived at your estimate for potential burdens, benefits, or costs-

I arrived at the conclusion that physicians may interpret this requirement as meaning that marijuana would be a treatment of last resort by discussing the proposed rules with a small number of physicians.

*Provide specific examples to illustrate your views-

Many of those in the General Assembly who fought for this bill did in the spirit of reducing opioid dependency among patients experiencing pain. This could be one example of a situation in which a complementary use of marijuana as medicine might be considered immediately.

*Offer alternatives-

Remove subsections (a)-(c) of rule (B)(7) within Standards of Care section, or, apply perhaps apply it to minors only or other specific situations

I have smoked medical marijuana which helped my numbness and pain. Marijuana you buy has inflamed my pain, I don't do it. I'm hoping I will be able to get medical marijuana. I have multiple sclerosis since 1998 it isn't getting any better. The time I
Dear Physicians Rules Board,
As you embark upon creating policy and rules for medical marijuana in Ohio, please consider the safety of our youngest citizens - placing that above all else. As someone who is certified (OCPSII) in prevention and has worked in the field, I fear business and revenue will come between smart marijuana policy and Ohioans.

• All marijuana products should come in childproof containers to prevent poisonings, which have increased remarkably in Colorado.
• Doctors and clinical directors should be well trained in the most up-to-date science on marijuana, including addiction, effects on youth, mental health considerations, and interactions with other drugs.
• Doctors who recommend marijuana should also recommend a specific dose. We don't allow patients to determine the dosage of their medications; if we're going to treat marijuana like medicine, we should dose it like medicine.

To Whom it May Concern,
After reading the most recent article in the Cincinnati Enquirer of Sunday, January 1, 2017, I am once again disgusted with the lack of due diligence in Ohio's government. Seems these folks want to keep we Ohioans in the dark ages once again. Seriously? There are so many people that are suffering due to the lack of knowledge which exists here. Marijuana was created by God and for a purpose. As it appears to provide pain relief, control of seizures and many other beneficial purposes, why the delay in making it readily available for those in need? The article says that folks can get it from other States where it is legal and bring it here? Doubtful. Most States have it clearly stated on the products that it is not to be removed from that particular State. So, how is that possible? Like dangling the carrot of life but only to those that can either move or smuggle the stuff in. What are you all thinking or not? Take note from other States where it is working, helping and there are no problems. Drop the conservative crap that Ohio so stupidly holds on to. Get rid of the alcohol that takes so many innocent lives. The bars. The drunks. And not just the ones that people think are useless drunks but those that wear their suit and tie everyday, work their medical jobs and go to Happy Hour and become a living mess only to hit the road and possibly kill a family or worse. Wake up Ohio!! Quit pushing crap on us as to how dangerous marijuana is. I know better. Many responsible folks know. Recreational may not be the ticket for Ohio but the medical is imperative. I take prescribed, legal narcotics daily which I detest but need to function and live without severe chronic pain. All the doctors know what to do and worse, big Pharma. Would much rather try something natural and not created in a laboratory from chemical of unknown origin. Man made. But, am sure too, money is the motivator here. Not the welfare of people in pain. Bad people are going to give a bad name to something which the government has told us is bad. It's crap. Tell the truth. Get rid of the alcohol as you say it's ok.

Dear regulators:
I would like to receive more information about OHIO's training program for medical staff that may be involved with the upcoming Medical Marijuana sale and distribution plans in Ohio. When and where will the training sessions occur and to whom will the $250.00 be paid. My DEA is current and otherwise unrestricted. I have practiced as a PA in Ohio for several decades. Please know that the use of the term "recommendation" and the requirement for the submission of an annual report are required by the Ohio Revised Code, which is enacted by the Ohio legislature and signed by the Governor, and not the creation of the Medical Board. The Medical Board is required to adopt rules that are in compliance with the language of the sections of the Ohio Revised Code that the rules amplify and implement. The Medical Board cannot adopt a rule that conflicts with the Ohio Revised Code.

The statutes authorizing medical marijuana usage in Ohio do not authorize a physician to prescribe medical marijuana. Instead, the physician is authorized to "recommend" medical marijuana. Prescribing marijuana is prohibited by federal law. An Ohio physician who would "prescribe" medical marijuana would be subject to criminal prosecution by the federal government. This is also the reason why dispensaries, and not pharmacies, must be the source of the medical marijuana. A pharmacist

1. The reason to develop a new category [recommendation] as opposed to a prescription is incomprehensible. The requirements to meet the "recommendation" are so similar to those required for narcotics – why develop a new process?
2. The requirement for an annual report to the Board is wholly unnecessary; the obvious intention being to dissuade physicians from getting involved in this at all.

Thank you for the clarification about the wording of the draft regulation via-a-vis the statutory provision. If I had been advising the Legislature, I would have suggested doing away with this provision. But I do understand why the legislators might have added it. There may still be issues with patients moving, physicians retiring, and so on as I mentioned in my comments. Since I do have experience in this area, as noted in my original e-mail, I would be pleased to help the Board in any way that I
Thank you for the opportunity to offer comments on the draft regulations governing the physician certificate to recommend medical marijuana. Although at this time my practice is in Kentucky, I do hold an unrestricted Ohio medical license (35.127654). I worked in Colorado for five years, and in my practice of palliative medicine there I managed approximately 50 patients who were using medical marijuana under the auspices of that state’s program. I have had the opportunity to see a medical marijuana program up close and personal, so to speak, and my experience informs the following comments on the draft regulations.

I appreciate the State Medical Board’s intent to balance access and safety. Happily, cannabis is a safe medication. There has never been, to my knowledge, a recorded fatal overdose. In Colorado and elsewhere, access has been a bigger problem than safety. I am concerned that some parts of the draft regulations could unduly limit access.

1. Section 4731-32-02 (A) makes eligibility to recommend contingent on eight requirements. The first six, it seems to me, would already be known by the Board as part of the medical licensure process — which you recognize by stating that the draft rules “closely follow established procedures and standards” for licensure. Subsection (B) appears to contemplate a lengthy application process in which, per (b)(2)(a), “[a]ll applications materials...will be thoroughly investigated.” In my view, the tone of this subsection is hostile, and a cumbersome application process would create a disincentive for physicians to seek the certificate.

A streamlined process would simply permit licensed physicians who meet the educational requirement of (A) (7) and the financial conflict of interest requirement (A) (8) to obtain the certificate and be permitted to recommend medical marijuana. It seems to me that licensees already have to meet the first six requirements under subsection (A). Adding more paperwork does not improve public safety, but it does have the potential to drastically reduce access.

2. The educational requirement laid out in (A) (7) is a good idea, although I am not sure that licensed physicians who are complying with the existing CME requirement would require assistance with “diagnosing qualifying medical conditions.” I am sure the Board realizes that high-quality educational courses about medical marijuana are difficult to find. I would be happy to offer specific recommendations and ideas.

3. I applaud the requirement under (A) (8) that the physician have no financial conflicts of interest. How this will be documented will affect the overall burden of the application process. In Colorado the physician’s statement on behalf of a patient includes an attestation that he or she has no financial interest in the medical marijuana industry. I urge the Board to adopt a similar, simple attestation.

4. Turning to Section 4731-32-03, I have concerns about subsection (D) (1) (b). The Board apparently contemplates two scenarios — either the patient is asking a physician for recommendation for the first time, (D) (1) (a), or the patient already has a recommendation and now is asking the physician to renew it, (D) (1) (b). The first scenario is uncomplicated. The second scenario is more likely. I think the Board should adopt a similar, simple attestation.

Training with 2 hours of CE is not adequate. Training programs are available that are more complete and offer relevant studies to provide necessary information to prescribers. Your own survey of prescribers shows that Ohio physicians are mostly “unlikely” to recommend MM and mostly due to “lack of peer reviewed research” or “lack of training.” It doesn’t make sense to only have a CE that can be completed after dinner to provide this knowledge. Especially in the environment that was created for dispensing in Ohio with potentially no health care professional at the dispensary. If the reasoning for this 2 hour training was to make sure that CE would not be a roadblock for adequate numbers of recommenders, then I would suggest the rules committee add pharmacists as qualified recommenders in the program. Your survey indicated there are 46,000 pharmacists in Ohio. There are also plenty of pharmacists with Ohio Licenses more than ready to work with busy physicians to provide recommendations on drug interactions, strain, dose and route of administration of cannabis.

The MM CE program from the Answer Page has blocks of CE for MM training in 3 hours, 6 hours and 22.5 hours for full certification.

I would think at least the 6 hour course would make a better recommender for the program. Drug interactions/contraindications require at least 2 hours of CE alone.

More education can accomplish two things. The more knowledgeable the prescriber becomes with phytocannabinoids the more likely they are to feel comfortable discussing them with their patients. And secondly I think we will actually have more prescribers becoming certified as the knowledge sparks better interest in using cannabis as a mode of therapy.

Our colleagues in Connecticut rely on a knowledgeable pharmacist at the dispensary to help patients. In talking with them about their practices, it sounds like the physician simply recommends “medical marijuana” and then the dispensary pharmacist helps determine the appropriate type of MM to use. It could be edible in an elderly patient’s case or vaporized in a younger patient with spasticity from multiple sclerosis. They usually start cannabis naïve patients with a low dose and then follow up with higher doses if needed. My peer in Illinois, Joe Friedman, R.Ph., tells me that he does a thorough assessment of each patient at his dispensary to determine contraindications and appropriate therapy. He is finding many patients are wanting to get off sedative hypnotics, benzodiazepines for sleep and opiates.

We find ourselves in a quandary of sorts in Ohio. With our legislation not requiring a pharmacist or other healthcare professional to provide recommendations on the CE certificate.

Thanks for the feedback. I did not realize the requirement was in the Ohio Revised Code. (Sallie’s response: Thank you for submitting comments on the proposed rules. They will be reviewed as part of the rulemaking process.

However, as to the requirement in 4731-32-03(H) for the submission of an annual report, please be aware that the annual report is required by Section 4731.30(E), Ohio Revised Code. That section as enacted by the General Assembly and Governor provides as follows: “Annually, the physician shall submit to the state medical board a report that describes the
Please see my comments to the proposed Physician Certificate to Recommend Medical Marijuana and Petition for Added Qualifying Condition
I have interest in these proposed regulations as a neurologist specializing in epilepsy treatment at an academic medical center. My practice has a significant proportion of patients with poorly controlled epilepsy. There is keen interest among many patients with epilepsy in treatment with medical marijuana and the discussion comes up several times a week in my clinical practice.

**Rule 4731-32-03 Standard of Care**
The proposed documentation requirements for the medical record seem overly burdensome for the physician. I certainly understand the rationale behind these recommendations however, the public seems to think that getting medical marijuana will be as easy as getting a normal prescription. I hope the medical board or the state pharmacy board will launch educational efforts to inform the public what is needed for the physician to make a recommendation for medical marijuana.

Section C (5) states: “The patient’s consent prior to completing a recommendation for treatment with medical marijuana.” This should specify if verbal consent or written consent is needed.

The regulations that are being put on doctors, in order to even recommend medical marijuana is enough red tape to wrap the world ten times.

I am an injured (Service Connected) Veteran, and my doctor is not authorized to recommend MM. She was alright with it when I wanted to stop taking all of my morphine, and Percocet to control pain.

**PLEASE ALLOW US TO MAKE OR OWN CHOICES, WITH OUT DOCTORS BLESSING.** Don't make it that I have to get back on harmful narcotics, that cause numerous health issues. MARIJUANA IS GOOD!

I have had Degenerative Arthritis for many years (20+ or -). At this time I on Naproxen 500 mg, before that I was on many different meds for it over the years. My doctor also gives me a prescription of Hydrocodone of which I never use unless the pain is unbearable. A script of 20 last me better then six months. I read many articles on line about the treatment of Arthritis. The best and most clinical trials for Arthritis that I read to date are from Israel where their government has been much more positive in researching the medical effect of marijuana than America is or has been. Israel trials have shown great relief for Arthritis pain. I have one question, at my age and living on a fix income now, why would you not let me grow a plant or two a year? My wife and I have green thumbs and by growing my own it would save me money and would keep everything at my resident and would never be outside my home. This make sense to for I would never have to go to a government approved

I am unsure of the words "attempted or considered" in the Medical Board Draft Rule

**PHYSICIAN CERTIFICATE TO RECOMMEND MEDICAL MARIJUANA** found in Rule 4731-32-03(B)(7) Standard of Care
In order to practice within the minimal standards of care when recommending treatment with medical marijuana, a physician shall comply with all of the following requirements

(7) Documented review that that standard medical treatment has been attempted or considered, and one of the following is met:
   (a) The patient had inadequate treatment response to standard medical treatment;
   (b) The patient was unable to tolerate the standard medical treatment;
   (c) Standard medical approaches are not appropriate in this patient for other documented reasons

Does this require the Physicians to exhaust all standard medical treatments even if the patient has been using marijuana

I strongly recommend the deletion of 4731-32-05-B found in Medical Board of Ohio draft rule “Petition to Request Additional Qualifying Condition or Disease”

(B) No later than October 15 of each year, the board shall designate a period during which petitions will be accepted in the next calendar year. Petitions will not be accepted after the expiration of the acceptance period.

**From a Practical Viewpoint:**
1 - Establishing an allowable time period where petitions will be accepted is arbitrary.
2- An end of year rush to evaluate potential numerous petitions will lead to petitions not being properly evaluated.

**From a Legal viewpoint:**
1- The proposed rule in Prohibitions has no basis in statutory authority as passed in HB523.
2- For example, the Attorney General has no such time windows where petitions are deemed unacceptable.

**From a Political Viewpoint:**
An addendum needs to be added to allow any medical marijuana patient the ability to purchase a marijuana grow license. The license would be at 3 different level, I, II, and III.

Level I would allow medical marijuana patients the ability to purchase marijuana from a dispensary. They would need to show their level I license to have the ability to purchase anything in the dispensary. The cost for this license should not exceed $100. If income levels for the household are at the poverty line, this cost if waived.

Level II would allow medical marijuana patients the ability to grow their own marijuana plants and all the privileges as level I. The number of plants should not exceed 20 and the amount of marijuana on site should not exceed the amount reasonable received from 20 marijuana plants. These are non-transferable plant counts. Cost should not exceed $100.

Level III would allow medical marijuana patients the ability to produce their own extracts, resin, rosin, hash, or any other "concentrated" marijuana form. This level would allow all the privileges as level II. Before receiving the level III license, patients would need to complete a 16 hour class on extracts, safety, and the proper way to prepare them, among other topics. Cost should not exceed $100 plus cost associate with the class.

The reason this needs to be done is:
1. This would bring in more money to the State. At least 75% of the money received from the licenses would be put toward marijuana research and medical studies.
2. This would allow people to grow their own marijuana and save a substantial amount on money. The current legislation would bar low income people from being able to use medical marijuana. This is not acceptable, growing marijuana is not a difficult or unsafe en-devour and there is no reason patients should not have access to cheap medical marijuana. This is allowed in many other states and there have been zero issues with home grown marijuana. It is only a benefit, to the State, and to the patient.

In all circumstances where "patient" or "medical marijuana patient" is defined, you should add " The patient is defined as someone that is also, not withstanding anything to the contrary, exempt from all "drug free workplace" testing or any other testing for any chemicals found in cannabis, cannabis extracts, or any related chemical from, or related to marijuana, or constituents found therein.

COMMON SENSE REASONING:
By subjecting patients to drug testing that is not applied to other medical treatments, it is considered a sever restriction from access, access my be available but not without causing irreversibly negative effects on the patients ability to stay solvent and employed. This restriction violates the legislation that was passed legalizing medical cannabis because it only applies to select patients in the population. An employer does not have the authority to dictate the medical treatment received by an employee. Therefore the same should apply in this case.

Since the highest level of the executive branch of the federal government, POTUS, has enforced the status quo, of letting the State dictate how they handle medical or recreational marijuana, the ability to decide the harm and medical benefits of cannabis is reserved de facto, to the States. This in effect eliminates the guidelines for marijuana set by the DEA scheduling, and effectively removes the requirement from "drug free workplace" or any other program designed to test for the presence of impairment at the workplace.

EXAMPLE:
I am an Air Force veteran. I suffer, and I do mean suffer, from PTSD, Fibromyalgia, Major Depressive Disorder, Anxiety, Chronic Pain.. Will VA doctors be able to recommend medical marijuana in Ohio under these rules, or are we left out in the

Documented review of the patient's current medication to identify possible drug interactions, including benzodiazepines and opioids.
I see nothing to determine the AMOUNT of other substances used by a patient for 'last resort' medications. For instance, if a patient is taking the lowest possible medications that may be deemed to interact, the subject of 'why' and 'the amount' of the other medicine. For instance if a patient is taking 0.05 mg of a benzodiazepine or 5mg of oxycodone because they cannot tolerate more of them and the marijuana would REPLACE these other drugs, why can't the patient be allowed to discontinue the current drugs if the marijuana works to replace them? They are not working, they are being prescribed the lowest possible dosages due to side effects, and the patient would gladly give them up to have a better medication (like marijuana) that would replace the current meds...why not allow them? I take a 0.05 mg of clonazepam. Due to withdrawal problems this must continue even if marijuana fixes the health issues but it's such a minor dosage. Why should it matter? If opioids are stopped/replaced by medical marijuana to fix the health issues, what is the danger? The dosages are other meds aren't being considered and should be. Why aren't you incorporating minimum doses of meds that if taken in larger doses could be a problem but in the lowest dosages could be continued without interaction. I see needy patients falling through the cracks who

I have read the list of conditions for the use of medical marijuana program.I strongly believe you are missing one important condition. I am currently dealing with Panic Attacks, anxiety and depression and have been for the last 3 years, it cost me my job after 30 years after seeing many DR and going to counseling sessions, so they have put me on three different meds that make about sick besides not working, I have tried marijuana and it works so well for me but I do have the fear of breaking the law as I have never been in trouble with the law in my life. I just want to feel better and have a better quality of life.
State Medical Board of Ohio  
30 E. Broad Street, 3rd Floor  
Columbus, Ohio 43215  

RE: Medical Marijuana Physician Rules  
To Whom It May Concern:  

Thank you for the opportunity to comment on the updated proposed Administrative Rules of Ohio regarding Physician Certificate to Recommend Medical Marijuana and Petition for Added Qualifying Condition. The Ohio Pharmacists Association (OPA) represents pharmacists in all practice settings; most of whom will be impacted by the State Medical Board’s proposed rules. As we explained during our testimony on HB 523 in the 131st General Assembly, our association has serious concerns about the loose laws developed to facilitate patient access to medical marijuana, and in light of that, OPA believes that thoughtful rules are necessary to ensure public safety is not compromised.

We thank you for the ability to comment on the proposed rules, and we look forward to finding agreeable policy so that physicians, nurses, pharmacists, and other health professionals can work to ensure public safety in conjunction with the dispensation of a Schedule I drug.

4731-32-02 Certificate to Recommend Medical Marijuana  

OPA feels that two hours of training is insufficient for a physician to recommend medical marijuana. This is not to discount the expertise and training of physicians, but for a drug that has yet to be approved federally, and with much scientific disagreement on medical marijuana’s safety, efficacy, and legitimate utilization, OPA believes that more training is necessary for any health provider involved in the medical marijuana supply chain.

The state of Ohio’s own survey of prescribers shows that physicians are mostly "unlikely" to recommend medical marijuana, mostly due to "lack of peer reviewed research" or "lack of training." This should be evidence that training should be more extensive and developed than something that can be accomplished faster than a football game – especially since the current laws and proposed rules lack the regular checks and balances at the point of dispensing that exist for all other drugs.

Rule 4731-32-03 Standard of Care  

OPA supports the requirements that physicians utilize OARRS to ensure no patterns of misuse are occurring.
In (D)(2)(f), amongst the requirements that a physician must include on a recommendation is a requirement to include “Any instructions for use of medication marijuana, as determined by the physician.” Several members shared concerns that a physician could theoretically leave vague, incomplete, or no instructions whatsoever for a patient. Of course, this is not the standard of care for any medication. Even common, over-the-counter products like acetaminophen have directions for use.

Due to the fact that medical marijuana science is still underdeveloped and unproven, OPA feels that directions and instructions for use should defined and clear – especially when the crucial drug utilization review by a licensed pharmacist is not required in the law. OPA strongly opposes any language that would not require clear instructions for appropriate utilization or language that could infer open-ended usage of the product by the patient.

Without an iron-clad mandate on who is/are ultimately responsible for determining the recommended amount, type of medical marijuana, and percentages of constituents, then there is no responsibility to patient. And regardless of who is/are responsible for determining what is ultimately recommended and dispensed, those individuals must be well educated in the effects of constituent percentages, differences in ingested vs vaporized marijuana, and what doses have been shown in scientific literature to produce a therapeutic effect. This is why several states with medical marijuana laws in place mandate that a pharmacist be present on site at every dispensary to aid in this necessary component of medical marijuana distribution.

OPA recommends tightening the requirement for instructions or requiring that a pharmacist, through consultation with the physician and patient, have the ability to create instructions if they are missing, vague, or incomplete; or have the ability to change the instructions if the pharmacist feels that the recommended drug therapy is inappropriate, unsafe, or unclear.

In (H), there is a requirement that physician send the board an annual report on the effectiveness of medical marijuana treatment. OPA recommends developing this language further to include specifics of what shall be included in the report, or to standardize certain questions to get a true “apples to apples” comparison on certain measures of interest from practice to practice. With medical marijuana research still in its infancy, and a lack of scientific certainty on its effectiveness in many of the disease states it’s now allowed to be recommended for in Ohio, it would seem both essential and helpful to get a thorough understanding of how patients are responding to treatment. The de-identified information should at least include the medical condition, what other medications are taken in conjunction with marijuana, the types of marijuana being recommended for certain disease states, and accounts of follow-up reports from patients. With the current language, it would seem that a physician could report, “I recommended medical marijuana to 78 patients this year, and all of them seem fine.” While we would find that type of report unlikely, we do feel that some content minimums like those mentioned above should be required.

Thank you for engaging us in this process, and thank you for the opportunity to comment.
Use of Prescription Pain Medications Among Medical Cannabis Patients: Comparisons of Pain Levels, Functioning, and Patterns of Alcohol and Other Drug Use

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ABSTRACT. Objective: Management of chronic pain is one of the most common reasons given by individuals seeking medical cannabis. However, very little information exists about the concurrent use of cannabis and prescription pain medication (PPM). This study fills this gap in knowledge by systematically comparing medical cannabis users who use or do not use PPM, with an emphasis on understanding whether concurrent use of cannabis and PPM is associated with more serious forms of alcohol and other drug involvement. Method: Data from this study were collected from a medical cannabis clinic in southwestern Michigan (N = 273). Systematic comparisons were made on measures of sociodemographics, reasons for substance use, pain, functioning, and perceptions of PPM and medical cannabis efficacy. Results: PPM users tended to be older and reported higher levels of pain and lower levels of functioning. The overall sample exhibited higher lifetime and past-3-month rates of alcohol and other noncannabis drug use than did the general population. Approximately 40% of subjects reported combining cannabis with alcohol, but no significant difference was observed between PPM users and nonusers. PPM users and nonusers did not exhibit any difference in either lifetime or past-3-month use of other drugs, including cocaine, sedatives, street opioids, and amphetamines. PPM users rated the efficacy of cannabis higher than PPM for pain management and indicated a strong desire to reduce PPM usage. Conclusions: Use of PPM among medical cannabis users was not identified as a correlate for more serious forms of alcohol and other drug involvement. However, longitudinal study designs are needed to better understand the trajectories of alcohol and other drug involvement over time among medical cannabis users. (J. Stud. Alcohol Drugs, 76, 406–413, 2015)

POLICIES AND PRACTICES SURROUNDING medical cannabis continue to evolve and suggest a growing interest and need for researchers and clinicians to identify and understand different user groups, their demographics, perceptions of efficacy, and reasons for use. As of October 2014, 23 states and the District of Columbia had enacted laws permitting cultivation and use of medical cannabis for certain medical and mental health conditions (Bachhuber & Barry, 2014; NORML, 2014). Nearly half of these states include some provision for pain-related conditions or for the use of medical cannabis (H. B. 153, 2014; S. B. 1182, 2014; Wilson, 2014).

Among the states with medical cannabis laws, variability exists regarding how much a person may possess, where and how the cannabis can be accessed and transported, and the specific regulations for cultivation. Variability also exists with respect to the conditions that qualify an individual for receipt of medical cannabis. However, all current laws include some provision for pain-related conditions or for the management of chronic pain (NORML, 2014).

Increasingly, medical cannabis is being presented as an alternative to opioids or as an adjunctive approach that could augment the analgesic effects of opioids (Lucas, 2012). However, cannabis may be problematic for some patients, especially those who are prescribed prescription pain medication (PPM) and use marijuana and PPM concurrently. For example, DeGeorge et al. (2013) examined PPM misuse among persons prescribed hydrocodone. Using biologically based measures, they found that patients who used cannabis were significantly more likely to be taking another nonprescribed medication than were patients who did not use cannabis. Pesce et al. (2010) also found that patients with chronic pain who used cannabis were 3.7 times more likely to test positive for other illicit drugs (e.g., methamphetamine and cocaine) than were non–cannabis users (see also Manchikanti et al., 2008). Fiellin et al. (2013) also presented evidence for cannabis as a possible gateway drug to the misuse of prescription opioids among both men and women 18–25 years of age.
Recently, Bachhuber et al. (2014) investigated whether the availability of medical cannabis would affect PPM overdose rates, given that medical cannabis may potentially lead to increased levels of substance use through the gateway effect (Fiellin et al., 2013), or possibly alter the pharmacokinetics of opioids. Using age-adjusted opioid analgesic overdose death rates, Bachhuber et al. (2014) found the presence of state medical cannabis laws to be associated with significantly lower state-level opioid overdose rates. At the same time, inferences of causality cannot be drawn from this ecological study of state-level effects, and it remains unclear whether access to medical cannabis could influence PPM misuse (Bachhuber et al., 2014).

The risk of acute toxicity from cannabis is low, and cannabis may be safer than PPMs. Although the evidence on medical cannabis for pain suggests that it might relieve pain in the short term (e.g., Berman et al., 2004; Johnson et al., 2010; Naef et al., 2003; Rog et al., 2005), the long-term benefits remain unclear (Joy et al., 1999; Ste-Marie et al., 2012; Volkow et al., 2014), making it difficult for providers and policy makers to know whether and for whom medical cannabis would be both safe and effective, in what dose, or for how long. Addressing these issues requires a strong foundation of empirical evidence using a variety of methodological designs.

To date, few studies have been conducted to understand the characteristics of persons who are seeking and using cannabis specifically for pain-related purposes. Several studies have provided descriptive data on typical medical marijuana patients and generally reflect that this is a diverse group with complicated co-occurring medical and psychiatric problems (Bonn-Miller et al., 2014; Ilgen et al., 2013; Reinaman et al., 2011). This prior work also indicates that prescription opioid use is common among those seeking medical cannabis.

The purpose of the current study is to better elucidate patterns of alcohol and other drug use, functioning, and perceived efficacy of pain treatments among medical cannabis users with and without concurrent use of PPM. By doing so, this study might help clarify whether concurrent use of medical cannabis and PPM is associated with more serious involvement of alcohol and other drugs. This study also provides comparative data to better understand the extent to which individuals seeking cannabis perceive it to be beneficial as well as their perceptions of the relative analgesic effects of cannabis and opioids. This information could help to inform the development of targeted policies and practice guidelines for medical cannabis.

**Method**

**Sampling and recruitment**

Data for this study were derived from a larger survey of persons seeking medical cannabis certification or re-certification at a certification clinic in the upper Midwest (see Ilgen et al., 2013). Persons awaiting an appointment to obtain certification or recertification for medical cannabis were invited by a research staff member (not employed by the clinic) to participate in the study. Of the 370 persons invited, 94.1% (N = 348) provided verbal consent to participate. This current report focuses on a subset of the subjects who endorsed using cannabis in the past month specifically for pain reduction (N = 273). This study was approved by the institutional review board at the University of Michigan. Further details of the current study can be obtained in Ilgen et al. (2013).

**Measures**

**Use of prescription pain medication.** We divided this sample into two mutually exclusive groups based on whether the subject endorsed use of PPM within the past month (PPM–Yes, n = 172, 63.0%; PPM–No, n = 101, 37.0%).

**Use, misuse, and efficacy of prescription pain medication.** Subjects who endorsed past-30-day PPM use were asked whether they were trying to limit their use of PPM, as follows: (a) “I am trying to use prescription pain medications for nonmedical reasons less often than I used to,” and (b) “I am trying to use prescription pain medications for pain relief less often than I used to.” Response options were on a 5-point Likert-type scale (1 = strongly agree to 5 = strongly disagree).

Our measurement of PPM misuse was based on items from the Current Opioid Misuse Measure (COMM; Butler et al., 2007). The scoring guidelines of the COMM were originally developed for use in pain management clinics, which are quite different from medical cannabis certification clinics. Thus, the present study used a subset of five items from the COMM, which were used to create an index of PPM misuse: (a) “How often have you taken your medications different from how they are prescribed?”; (b) “How often have you needed to take pain medications belonging to someone else?”; (c) “How often have you had to take more medication than prescribed?”; (d) “How often have you had to borrow pain meds belonging to someone else?”; and (e) “How often have you used your pain meds for non-pain symptoms?” Each of these items used a 5-point Likert-type response option (0 = never to 4 = very often). An index was created by summing across all the item scores. Thus, lower scores reflect lower levels of PPM misuse.

Subjects were also asked how helpful PPMs were in reducing pain (0 = not at all, 10 = very). For comparative purposes, subjects were also asked about how helpful cannabis was in reducing pain (0 = not at all, 10 = very).

**Pain and functioning.** The Numerical Rating Scale (NRS) was used to assess pain level on an 11-point scale.
(0 = no pain, 10 = severe pain) (Farrar et al., 2001). Two questions were asked: (a) average pain over the past 30 days and (b) current pain level. The Short Form-12 Health Survey (SF-12) was used to assess functioning (Ware et al., 1995, 1996).

The mental component score (MCS) and physical component score (PCS) of the SF-12 were used for the current study. The MCS and PCS measure the perception of impact of mental health symptoms and physical problems (respectively) on one’s daily activities based on a 6-point Likert-type response scale (1 = all of the time, 6 = none of the time). For both the MCS and PCS, standardized scores are computed and range from 0 to 100, with 100 representing the highest level of functioning.

Alcohol and other drug use. The Alcohol Use Disorders Identification Test (AUDIT) was used to assess problematic alcohol use (Babor et al., 1989). The AUDIT asks participants about quantity and frequency of alcohol use over the past year in addition to questions about potential consequences of alcohol use. Prior research has established the reliability and validity of the AUDIT (Reinert & Allen, 2002), and current guidelines recommend a cutoff of 8 or higher as the best screen for a potential alcohol use disorder (Conigrave et al., 1995).

Assessment of other noncannabis drug use involved items adapted from the World Health Organization’s Alcohol, Smoking and Substance Involvement Screening Test (WHO ASSIST Working Group, 2002). Subjects were asked about lifetime and past-3-month use of cocaine, sedatives or sleeping pills, street opioids, amphetamines, hallucinogens, and inhalants. Subjects were also asked about use of cannabis combined with alcohol, other drugs, and PPMs.

Data analysis

The analysis for this study involved an analysis of the overall sample of persons who had self-reported cannabis use in the past month for pain. This sample was then divided into two unique groups based on whether they reported past-month cannabis use for pain-related purposes. The sample was then divided into two unique groups based on whether they reported overall sample of persons who had self-reported cannabis use in the past month for pain-related purposes. This sample was then divided into two unique groups based on whether they reported past-month cannabis use for pain-related purposes. The sample was then divided into two unique groups based on whether they reported past-month cannabis use for pain-related purposes. This sample was then divided into two unique groups based on whether they reported past-month cannabis use for pain-related purposes.

Results

Sample description

The current study included 273 subjects who reported past-month cannabis use for pain-related purposes. On average, subjects in this study were approximately 40.3 years of age, male (69.2%), married or cohabitating (50.0%), and White (99.6%). The majority of subjects reported at least some education at the college level (59.0%). Of the 273 subjects, 172 (63.0%) reported using PPM within the past month for pain-related purposes (PPM users). Non–PPM users were significantly younger than PPM users ($M$ [SD] = 37.7 [11.7] vs. 41.9 [12.8] years; $t$ = -2.77, $p$ = .006). No other significant differences were observed across the PPM grouping variable.

Pain and functioning

NRS pain rating scale scores ranged from 0 to 10, with higher scores representing higher levels of pain. PPM users reported higher levels of current pain than did PPM nonusers ($M$ [SD] = 6.18 [2.05] vs. 5.41 [2.28]; $t$ = -2.74, $p$ = .007), but no significant differences were observed on the measure of average pain (Table 1). PPM users also had comparably lower levels of physical functioning based on the SF-12–PCS ($M$ [SD] = 34.86 [8.33] vs. 38.80 [8.71], $t$ = 3.66, $p$ < .001). No significant difference was observed on the SF-12–MCS.

Use of alcohol and other drugs

The next stage of the analysis examined differences in levels of alcohol and other noncannabis drug involvement. AUDIT scores ranged from 0 to 40 ($M$ = 3.7, $SD$ = 4.95). Fourteen percent of the overall sample reached or exceeded the AUDIT threshold score of 8 to represent alcohol misuse. Approximately 40% of the overall sample reported using cannabis with alcohol. No significant differences were observed among PPM users and nonusers for the alcohol use measures.

Lifetime use of other (noncannabis) drugs was common among the overall sample. More specifically, 37.1% of the sample reported lifetime use of cocaine, and 27.2% of the sample reported lifetime use of amphetamines (Table 2). Past-3-month use of all substances was relatively low (e.g., cocaine = 2.6% and amphetamines = 3.8%). Although no significant differences were observed in percentage of lifetime and past-3-month use of other drugs, PPM users were significantly more likely to combine use of cannabis with other drugs than were PPM nonusers. No differences in lifetime or past-3-month use of other drugs were noted across the PPM grouping variable. However, PPM nonusers were significantly less likely to combine cannabis with other drugs than were PPM users (6.9% vs. 19.2%, $p$ = .01).
TABLE 1. Comparison of medical cannabis users who used or did not use prescription pain medications (PPMs) on measures of sociodemographics, pain levels, and functioning

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall (N = 273)</th>
<th>PPM nonuser (n = 101)</th>
<th>PPM user (n = 172)</th>
<th>Test statistics (df)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, in years, M (SD)</td>
<td>40.3 (12.5)</td>
<td>37.7 (11.7)</td>
<td>41.9 (12.8)</td>
<td>t(225.34) = -2.77</td>
</tr>
<tr>
<td>Gender, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p = .006</td>
</tr>
<tr>
<td>Male</td>
<td>189 (69.2)</td>
<td>74 (73.3)</td>
<td>115 (66.9)</td>
<td>χ²(1) = 1.23</td>
</tr>
<tr>
<td>Female</td>
<td>84 (30.8)</td>
<td>27 (26.7)</td>
<td>57 (33.1)</td>
<td>p = .268</td>
</tr>
<tr>
<td>Marital status, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not married</td>
<td>136 (50.0)</td>
<td>49 (48.5)</td>
<td>87 (50.9)</td>
<td>χ²(1) = 0.141</td>
</tr>
<tr>
<td>Married</td>
<td>136 (50.0)</td>
<td>52 (51.5)</td>
<td>84 (49.1)</td>
<td>p = .701</td>
</tr>
<tr>
<td>Race, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-White</td>
<td>1 (0.04)</td>
<td>0 (0.0)</td>
<td>1 (0.006)</td>
<td>χ²(1) = 0.589</td>
</tr>
<tr>
<td>White</td>
<td>272 (99.6)</td>
<td>101 (100.0)</td>
<td>171 (99.4)</td>
<td>p = .442</td>
</tr>
<tr>
<td>Education, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;High school</td>
<td>9 (3.0)</td>
<td>3 (3.0)</td>
<td>6 (3.5)</td>
<td>χ²(2) = 0.330</td>
</tr>
<tr>
<td>High school or equiv.</td>
<td>102 (38.0)</td>
<td>40 (39.6)</td>
<td>62 (36.3)</td>
<td>p = .848</td>
</tr>
<tr>
<td>&gt;High school</td>
<td>161 (59.0)</td>
<td>58 (57.4)</td>
<td>103 (60.2)</td>
<td></td>
</tr>
<tr>
<td>NRS, 0–10 scale, M (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current pain</td>
<td>5.90 (2.16)</td>
<td>5.41 (2.28)</td>
<td>6.18 (2.05)</td>
<td>t(188.47) = -2.74</td>
</tr>
<tr>
<td>Average pain</td>
<td>6.91 (1.73)</td>
<td>6.69 (1.78)</td>
<td>7.05 (1.69)</td>
<td>p = .007</td>
</tr>
<tr>
<td>SF-12, 0–100 scale, M (SD)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental component</td>
<td>49.18</td>
<td>50.31</td>
<td>48.51</td>
<td>t(218.14) = 1.31</td>
</tr>
<tr>
<td>Physical component</td>
<td>36.32</td>
<td>38.80</td>
<td>34.86</td>
<td>t(201.17) = 3.66</td>
</tr>
</tbody>
</table>

Notes: Cell values do not add up to overall sample size because of small amounts of missing data due to nonresponse. These missing data were handled using listwise deletion. Subscripts with variables represent theoretical score range. Equiv. = equivalent; NRS = Numeric Rating Scale (0 = no pain, 10 = severe pain); SF-12 = Short Form-12 Health Survey (impact on functioning, 1 = all of the time, 6 = none of the time).

TABLE 2. Comparison of medical cannabis users who used or did not use prescription pain medications (PPMs) on measures of alcohol and other drug use

<table>
<thead>
<tr>
<th>Variable</th>
<th>Overall (N = 273)</th>
<th>PPM nonuser (n = 101)</th>
<th>PPM user (n = 172)</th>
<th>Test statistics (df)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol, AUDIT score M (SD)</td>
<td>3.7 (4.95)</td>
<td>3.9 (5.87)</td>
<td>3.5 (4.3)</td>
<td>t(164.58) = 0.57</td>
</tr>
<tr>
<td>AUDIT ≥ 8, n (%)</td>
<td>38 (13.9)</td>
<td>17 (16.8)</td>
<td>21 (12.4)</td>
<td>χ²(1) = 1.05</td>
</tr>
<tr>
<td>Cocaine, n (%)</td>
<td></td>
<td></td>
<td></td>
<td>p = .304</td>
</tr>
<tr>
<td>Lifetime</td>
<td>99 (37.1)</td>
<td>36 (37.1)</td>
<td>63 (37.1)</td>
<td>χ²(1) = 0.01</td>
</tr>
<tr>
<td>Past 3 months</td>
<td>7 (2.6)</td>
<td>2 (2.1)</td>
<td>5 (2.9)</td>
<td>p = .999</td>
</tr>
<tr>
<td>Sedatives, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifetime</td>
<td>66 (24.9)</td>
<td>18 (18.9)</td>
<td>48 (28.4)</td>
<td>χ²(1) = 3.05</td>
</tr>
<tr>
<td>Past 3 months</td>
<td>23 (8.7)</td>
<td>8 (8.2)</td>
<td>15 (8.9)</td>
<td>p = .699</td>
</tr>
<tr>
<td>Street opioids, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifetime</td>
<td>32 (12.1)</td>
<td>8 (8.2)</td>
<td>24 (14.4)</td>
<td>χ²(1) = 2.16</td>
</tr>
<tr>
<td>Past 3 months</td>
<td>5 (1.9)</td>
<td>1 (1.0)</td>
<td>4 (2.4)</td>
<td>p = .42</td>
</tr>
<tr>
<td>Amphetamines, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lifetime</td>
<td>72 (27.2)</td>
<td>20 (20.8)</td>
<td>52 (31.0)</td>
<td>χ²(1) = 3.15</td>
</tr>
<tr>
<td>Past 3 months</td>
<td>10 (3.8)</td>
<td>4 (4.2)</td>
<td>6 (3.6)</td>
<td>p = .076</td>
</tr>
<tr>
<td>Cannabis combined with alcohol, n (%)</td>
<td>109 (39.9)</td>
<td>39 (37.0)</td>
<td>70 (40.7)</td>
<td>χ²(1) = 0.115</td>
</tr>
<tr>
<td>Cannabis combined with other drugs, n (%)</td>
<td>40 (14.7)</td>
<td>7 (6.9)</td>
<td>33 (19.2)</td>
<td>χ²(1) = 7.64</td>
</tr>
</tbody>
</table>

Notes: AUDIT = Alcohol Use Disorders Identification Test.
Table 3. Unadjusted and adjusted associations with prescription pain medication (PPM) misuse based on Poisson regression analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted</th>
<th>Adjusted</th>
<th>Expected values (M [95% CI])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>-.017***</td>
<td>-.018***</td>
<td>Younger age (1q = 32): 4.3 [3.9, 4.7]</td>
</tr>
<tr>
<td>Current pain</td>
<td>.03</td>
<td>.037</td>
<td>Older age (3q = 52): 3.1 [2.8, 3.5]</td>
</tr>
<tr>
<td>SF-12–Physical component score</td>
<td>-.004</td>
<td>.245</td>
<td>Low pain (1q = 5): 3.5 [3.2, 3.8]</td>
</tr>
<tr>
<td>Perceived efficacy of PPMs</td>
<td>.03*</td>
<td>.012*</td>
<td>High pain (3q = 8): 3.9 [3.5, 4.4]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notes: All covariates based on Poisson regression. Unadjusted models included only the indicated covariate with the PPM misuse score in the regression model. Adjusted models included all covariates in the model. Expected values for the first quartile (1q) and third quartile (3q) of each variable were estimated with simulation procedures using the posterior distribution of the adjusted models, while holding all other model covariates at their mean. CI = confidence interval; N.A. = not applicable; SF-12 = Short Form-12 Health Survey (impact on functioning).</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Perceived efficacy and misuse of prescription pain medications

PPM users provided perceived efficacy ratings related to pain for both cannabis and PPMs (1 = not at all helpful, 10 = very helpful). Among PPM users, cannabis was perceived to be more efficacious (M = 7.57, SD = 1.95) than PPMs (M = 5.31, SD = 2.56). This was a statistically significant difference based on a pairwise t test, t(160) = 9.57, p < .0001. The strength of the association between these ratings was modest (r = .21, p = .008). PPM users rated the efficacy of cannabis for pain slightly lower than individuals who were non-PPM users (M [SD] = 7.56 [1.95] vs. 8.27 [1.58]), t(236.7) = -3.22, p = .001.

PPM users reported high levels of agreement (1 = strongly agree, 5 = strongly disagree) when asked whether they were trying to reduce use of PPMs for pain (M = 2.1, SD = 1.75). Similar levels of agreement were observed regarding efforts to reduce use of PPMs for nonmedical reasons (M = 2.65, SD = 2.0). These differences were statistically significant based on a pairwise t test, t(80) = -3.49, p < .001.

As previously described, a PPM misuse index was created by summing responses across a series of items derived from the COM. In this study, the observed PPM misuse scores ranged from 0 to 18 (M = 4.6, SD = 3.8), with higher scores indicating higher levels of PPM misuse. Given the relatively small size of the PPM-user group, only a limited number of associations with other study variables were examined. Age was examined given that it exhibited significant associations with other variables in the exploratory analysis. Current pain rating, the SF-12–PCS, and perceived efficacy of PPMs were also selected given their conceptual relevance to PPM misuse.

The distribution of the PPM misuse score was consistent with the distribution of count-based measures; therefore, the associations were examined using Poisson regression analysis. Table 3 provides unadjusted and adjusted associations between each study variable and the PPM misuse. Age and perceived efficacy of PPMs were significantly associated with PPM misuse in both the unadjusted and adjusted models. Current pain was significant only in the adjusted model, and the SF-12–PCS was not significant in either model.

To facilitate the interpretation of the adjusted model, expected values were estimated with simulation procedures using the posterior distribution of the adjusted models. Expected values were estimated for the first and third quartile (i.e., 25th and 75th percentile rank) for each variable, while holding the other variables at their mean. These analyses showed that age exhibited the strongest effect with respect to PPM misuse. Younger adults (first quartile = 32 years of age) had an expected PPM misuse score of 4.3 (95% CI [3.9, 4.7]), whereas older adults (third quartile = 52 years of age) had an expected score of 3.1 (95% CI [2.8, 3.5]). Although current pain and perceived efficacy of PPMs were statistically significant, the effect sizes were not practically significant (Table 3).

Discussion

The laws and policies surrounding medical cannabis have changed rapidly over the past 10 years, but the research on the characteristics and needs of persons who are seeking medical cannabis is limited. The purpose of this study was to provide descriptive data on the characteristics of persons who are seeking and using cannabis specifically for pain-related purposes. Pain as a presenting problem is commonly endorsed by adults seeking medical cannabis, and medical cannabis is often presented as a viable alternative (or adjuvant agent) to PPMs that have risks in terms of misuse and potential adverse outcomes (e.g., Berman et al., 2004; Johnson et al., 2010; Lucas, 2012; Naef et al., 2003; Rog et al., 2005). This study is the first to make systematic compari-
sons among medical cannabis users who use and do not use PPMs.

Among this sample of medical cannabis users, those who used PPMs tended to be older and exhibited slightly higher levels of pain and lower levels of physical functioning. However, no other differences with respect to sociodemographics and functioning were observed. One of the concerns of medical cannabis relates to the psychoactive properties of the substance and the possibility of it leading to more serious levels of drug involvement, particularly in the context of receiving PPMs. This is especially important because pain clinics face increasing pressures to monitor prescription opioids and other drugs (Manchikanti et al., 2008) and because the interaction between cannabinoids and PPMs is not well understood (Abrams et al., 2011). Although the overall sample exhibited higher lifetime and past-3-month rates of use of alcohol and other drugs than did the general population, no differences were observed between PPM users and nonusers in terms of rates of co-occurring substance use. These data provide preliminary results that use of PPMs among cannabis users might not be a reliable risk indicator for more serious forms of drug involvement. At the same time, this claim needs to be examined using a longitudinal research design.

It is important to highlight that approximately 40% of the overall sample reported combining cannabis with alcohol—no differences were observed among PPM users and nonusers. The interaction between cannabis and alcohol is not well understood and remains a crucial gap in the cannabis research.

Swartzwelder et al. (2012) provide preliminary evidence for the combined effects of these substances, with a significant age–drug interaction on working memory. Shillington and Clapp (2001) also examined the relation between college student alcohol and cannabis use. Polysubstance use—that is, combining alcohol and cannabis—was associated with more substance-related problems than alcohol-only use. However, most prior research was based on recreational users of alcohol and cannabis, and more work is needed to understand the co-use of these substances among adults who report medical cannabis use for pain management.

PPM users reported combining cannabis with other drugs at a significantly higher rate than non–PPM users. Because these data were based on a pilot study, our measurement was not granular enough to determine the types of drugs that were combined. Clearly, improved measures are needed, but nonetheless, very little research has been conducted to understand the combined use of cannabis and other substances. Despite the limitations in measurement and study design, these findings suggest a need to provide greater patient education regarding substance misuse when patients are seeking certification or recertification for medical cannabis. Such patient education can also be provided at cannabis dispensaries where certified cannabis users access this substance.

A number of general indicators of problems associated with PPMs were observed in this study. For example, PPM users rated the efficacy of cannabis for pain management higher than that of PPMs, which suggests that PPM users may have pain-related needs that are not being sufficiently addressed by their PPMs. PPM users provided high levels of agreement on questions related to efforts to reduce use of PPMs for pain and nonmedical reasons. Although this finding implies that the PPM users believe they are taking too many PPMs for both pain and nonpain purposes, more information is needed about their motivations. More specifically, additional research is necessary to understand the perspective of the individual user to better identify whether the efforts to reduce use are for purposes of safety (e.g., to avoid becoming dependent), side effects of the medication, or some other reason. This is an opportunity for qualitative research to better understand the user experience.

The majority of PPM users endorsed some form of PPM misuse—a finding that was consistent with the full sample of the parent study (see Ilgen et al., 2013). The high rates of PPM misuse in this sample highlight the extent to which these participants are at elevated risk for PPM-related problems such as the development of an opioid use disorder and/or other opioid-related adverse outcomes such as overdose, accidents, etc. As previously mentioned, the recent work of Bachhuber et al. (2014) showed that states with medical cannabis laws had a 24.8% lower mean annual opioid overdose mortality rate. This suggests that medical cannabis could be a safer alternative to PPMs, but further research is needed to illuminate the underlying causal relationships.

In this study, we used items adapted from the COMM as an index to identify factors associated with PPM misuse. Although a few variables were identified as significant in the multivariate model (i.e., younger age, lower physical functioning, higher perceived efficacy of PPMs), the simulation procedures suggest that these factors have minimal practical significance. One of the obvious limitations is that the constructed index needs further development to establish a stronger base of reliability and validity. Our selection criteria also relied on any past-month use of medical cannabis for chronic pain, but we were unable to quantify the actual amount. Moreover, the extent to which cannabis use represents medical or recreational use is unknown. Based on the state’s certification laws, patients in this study were able to legally grow and possess cannabis and use it at their own discretion. No formal prescription exists to specify the specific indication, dose, or timing of use. Consequently, differentiating medical versus nonmedical use following certification is not possible. In all likelihood, significant variability exists both between and within participants in the degree to which each instance of use was motivated by factors related to medical or other nonmedical reasons.

Future research is needed to develop standardized measures of cannabis use, preferably measures that could be
used to triangulate self-reports. Recently, Phillips et al. (2014) provided evidence of the feasibility of using text messaging as an ecological momentary assessment method for measuring cannabis use among college students. Although they reported findings that suggested this is a promising direction, it is unclear whether samples of medical cannabis users recruited from community-based certification centers are regular users of this technology.

It is also important to note that this study uses data derived from a single medical marijuana certification center, and the majority of subjects were White. At present, no information is available regarding the number of certification centers, their locations, and the demographics of persons seeking certification or recertification. The absence of these data necessarily limits the generalizability of the current study and points to the need for more research related to medical cannabis certification.

Overall, this study provides much needed information to understand the population of medical cannabis users, particularly in the context of use of PPMs. The findings of this study need to be considered within the context of the study limitations, several of which have been identified previously in this discussion. Advancing this line of research necessarily requires improvements in both study design and measurement.

Regarding study design, a longitudinal approach is needed to better understand the trajectories of substance use among medical cannabis users (Ilgen et al., 2013), with ongoing comparisons among persons using and not using PPMs. The improvement of measurements also is essential for building this knowledge base—e.g., motivations and reasons for use of medical cannabis, perceived efficacy of cannabis and PPMs, and PPM misuse. This line of research should be considered a priority in the studies of alcohol and other drugs, given the rapidly changing landscape of medical cannabis laws and policies.

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January 13, 2017

State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, OH 43215

Submitted electronically at medicalmarijuana@med.ohio.gov

Re: Physician Certificate to Recommend Medical Marijuana and Petition for Added Qualifying Condition

x is a not-for-profit, tax-exempt corporation organized and operated for patient care, medical research and education. The Cleveland Clinic Foundation and its affiliates comprise the Cleveland Clinic Health System (CCHS). CCHS operates thirteen hospitals with approximately 3,900 staffed beds, twenty-one outpatient family health centers and ten ambulatory surgery centers with over 3,400 salaried physicians and scientists. Last year, the Health System had more than 6.6 million patient visits and 178,000 hospital admissions. CCHS is the single largest private employer in the State of Ohio with more than 49,000 employees and is also the largest provider of Medicaid services to beneficiaries in the State of Ohio.

We appreciate the opportunity to comment on the aforementioned Draft Rules. The Medical Board has clearly taken a thoughtful and diligent approach to this process. Cleveland Clinic is in agreement with the approach and process as outlined in the Draft.

We do wish to comment, however, on the final section, 4731-32-05 Petition to Request Additional Qualifying Condition or Disease. We find the process as written to be grounded in a solid, evidence-based approach and the timelines as proposed are appropriate. However, we would urge the Board to consider whether it would be appropriate to expand its application, not solely to petitions to request additional qualifying conditions or diseases, but also to modification or further definition of existing conditions and/or removal of qualifying conditions or diseases for which recommendation of marijuana is no longer appropriate.

It is almost certain that the list of conditions for which marijuana can be used will change. And while we expect that we will discover new uses for the plant and its components, we can also expect that evidence will emerge to show that marijuana is not efficacious and may in fact be harmful for some conditions. We believe it would be advisable to have a process whereby conditions can be expanded, refined, or narrowed as our knowledge expands.

The Cleveland Clinic suggests the following modifications may facilitate such a process:

4731-32-05 Petition to Request Additional, Modification or Removal of a Qualifying Condition or Disease

(A) A petition to request the approval modification of the list of a conditions or diseases to be designated as a qualifying medical condition shall be submitted to the board in the manner required by the board.
(B) No later than October 15 of each year, the board shall designate a period during which petitions will be accepted in the next calendar year. Petitions will not be accepted after the expiration of the acceptance period.

(C) A petition shall include all of the following information:

1. The name and contact information for the person submitting the petition.
2. The specific disease or condition requested to be added, modified or removed as a qualifying condition;
3. Information from experts who specialize in the study of the disease or condition;
4. Relevant medical or scientific evidence pertaining to the disease or condition;
5. Evidence that conventional medical therapies are insufficient to treat or alleviate the disease or condition (for addition);
6. Evidence supporting the use of medical marijuana to treat or alleviate the disease or condition, supporting refinement or modification of the definition of an existing Qualifying Condition, or supporting the removal of an existing Qualifying Condition from the list, including journal articles, peer-reviewed studies, and other types of medical or scientific documentation;
7. Letters of support provided by physicians with knowledge of the disease or condition. This may include a letter provided by the physician treating the petitioner, if applicable.

(D) The state medical board shall not consider a petition seeking to add a broad category of diseases or conditions. (Note: We request further definition of the word “broad” as used here, given that broad categories such as “Cancer” are already on the list)

(E) In making its decision, the board shall review the petitions and supporting material.

1. The board may consolidate the review of two or more petitions submitted for the same or similar diseases or conditions.
2. The board may establish a limit on the number of petitions to be considered in a calendar year.
3. The board shall consult with one or more experts who specialize in the disease or condition.
4. The board shall review any appropriate and relevant medical or scientific evidence pertaining to the disease or condition.
5. The board shall consider whether conventional medical therapies are insufficient to treat or alleviate the disease or condition.
6. The board shall review evidence supporting the use of medical marijuana to treat or alleviate the disease or condition.
7. The board shall review any appropriately submitted letters of support provided by physicians with knowledge of the disease or condition, including any letter provided by a physician treating the petitioner, if applicable.
8. The board shall review any other appropriate and relevant evidence regarding the disease or condition.

(F) The board will issue a written decision no later than 180 days after the acceptance period closes unless the board determines that good cause exists to allow an extension. The board shall notify the petitioner of its decision and publish the decision on the medical marijuana control program website.
(G) Any petition for a condition that has been previously reviewed by the board and rejected will not be considered by the board unless new medical or scientific evidence that supports the request is offered.

We are thankful for the opportunity to comment on this very important policy matter. If you wish to further discuss these comments, please contact
CANNABINOID AND OPIOID INTERACTIONS: IMPLICATIONS FOR OPIATE DEPENDENCE AND WITHDRAWAL

J. L. SCAVONE, R. C. STERLING AND E. J. VAN BOCKSTAELE

Abstract—Withdrawal from opiates, such as heroin or oral narcotics, is characterized by a host of aversive physical and emotional symptoms. High rates of relapse and limited treatment success rates for opiate addiction have prompted a search for new approaches. For many opiate addicts, achieving abstinence may be further complicated by poly-drug use and comorbid mental disorders. Research over the past decade has shed light on the influence of endocannabinoids (ECs) on the opioid system. Evidence from both animal and clinical studies point toward an interaction between these two systems, and suggest that targeting the EC system may provide novel interventions for managing opiate dependence and withdrawal. This review will summarize the literature surrounding the molecular effects of cannabinoids and opioids on the locus coeruleus–norepinephrine system, a key circuit implicated in the negative sequelae of opiate addiction. A consideration of the trends and effects of marijuana use in those seeking treatment to abstain from opiates in the clinical setting will also be presented. In summary, the present review details how cannabinoid–opioid interactions may inform novel interventions in the management of opiate dependence and withdrawal.

OPIOID ADDICTION: A PERSISTENT SOCIETAL PROBLEM

Background

Overall, illicit drug abuse in the United States exceeded $180 billion in 2008 according to the National Institutes of Health. Abuse of heroin and prescription opioids have long constituted a significant economic burden to society both through the direct and indirect consequences of illicit opioid use. These costs include not only direct medical expenses, but also the costs of criminal activities associated with drug acquisition, social welfare, secondary medical issues associated with high-risk needle sharing, and productivity losses. In 1996, the cumulative economic burden of heroin addiction in the United States was estimated to be $21.9 billion (Mark et al., 2001). In 2001, illicit use of prescription opioids cost the United States approximately $8.6 billion, and this number continues to rise (Birnbaum et al., 2006; Gilson and Kreis, 2009; Strassels, 2009).
Intravenous heroin use experienced a steady climb through the early 1980’s in the United States, until rates began to decline concurrent with the implementation of programs designed to increase awareness of the risks associated with intravenous drug use and needle sharing. However, since the mid-1990’s heroin use has experienced a resurgence, particularly among younger populations. In 2004, an estimated 3.7 million people in the United States had reported using heroin at some point in their lifetime according to data collected by the National Institute on Drug Abuse. The 2008 National Survey on Drug Use and Health determined that the number of heroin users over the age of 12 in the United States had increased dramatically from 153,000 in 2007 to 213,000 in 2008. Unlike prior surges in heroin use that were primarily characterized by injection drug use, recent climbs in heroin use rates are due to significant increases in inhaled or snorted heroin. Heroin purity increased dramatically during the 1990’s and has remained stable (OAS, 2005). Meanwhile, the cost of heroin has decreased and is now less expensive relative to other opioid alternatives, potentially underlying the trends in increased inhalation drug use (OAS, 1998). The high abuse liability of heroin was demonstrated in a 2004 study of drug use, which found that 67% of those that used heroin also met the criteria for abuse or dependence, a statistic markedly higher than that for other drugs of abuse such as cocaine, marijuana, or sedatives (OAS). In 2008, 341,000 individuals received treatment for heroin dependence (OAS, 2009) and with recent increases in use, this number is likely to continue to climb.

**Non-medical use of prescription opioids**

Heroin use, while extremely problematic, is restricted to a very small percentage of the population. However, non-medical use of prescription opioids is now becoming more prevalent with rates of use rapidly increasing. The misuse or abuse of prescription drugs occurs when a person takes a prescription drug that was not prescribed or taken in one dose or for reasons other than those prescribed. Abuse of prescription drugs can produce serious health effects, including addiction. The classes of prescription drugs that are commonly abused include oral narcotics such as hydrocodone (Vicodin®), oxycodone (OxyContin®), propoxyphene (Darvon®), hydromorphone (Dilaudid®), meperidine (Demerol®) and diphenoxylate (Lomotil®) and their non-medical use has increased dramatically in recent years. For example, in 1990, the number of individuals initiating abuse of prescription opioids was 573,000. By the year 2000, the number had risen to over 2.5 million according to the National Institutes of Health. A 2009 nationwide study reported that 6.2 million individuals were recent non-medical users of prescription opioids (OAS, 2009). Among high school seniors, as many as one in 10 used prescription opioids for non-medical purposes in 2009. For the first time, the number of individuals initiating prescription opioid use nearly equaled that of marijuana; a previously unprecedented and alarming finding. Concurrently, emergency department visits due to complications from non-medical use of hydrocodone and oxycodone rose by 170% and 450% respectively from 1994 to 2002. Furthermore, opioid-related deaths rose by more than 300% between 1999 and 2006 (OAS, 2009).

**THE CLINICAL OPIOID WITHDRAWAL SYNDROME AND UNDERLYING BRAIN CIRCUITRY**

**Clinical presentation and management**

Abstinence following chronic exposure to opiates is accompanied by a pronounced syndrome of aversive physical and emotional symptoms. Characteristic signs of opiate withdrawal include yawning, rhinorrhea, perspiration, dilated pupils, anxiety and restlessness, nausea and vomiting, diarrhea, increased heart rate or blood pressure, as well as a host of flu-like symptoms such as chills, joint and muscle aches, and increased body temperature (Jasinski, 1981; Gossop, 1988; Farrell, 1994; Wesson and Ling, 2003). In opiate-dependent individuals, the experience of a prolonged withdrawal syndrome often contributes to renewed illicit drug use and less-than-favorable treatment prognoses.

Pharmacotherapeutics designed to attenuate the severity of these opiate withdrawal signs can be used to promote improved outcome in the critical early phases of treatment. Currently, the pharmacotherapeutic options for opioid dependence and withdrawal are primarily designed around the principles of maintenance therapy and/or detoxification. Agonist replacement or maintenance therapy involves substitution of illicit opioid use with long-acting opioid-receptor agonists in a carefully controlled manner. Ideal agonist replacement drugs often bind to opioid receptors with greater affinity and are metabolized more slowly than commonly abused illicit opioids. Alternatively, opioid detoxification employs opioid receptor antagonists that provide potent and high-affinity blockade of mu-opioid receptor (MOR). These compounds work by inducing withdrawal, often through the displacement of illicit opioids from receptor binding sites in the nervous system.

To assist with opioid detoxification and the associated withdrawal syndrome, alpha-2 adrenergic receptor agonists are also used to address the noradrenergic hyperactivity that is a hallmark of opioid withdrawal. Clonidine and lofexidine are centrally-acting α-2 adrenergic receptor agonists used during rapid opioid detoxification to regulate noradrenergic hyperactivity associated with opioid withdrawal. These agents are often co-administered with opioid receptor antagonists during detoxification. Clonidine rapidly and effectively reduces withdrawal symptoms, but can cause postural hypotension through its actions on noradrenergic control of cardiovascular function (Gossop, 1988). Lofexidine, which works similar to clonidine but involves lessened risk of hypotension, has shown greater efficacy than clonidine in recent studies (Strang et al., 1999; Gerra et al., 2001; Meader, 2010). The activity of these agents is heavily reliant on their activity within a key
noradrenergic nucleus within the brain- the locus coeruleus (LC).

Noradrenergic circuitry

The LC is located in the anterior pons of the brainstem, near the fourth ventricle. This nucleus provides the majority of noradrenergic input to the central nervous system, and is highly interconnected with many different brain regions, allowing for the regulation of cognition, pain, emotional state, anxiety, arousal, and stress (Aston-Jones and Bloom, 1981; Aston-Jones et al., 1986; Nestler et al., 1999; Carrasco and Van de Kar, 2003; Dunn et al., 2004). The widespread downstream effects of LC neurotransmission occur as a result of the diverse network of projections sent to and from this nucleus to the entire neuraxis. The LC is a key anatomical locus where opioid and stress signaling intersect. Many of the neurons projecting from the nucleus paragigantocellularis (PGi) and nucleus prepositus hypoglossi (PH) provide enkephalin to the LC (Aston-Jones et al., 1986, 1991), while corticotropin releasing factor (CRF) innervation arises predominantly from the PGi, paraventricular nucleus of the hypothalamus (PVN), and peri-coerulear region (Valentino et al., 1993, 1998a). The LC is extremely sensitive to opioid and stress peptides delivered by afferent fibers due to the high density of opioid and CRF receptors (Pert et al., 1976; Valentino et al., 1983; Aston-Jones et al., 1986; Tempel and Zukin, 1987; Ding et al., 1996; Van Bockstaele et al., 1996a; Reyes et al., 2007). The kappa-opioid receptor (KOR) and delta-opioid receptor (DOR) have a prominent pre-synaptic distribution in the LC and are poised to auto-regulate neurotransmitter release from LC afferents (Van Bockstaele et al., 1997; Kreibich et al., 2008; Reyes et al., 2009a). The MOR has a dense post-synaptic distribution along the plasmalemma of somata and dendrites of LC neurons (Van Bockstaele et al., 1996a,b). The MOR-mediated sensitivity and response of this region to opioid exposure has been extensively studied and characterized.

Molecular expression of opioid dependence and withdrawal in LC circuitry

MOR is a G-protein coupled receptor that typically signals through G_\text{\textalpha}_\text{\textalpha} alpha-subunit proteins to inhibit the activity of adenyl cyclase (AC) I and VIII, thereby reducing cyclic AMP (cAMP) production, impacting Na\textsuperscript{+} current and neuronal excitability (Childers et al., 1992; Dhawan et al., 1996). Additionally, opioids also inhibit the LC by coupling opioid receptor activation to G-protein-gated inwardly rectifying K\textsuperscript{+} (GIRK) ion channels (Christie et al., 1987; North et al., 1987; Nestler, 1992, 2001). Direct effects of opioid exposure can include receptor desensitization and internalization via a clathrin-mediated mechanism (Van Bockstaele and Commons, 2001; Van Bockstaele et al., 2001; Alvarez et al., 2002; Dang and Williams, 2005; Johnson et al., 2005; Arttamangkul et al., 2006; Gintzler and Chakrabarti, 2006). In this manner, MOR activation by opioids has an acutely inhibitory effect in the LC, resulting in sedation, hypolocomotion, analgesia, and respiratory depression.

Following repeated exposure to opioids, a number of cellular adaptations occur within this region that significantly impact the development of opioid dependence and manifestation of opioid withdrawal. Suppression of AC-I and AC-VIII by opioid exposure leads to decreased cAMP levels and protein kinase-A (PKA) activity, and decreased phosphorylation of cAMP response element binding protein (CREB), a downstream effector of PKA. By binding to regulatory DNA sequences called cAMP response elements (CREs), CREB is able to alter the expression of key proteins in the cAMP pathway. Opioid exposure alters the phosphorylation level of CREB, thereby regulating the transcriptional activation of CREB target genes. These transcriptional changes may include increased expression of AC-VIII, PKA catalytic and regulatory subunits, CREB, and tyrosine hydroxylase (the rate-limiting enzyme in norepinephrine synthesis). As an end result of these adaptations, the cAMP pathway is upregulated and the electrical excitability in the LC increases (Widnell et al., 1994; Lane-Ladd et al., 1997; Nestler and Aghajanian, 1997; Boundy et al., 1998; Coven et al., 1998; Nestler, 2001).

Through its wide array of projections throughout the brain, hyperactivity in the LC during opiate withdrawal has the potential to impact signaling in a number of brain regions, primarily in the frontal cortex to which it provides the sole noradrenergic input [reviewed (Valentino and Aston-Jones, 1995; Berridge and Waterhouse, 2003; Van Bockstaele et al., 2010)]. Alterations in LC activity have been implicated in the somatic expression of withdrawal (Taylor et al., 1988; Rasmussen et al., 1990; Koob et al., 1992; Maldonado and Koob, 1993; Funada et al., 1994; Maldonado, 1997), and it has been shown that these effects are mediated by the excitatory input from the nucleus PGi (Rasmussen and Aghajanian, 1989; Maldonado, 1997; Van Bockstaele et al., 2000, 2001; Johnson et al., 2002).

Upon the removal of opioids from the system, a surge in noradrenergic activity from the LC contributes significantly to the somatic expression of opioid withdrawal (Crawley et al., 1979; Swann et al., 1982; Van Bockstaele et al., 2008). Within noradrenergic targets of the LC, opiate withdrawal-mediated LC disturbances can be appreciated in terms of increased tyrosine hydroxylase, c-Fos and FosB expression, along with enhanced activation (phosphorylation) of cyclic adenosine monophosphate (c-AMP) pathway members (Stornetta et al., 1993; Nestler et al., 1994; Maldonado et al., 1995; Nestler and Aghajanian, 1997; Nestler, 2001; Van Bockstaele et al., 2001; Maldonado, 2003). Both intrinsic and extrinsic factors to the LC contribute to the withdrawal phenomenon. The cAMP-related cellular adaptations that occur in response to chronic opioid exposure cause enhanced excitability in LC neurons. When coupled with the removal of inhibitory opioid input upon withdrawal or detoxification, this combination results in the dysregulation of the LC-
noradrenergic circuit (Nestler et al., 1994; Nestler, 2001). In addition to upregulated cAMP pathway activity in the LC, excitatory amino acid influx to the LC from its afferents also contributes to the molecular expression of opioid withdrawal (Akaoka and Aston-Jones, 1991; Aghajanian et al., 1994; Maldonado, 1997; Van Bockstaele et al., 2001). Common therapeutic approaches employed in the management of opioid withdrawal are targeted to adrenergic receptors with the intent of counteracting cellular hyperactivity and restoring LC homeostasis.

Therapeutic agents targeting the brain's noradrenergic circuitry have demonstrated clinical efficacy in attenuating the noradrenergic hyperactivity that is observed during opiate withdrawal (Gold et al., 1979; Gossop, 1988; Gold, 1993; Gowing et al., 2004). However, in some individuals, the use of alpha-2 adrenergic receptor agonists is limited by the presence of side effects such as hypotension, sedation, and cognitive impairment, or by incomplete abolition of withdrawal symptoms (Gossop, 1988; Gerra et al., 2001; Lobmaier et al., 2010). It remains important to investigate other receptor systems that interact with the opioid system in noradrenergic brain regions and may serve as potential therapeutic targets.

CANNIBINOID MODULATION OF NORADRENERGIC CIRCUITRY

The endocannabinoid (EC) system

Through significant advances in our understanding of the cannabinoid system in recent years, we now understand that the endogenous cannabinoid system—or EC system—is the primary regulator of cannabinoid functions in the brain. The EC system has been implicated in a variety of physiological functions due to abundant expression of its receptors and endogenous ligands in the central nervous system (Herkenham et al., 1991; Mackie, 2005b, 2008). The EC consists of receptors, ligands and enzymes responsible for their biosynthesis and degradation. Endocannabinoids are lipophilic arachidonic acid derivatives that are released in an activity-dependent fashion from the postsynaptic cell (Piomelli et al., 1998; Piomelli, 2003, 2005; Di Marzo et al., 2005; Basavarajapapa, 2007). Two major ECs have been identified: anandamide (Devane et al., 1992; Di Marzo et al., 1994) and 2-arachidonoylglycerol (2-AG) (Mechoulam et al., 1995, 1998; Sugiura et al., 1995; Stella et al., 1997; Martin et al., 1999).

Endocannabinoids control emotional reactivity, motivated behaviors and energy homeostasis primarily by targeting brain cannabinoid type 1 receptors (CB1r) (Mechoulam et al., 1998; Gifford et al., 2001; Fride, 2002; Kreitzer and Regehr, 2002; Wilson and Nicoll, 2002; Piomelli, 2005; Wittkin et al., 2005; Mackie, 2008; Steiner et al., 2008; Steiner and Wotjak, 2008). The CB1r is one of the most plentiful G-protein coupled receptors within the brain, and cannabinoid signaling through this receptor mediates a wide variety of peripheral and central processes (Howlett et al., 1990, 2002; Freund et al., 2003; Szabo and Schlicker, 2005; Demuth and Molleman, 2006).

The EC, noradrenergic circuitry and stress

The EC and noradrenergic systems are significantly and dynamically impacted by stress (Cassens et al., 1980; Flugge et al., 2004; Gorzalka et al., 2008; Hill and McEwen, 2010; Shinba et al., 2010) and noradrenergic transmission is responsible for cannabinoid-induced activation of the hypothalamic–pituitary–adrenal (HPA) axis (McLaughlin et al., 2009). Under conditions of acute stress, NE is increased centrally and peripherally (Cassens et al., 1980; Abercrombie and Jacobs, 1987; Page and Valentino, 1994; Valentino et al., 1998; Ferry et al., 1999; Nestler et al., 1999; Sands et al., 2000) while the EC system tonically constrains the activation of neural circuits, including the HPA axis (Gorzalka et al., 2008; Steiner and Wotjak, 2008). However, disrupted noradrenergic and EC signaling is associated with an inability to adapt to chronic stress (Nestler et al., 1999; Wong et al., 2000; Flugge et al., 2004; Hill and Gorzalka, 2004; Gorzalka et al., 2008; Hill et al., 2008). We recently demonstrated that pre-treatment with a cannabinoid receptor agonist diminishes acute stress-induced noradrenergic transmission in the mPFC (Reyes et al., 2012). Cannabinoid pre-treatment also resulted in a decrease in climbing during a single exposure to swim, an arousal-related behavior that has been attributed to availability of NE (Detke et al., 1995).

Furthermore, we tested the effect of acute stress on α2-AR–cannabinoid interactions in rats (Reyes et al., 2012). Chronic CB1r stimulation with WIN 55,212-2 in slices from unstressed animals desensitized the cortical α2-AR response, similar to the desensitization produced by acute WIN 55,212-2 pretreatment. However, when animals were exposed to chronic WIN 55,212-2 and then given a forced swim stress before brain slices were prepared for electrophysiology, the cortical α2-AR response did not desensitize and is similar in magnitude to subjects that are neither stressed nor exposed to CB1r stimulation. These findings indicate that stress sensitizes the cortical α2-AR response, making it resistant to desensitization by chronic activation of CB1rs. These data reveal the stress-dependent nature of cannabinoid interactions and implicate pre- and postsynaptic ARs. However, although information regarding interactions between the two systems is emerging, there remain gaps in our knowledge regarding how cannabinoids modulate noradrenergic circuitry under different physiological conditions.

Anatomical and electrophysiological studies within the coeruleo-cortical pathway demonstrate cannabinoid sensitivity within noradrenergic cells (Mendiguren and Pineda, 2004, 2006a,b, 2007; Oropeza et al., 2005, 2007; Muntoni et al., 2006; Page et al., 2007; Scavone et al., 2010). Convergent lines of evidence (Muntoni et al., 2006; Mendiguren and Pineda, 2006a) have demonstrated an interaction between the cannabinoid and noradrenergic systems in areas such as the mPFC (Oropeza et al., 2005, 2007; Page et al., 2007, 2008), nucleus accumbens (NAc) (Carvalho and Van
Bockstaele, 2011; Carvalho et al., 2010a,b), LC (Oropeza et al., 2005; Scavone et al., 2010) and the nucleus of the solitary tract (NTS) (Jelsing et al., 2009; Carvalho et al., 2010a,b). Recent anatomical evidence demonstrates the presence of cannabinoid receptors in noradrenergic cells within the NAC and NTS (Carvalho et al., 2010a), frontal cortex (Oropeza et al., 2007; Page et al., 2008; Reyes et al., 2009b), and LC (Scavone et al., 2010).

While the interactions between the noradrenergic and opioid systems have been well characterized in addiction [reviewed in (Van Bockstaele et al., 2001, 2010; Berndge and Waterhouse, 2003; Weinshenker and Schroeder, 2007; Aston-Jones and Kalivas, 2008; Sara, 2009)], the field of cannabinoid–opioid interactions in noradrenergic cells is relatively in its infancy. However, increasing numbers of groups have begun to uncover and probe the close interaction between the cannabinoid and opioid systems in the brain and periphery [reviewed in (Manzanares et al., 1999; Fattore et al., 2004, 2005a; Corchero et al., 2004a; Vigano et al., 2005a; Welch, 2009; Parolaro et al., 2010)].

CANNABINOID–OPIOID INTERACTIONS

Opioid and cannabinoid receptors are major targets for many drugs of abuse and widely-used analgesics. These receptor systems are known to mediate common signaling pathways central to clinical issues of tolerance, dependence and addiction (Manzanares et al., 1999; Pasternak, 2005; Demuth and Molleman, 2006). Drugs that target both the CB1r and MOR systems possess shared pharmacological profiles. Agonists of both receptor types have been shown to cause antinociception, sedation, hypotension, motor depression, and drug reward/reinforcement (Manzanares et al., 1999; Massi et al., 2001; Maldonado and Valverde, 2003; Corchero et al., 2004a). Cannabinoids may be able to modulate opioid function at a number of different levels within the cell, ranging from direct receptor associations, to alterations in endogenous peptide release, or to post-receptor interactions via shared signal transduction pathways. Evidence of these interactions can be observed through the various studies demonstrating cross-tolerance, mutual potentiation, and receptor cross-talk (Manzanares et al., 1999; Cichewicz and McCarthy, 2003; Maldonado and Valverde, 2003; Corchero et al., 2004a; Vigano et al., 2005a; Roberts et al., 2006; Cox et al., 2007; Barta et al., 2009; Welch, 2009; Parolaro et al., 2010). Importantly, drugs that target the cannabinoid system often seem to affect the opioid system in tandem. Individual modulation of CB1r or MOR has been shown to alter indices of noradrenergic activity (Nestler, 1993; Nestler et al., 1999; Oropeza et al., 2005; Szabo and Schlicker, 2005). Since the LC and associated noradrenergic circuitry are critical sites of dysfunction during opioid addiction and withdrawal, it is particularly important to develop a comprehensive understanding of both the anatomical substrates and biochemical mechanisms through which cannabinoids may be used to specifically and effectively target the opioid system in this region.

Anatomical considerations

Techniques used to discern the distribution of cannabinoid and opioid receptors and their endogenous ligands have provided valuable information pertaining to the interactions between these systems. Using immunohistochemical and immuno-electron microscopic techniques, anatomical data have revealed potential sites and systems where cannabinoids may be used to target the opioid system. Morphological substrates for cannabinoid–opioid interactions have been demonstrated through CB1r and MOR co-localization in multiple brain regions. These receptors co-localize within the dorsal horn of the spinal cord (Salio et al., 2001). In the NAc, a region critical to the reward circuitry, CB1r and MOR are both localized within neurons and in synaptically-linked pairs of cells (Pickel et al., 2004). Additionally, an ultrastructural study of the caudate–putamen revealed CB1r and MOR labeling targeted to specific patches of post-synaptic neurons with approximately 50% of all CB1r-positive dendrites containing the MOR (Rodriguez et al., 2001). However, only recently has the field begun to generate evidence for cannabinoid–opioid interactions within noradrenergic loci within the brain.

The MOR is abundant within many of the noradrenergic brain regions responsible for mediating the adaptations that occur in response to opiate exposure and in the precipitation of opiate withdrawal (Tempel and Zukin, 1987; Maldonado et al., 1992a, p. 664; Maldonado et al., 1992b; Mansour et al., 1995; Cheng et al., 1996; Ding et al., 1996; Moya et al., 1997; Pickel and Colago, 1999). Recent anatomical and functional evidence demonstrates the presence of cannabinoid receptors in noradrenergic cells within the NAc and NTS (Carvalho et al., 2010a,b), frontal cortex (Oropeza et al., 2007; Page et al., 2008; Reyes et al., 2009b), and LC (Scavone et al., 2010). Data from electrophysiological recordings in the LC also support these anatomical findings, providing evidence of cannabinoid sensitivity in this opioid-sensitive nucleus (Mendiguren and Pineda, 2006a,b). Physiological data following local infusions of cannabinoids on to the opiodergic LC provide additional evidence of local cannabinoid effects (Muntoni et al., 2006). CB1r is expressed in the terminals of noradrenergic projections from the opioid-sensitive LC to the frontal cortex (Oropeza et al., 2007), suggesting that CB1r may be poised to modulate the norepinephrine release that occurs as a result of opioid dependence or withdrawal. Alternatively, indirect mechanisms involving GABA interneurons cannot be ruled out (Reyes et al., 2012). There is also evidence of CB1r and MOR co-localization in shared post-synaptic cellular compartments of the neurons that give rise to these projections (Scavone et al., 2010).

Co-localization of CB1r and MOR within noradrenergic brain regions is particularly noteworthy given the growing body of evidence that is strongly
suggestive of heterodimerization and/or closely-associated CB1r-MOR signaling complexes in vitro and in vivo (Rios et al., 2001, 2006; Mackie, 2005a; Schoffelmeer et al., 2006; Hojo et al., 2008). Additionally, recent studies report increased abundance of CB1r-heterodimers and opioid receptor-heterodimers in response to chronic drug exposure or repeated receptor stimulation (Kearn et al., 2005; Gupta et al., 2010). Potential implications of GPCR heterodimerization include altered subcellular localization or ligand binding properties, in addition to changes in signal transduction (Rios et al., 2001; Terrillon and Bouvier, 2004).

Cannabinoid-opioid system cross-talk

Downstream evidence of cannabinoid modulation of the opioid system can be observed through many accounts in the literature of cannabinoid-opioid synergy, cross-agonism, cross-antagonism, and cross-tolerance (Manzanares et al., 1999; Lichtman et al., 2001; Navarro et al., 2001; Valverde et al., 2001; De Vries et al., 2003; Cichewicz, 2004; Fattore et al., 2005b, 2007b). Numerous studies have revealed synergistic effects of cannabinoid-opioid pairings such as CP55,940 and morphine (Welch and Stevens, 1992; Tham et al., 2005), delta-9-tetrahydrocannabinol (Δ⁹-THC, psychoactive component of marijuana) and morphine in an arthritis model (Cox et al., 2007), and Δ⁹-THC and morphine in humans (Roberts et al., 2006). Moreover, combined sub-analgesic doses of Δ⁹-THC and morphine possessed synergistic antinociceptive properties while circumventing the development of tolerance inherent to chronic morphine exposure (Cichewicz et al., 1999; Cichewicz and McCarthy, 2003; Cichewicz, 2004; Smith et al., 2007). Cannabinoids have also been shown to exert cross-antagonism within the opioid system (Vigano et al., 2005a). Similar studies have implicated the endogenous cannabinoid system in opioid dependence, as inhibition of cannabinoid receptor signaling with the cannabinoid receptor antagonist SR141716A during chronic opioid exposure reduced opioid withdrawal signs (Rubino et al., 2000; Mas-Nieto et al., 2001). Additionally, cross-sensitization to the...
behavioral effects of cannabinoids and opioids has also been demonstrated (Cadoni et al., 2001).

The mechanisms through which cannabinoids are able to modulate the opioid system may be through alterations in the level of endogenous opioids or their receptors, or via changes in G-protein-mediated signaling through the opioid receptors or MOR–CB1r complexes (Fig. 1). Numerous studies have reported changes in the levels of endogenous opioids following cannabinoid administration, suggesting a regulatory role for CB1r in endogenous opioid release (Corchero et al., 1997a, 1999; Manzanares et al., 1998; Valverde et al., 2001). For instance, repeated Δ9-THC treatments increased the expression of endogenous opioid peptides in the rat spinal cord (Corchero et al., 1997a).

Alternatively, the direct interaction of CB1r and MOR has also been postulated as the mechanism for cannabinoid modulation of the MOR system. Resonance energy transfer studies reveal close associations between CB1r and MOR, while anatomical studies display the co-localization of these receptors in shared cellular compartments (Rodriguez et al., 2001; Salio et al., 2001; Pickel et al., 2004). Devi's group has proposed that cannabinoid and opioid receptors exist as heterodimeric systems that physically interact to integrate independent signal pathways (Rios et al., 2006). These receptor systems may also interact at the level of their intracellular signaling molecules. In addition to baseline receptor similarities, several studies have revealed cannabinoid-induced changes in MOR-dependent G-protein activation through GTPγS binding assays (Corchero et al., 1999; Vigano et al., 2005b; Ellgren et al., 2008; Rios et al., 2006). Cannabinoid–opioid cross-talk can also be observed through receptor expression levels, as repeated administration of Δ9-THC regulates MOR density in a time and region-dependent manner (Corchero et al., 2004b). Although the functional relationship between opioid and cannabinoid systems is becoming better established, the specific mechanisms of their interaction in the LC and associated circuits remain to be elucidated.

Shifts in the subcellular distribution of MOR during opioid withdrawal may bring this receptor into close proximity with the cannabinoid receptor, promoting direct receptor associations. Unlike most cell-membrane bound GPCRs, the cannabinoid receptor has a predominantly intracellular distribution in the brain (Rozenfeld, 2010). The distribution of CB1r within somatodendritic structures in the LC agreed with this distribution pattern (Scavone et al., 2010). Interestingly, in the LC somatodendritic MOR was observed to shift from its typical plasmalemmal localization to an intracellular distribution in response to naltrexone precipitated opioid withdrawal (Scavone and Van Bockstaele, 2009). If CB1r and MOR have similar subcellular distribution patterns during opioid withdrawal situations, hetero-dimerization may be a distinct possibility. Using cannabinoids to target this heterodimer during opioid withdrawal may then influence not only cannabinoid signaling, but perhaps also restore normalcy to dysregulated opioid pathways.

In addition to the possibility of direct CB1r–MOR associations, cannabinoid–opioid interactions may also occur at the signal transduction level since both receptors signal through the G_{i/o} alpha subunit, targeting the cAMP pathway. During opioid withdrawal, studies have demonstrated increased abundance of G_{i/o} alpha in the coeruleo-cortical pathway during opioid withdrawal (Nestler et al., 1989; Nestler, 1992). If compensatory changes in CB1r signaling transduction occur during opioid withdrawal, this may also account in part for the efficacy of cannabinoids in reducing opioid withdrawal signs observed both in preclinical and clinical studies. Cannabinoid modulation of endogenous opioid synthesis and release is yet another candidate mechanism that may contribute to WIN-mediated attenuation of opioid withdrawal signs (Fig. 2). Cannabinoid agonists have been shown to facilitate endogenous opioid signaling. Acute exposure to cannabinoid agonists increased extracellular levels of endogenous opioids (Pugh et al., 1995, 1996, 1997; Houser et al., 2000), and chronic cannabinoid exposure increased the abundance of endogenous opioid precursors such as prodynorphin, proenkephalin and pro-opiomelanocortin (Corchero et al., 1997a,b; Manzanares et al., 1998). Cannabinoid stimulation of endogenous opioid release has been linked to the attenuation of opioid withdrawal in an animal model. Exposure to Δ9-THC enhanced enkephalin release in the NAc attenuated the signs of naloxone-precipitated withdrawal (Valverde et al., 2001). Similar approaches could be taken within the coeruleo-cortical pathway to determine whether the WIN interventions used to attenuate withdrawal in morphine-dependent rats also facilitate endogenous opioid release within the LC.
Anatomical studies in the LC demonstrated that presynaptic CB1r-positive terminals contacted MOR-containing dendrites (Scavone et al., 2010). Presynaptic CB1r may be poised to regulate or facilitate neurotransmitter and neuropeptide release on to LC neuron; enkephalin release may help to stabilize the LC neurotransmitter and neuropeptide release on to LC neuron; enkephalin release may help to stabilize the LC during opioid withdrawal.

Implications of cannabinoid-induced alterations in opioid function in the LC

We previously identified important opposing CRF and opioid influences on LC activity and that changes in the sensitivity to one neuromodulator altered sensitivity to the other. Specifically, we showed that chronic opiate administration selectively increased the sensitivity of LC neurons to CRF (Xu et al., 2004). This was apparent as an increased magnitude of activation produced by microinfused CRF, as well as by stress. More importantly, sensitization of LC neurons to CRF in chronic morphine rats translated to a change in the behavioral repertoire in response to a challenge (Xu et al., 2004). Thus, exposure of morphine-dependent rats to swim stress resulted in excessive climbing at times when control rats would adopt a passive coping strategy of immobility. Climbing behavior in this model has been linked to activation of the brain norepinephrine system (Detke et al., 1995). This represents an example of how the level and mode of LC activity is the result of a balance of neuromodulators that are engaged and active at a particular time. The mechanism by which chronic opioids induce postsynaptic sensitization to CRF in LC neurons is currently unknown, although many changes in intracellular signaling systems within LC neurons have been documented to occur as a result of chronic opiate administration and these could contribute to altered postsynaptic sensitivity to CRF (Nestler et al., 1999).

Along these lines, it is critical to determine how repeated cannabinoid use affects MOR function in the LC. As cannabinoids significantly affect behavioral regulatory processes known to be LC-specific, such as the modulation of attention, arousal, anxiety, and stress (Nestler et al., 1999; Muntoni et al., 2006), cannabinoid-induced alterations in MOR activity within the LC may likely sensitize this region to input from stress-related pathways, and may underlie the behavioral abnormalities and cognitive deficits seen with repeated cannabinoid use. Long-term cannabinoid use is associated with a syndrome of cognitive impairment that notably includes significant attentional dysfunction, and anxiety and stress disorders (Chaperon and Thiebot, 1999; Lundqvist, 2005; Demuth and Molleman, 2006).

**POTENTIAL THERAPEUTIC TARGETS OF CANNABINOID–OPIOID INTERACTIONS**

Cannabinoid-induced decreases in opiate withdrawal expression

In the area of therapeutic utility, cannabis can be recommended as a palliative medical alternative for patients with multiple sclerosis and spinal cord problems where it has been shown to alleviate pain, muscle spasms and convulsions. In addition, it can be recommended to cancer and AIDS patients in order to prevent vomiting and nausea, which result as side effects of chemotherapy, radiation therapy and antiretroviral medications. It also stimulates appetite in people who suffer from this medical condition. Similarly, the therapeutic use of marijuana slows chronic pain and helps attenuate the tics in patients with Gilles Tourette’s syndrome. It also may be useful both in the reduction of physical and stress-related symptoms, which occur following the cessation of drug abuse. However, cannabis plays no role in curing these conditions, but only acts to ease their symptoms. Even in the abovementioned cases, there exist contraindications, and cannabis use is not recommended for use in patients with psychotic disorders and psychological or heart problems, cardiac arrhythmias, heart failure or patients who have had angina or a heart attack. Currently Dronabinol and Nabilone as cannabinoids are available for clinical use, but there are few studies reporting on their real effectiveness.

Because the cannabinoid system interacts so closely with the opioid system, the cannabinoid receptors are attractive potential therapeutic targets. Despite this, assessment of cannabis for the reduction of opioid withdrawal has been limited to qualitative survey data rating the efficacy of illicit substances for withdrawal symptoms (Hermann et al., 2005). At present, strict regulation of cannabinoid compounds and political controversy prevent rigorous clinical assessment of cannabinoid testing in the clinical setting. However in the absence of controlled clinical studies, data from experimental animal models provide an excellent source of information regarding potential therapeutic cannabinoid regimens. A number of preclinical studies investigating cannabinoid modulation of opioid dependence and withdrawal may have therapeutic implications for the treatment of the opioid withdrawal.
syndrome in the clinical population. Clinically, withdrawal from heroin or prescription opioids is characterized by a host of quantifiable physical and emotional symptoms that may include muscle aches and pain, agitation and anxiety, nausea, gastrointestinal upset, tachycardia, rhinorrhea, and chills (Wesson and Ling, 2003).

Similarly, in animal models of opioid dependence, withdrawal behaviors can be quantitatively assessed to determine whether cannabinoids can mediate the opioid withdrawal syndrome (Gellert and Holtzman, 1978; Fernandez Espejo et al., 1995). The use of various cannabinoid agents designed to augment or block cannabinoid signaling has been tested to determine their effects on the development of opioid dependence and the expression of opioid withdrawal.

By targeting the cannabinoid system and in turn modulating opioid signaling in noradrenergic cells, it may be possible to reduce the severity of opiate withdrawal signs (Fig. 3). Numerous studies have demonstrated that EC or delta-9-tetrahydrocannabinol (Δ9-THC) exposure during morphine withdrawal in both mice and rats reduces the severity of morphine withdrawal symptoms (Frederickson et al., 1976; Vela et al., 1995; Lichtman et al., 2001; Valverde et al., 2001; Yamaguchi et al., 2001; Del Arco et al., 2002; Cichewicz and Welch, 2003). Several studies have displayed the potential of EC interventions for normalizing opioid system dysfunction. Attenuation of morphine-withdrawal has also been achieved via administration of the endogenous cannabinoids 2-AG and anandamide (Vela et al., 1995; Yamaguchi et al., 2001). Common withdrawal behaviors diminished due to Δ9-THC administration were jumping, weight loss, head shakes and paw tremor, although findings varied considerably depending upon dosing paradigm (Vela et al., 1995; Lichtman et al., 2001; Yamaguchi et al., 2001). Peripheral effects of naloxone-precipitated withdrawal were also attenuated by Δ9-THC in guinea pig ileum (Frederickson et al., 1976). Only one study to date has tested the efficacy of a synthetic cannabinoid agonist, and found that HU210 was similarly efficacious to Δ9-THC and the EC 2-arachidonoylglycerol (2-AG) in reducing instances of paw tremor and jumping behavior. Interestingly, administration of Δ9-THC was shown to attenuate signs of morphine withdrawal by facilitating the endogenous enkephalin release (Valverde et al., 2001), an endogenous opioid that targets the opioid receptors in the LC (Johnson et al., 2002; Barr and Van Bockstaele, 2005). This finding is especially important given that endogenous peptide levels are decreased in response to chronic opioid exposure in LC pathways (Van Bockstaele et al., 2000).

Cannabinoid antagonists may also have therapeutic utility if administered prior to the development of opioid withdrawal. Modulation of opiate withdrawal behavior, associated protein expression, and morphine-sensitivity has also been achieved by the administration of cannabinoid receptor antagonist SR141716A in chronic opiate-exposed rodents (Rubino et al., 2000; Lichtman et al., 2001; Navarro et al., 2001; Singh et al., 2004; Vigano et al., 2004). Along similar lines, cannabinoids also appear to modulate heroin-seeking behaviors, though there is debate in the literature as to the nature of these effects. Several groups have shown that SR141716A can negate the reinforcing and motivational properties of heroin in animals trained to self-administer the drug (Navarro et al., 2001; De Vries et al., 2003; Fattore et al., 2005b). Others provide evidence for Δ9-THC-mediated enhancement of opioid self-administration (Solinas et al., 2004; Ellgren et al., 2007), which may also support a role for cannabinoid antagonists in the prevention of heroin-seeking. Collectively, these findings support the presence of functional crosstalk between cannabinoid and opioid systems and the ability to demonstrate this phenomenon using a variety of models and addiction paradigms.

Insights into potential cannabinoid–opioid therapeutic targets from the clinic

The debate surrounding medicinal cannabinoids has received added attention recently as regulatory concerns may prevent full consideration of studies that report multiple clinical applications for cannabinoids (Cohen, 2009a,b, 2010). Applications for medicinal cannabinoids that are already under investigation include the treatment of nausea, anorexia, neurodegeneration, inflammation, excito-toxicity and pain. The appetitive and anti-emetic properties of cannabinoids have led to the approval of their use in chemotherapy and AIDS patients. There is growing evidence for therapeutic cannabinoid effects on inflammatory and excito-toxic cellular processes that are linked to epilepsy, Parkinson’s disease, amyotrophic lateral sclerosis, spasticity, and CNS injury (Robson, 2001; Ramirez et al., 2005; Steffens et al., 2005; Machado Rocha et al., 2008; Garcia-Arencibia et al., 2009; Onaivi, 2009; Bosier et al., 2010; Fernandez-Ruiz et al., 2010; Gowran et al., 2011). Increasing numbers of publications have reported on the critical role of the cannabinoid system in addiction and substance abuse (Fattore et al., 2007a, 2008; Bosier et al., 2010), as well as the potential for potent modulation of the opioid system by cannabinoids (Fattore et al., 2005a; Lopez-Moreno et al., 2010; Robledo, 2010; Tucci, 2010).

Despite increasing accumulations of preclinical data suggesting that cannabinoid benefits may outweigh the risks in certain serious medical conditions, political conflict over the legalization of medicinal marijuana continues to preclude a smooth transition of these preclinical studies into clinical trial testing. This may persist in the near future as state and federal government debates over cannabis regulations continue. However, there are many therapeutic alternatives to smoking or ingested cannabis. The development of compounds designed to modulate EC levels or the use of synthetic cannabinoids with well-defined pharmacological properties may address many of the concerns associated with legalization of medical marijuana. In the meanwhile, indirect approaches can be taken to assess cannabinoid modulation of the opioid system among individuals in the treatment for substance
abuse. Co-abuse of cannabis and opioids is quite common in substance abusers, and investigation of this polydrug use may provide clues as to how cannabinoid–opioid interactions play out in the substance abuse treatment setting.

**Concurrent cannabis and opioid use**

Cannabis use is particularly widespread among opioid-dependent individuals (Nurco et al., 1988; Nirenberg et al., 1996), and numerous studies have examined the concurrent use of cannabis and opioids. Within those seeking treatment for opioid dependence, cannabis is consistently reported to be among the most frequently co-abused substances, along with benzodiazepines and cocaine. Estimates of cannabis use in clients have ranged anywhere from 20% to 95% of the population (Saxon et al., 1990; Nirenberg et al., 1996; Budney et al., 1998; Church et al., 2001; Epstein and Preston, 2003; Nixon, 2003; Aharonovich et al., 2005). The prevalence of cannabis use varies by geographical location, likely due to the associated changes in drug availability, cost, and potency. Nonetheless, despite this variability, cannabis use remains a prominent characteristic of the drug use profile of many opioid users. Among those prescribed chronic opioid therapy for pain, cannabis use was significantly more common than in the general population in every age group (Reisfield et al., 2009). Based on these observations, co-abuse of cannabis and opioids has become the focus of many clinical research initiatives.

The prevalence of cannabis use has been established within a number of methadone maintenance programs by urinary drug screen (UDS). For example, Marammani observed within a cohort of 1090 heroin-dependent individuals presenting for methadone maintenance between 1994 and 2005, that 64.6% of men and 57.1% of females reported concurrent opioid and cannabis use when entering treatment (Maremmani et al., 2010). One study of 98 males on methadone maintenance treatment (MMT) found that 55.1% used cannabis during treatment (Saxon et al., 1993), while another study reported an even higher 79% rate of use (Nirenberg et al., 1996). Cannabis use was evaluated prior to and during treatment in a sample of 196 persons in an Israeli methadone maintenance program. At treatment intake, 25% reported current cannabis use, and 52% had at least one cannabis-positive UDS during the first year of treatment. Approximately one-third of the sample met the cannabis abuse criteria, and used cannabis for at least 3 consecutive months during treatment (Weizman et al., 2004). In a study designed to determine predictors of relapse in 74 heroin-dependent individuals, 47.3% of the methadone-maintained sample reported using cannabis during the 8-week study period (Wasserman et al., 1998). Finally, in a retrospective analysis of cannabis use from three clinical trial cohorts on methadone maintenance (n = 408), 30.6% of the individuals in care were categorized as occasional users (<1/6 UDS cannabis positive), while 23.3% demonstrated frequent use (> 1/6 UDS positive) (Epstein and Preston, 2003).

Cannabis use has also been examined among individuals participating in other opioid-dependence treatment modalities. As part of a buprenorphine and behavioral therapy treatment trial, Budney et al. (1998) reported that 66% of their sample of opioid-dependent patients tested positive for cannabis use at least once during the 26–32 week study period; users of cannabis had an average of 45% of UDS result in cannabis-positive findings. Among 47 individuals on a 6-month outpatient naltrexone therapy program, cannabis use was also prevalent, observed in at least once in 68% of the sample with an average of 47% of all UDS’s being cannabis-positive (Church et al., 2001). Raby et al. (2009) observed that only 38.1% of 63 opiate-dependent individuals were cannabis abstinent during outpatient naltrexone treatment, while 28.6% were intermittent cannabis users, and 33.3% were classified as consistent cannabis users.

Longitudinal studies over the course of treatment have also revealed interesting trends. While some have observed levels of cannabis use to remain stable or increase early in treatment (Raby et al., 2009), other have failed to demonstrate this effect (Gottheil et al., 1993; Weinstein et al., 1993). In a study comparing the rates of cannabis use at months 1, 6, and 12 of maintenance treatment, there were differences between methadone and heroin maintenance. Among those on methadone maintenance, rates of cannabis-positive UDS fall from 63% at the start of treatment to 57.1% 6 months later, finally dropping to 48.5% at the 1-year mark. Meanwhile those on heroin maintenance increase over the study period from 54.5% to 69.5% (Musshoff et al., 2010).

**Cannabis use during treatment for opioid dependence**

Investigations of the effects of cannabis in opioid-dependent individuals have often focused upon the impact of cannabis use on treatment for opioid dependence. Among the outcomes assessed were treatment retention, illicit drug use, medication compliance, relapse, risk behaviors and opioid withdrawal signs. However, to date the findings remain equivocal as to the impact of cannabis use on outcomes of medication-assisted treatment. Additionally, numerous studies provide neutral evidence that cannabis use does not appear to significantly alter the course of treatment for opioid addiction.

Other illicit drug use rates do not appear to increase during treatment for opioid dependence among those using cannabis. There were no significant correlations between cannabis use and the likelihood of testing positive for opioid, benzodiazepine or cocaine use in a group of buprenorphine-treated persons (Budney et al., 1998), or in methadone-maintained individuals (Saxon et al., 1993; Epstein and Preston, 2003; Scavone et al., 2013). Findings from a meta-analysis on predictors of substance use in treatment-seeking opioid-dependent individuals found evidence for concurrent cannabis and opioid use during treatment, but no prospective effects of cannabis on increased opioid use following...
completion of treatment (Brewer et al., 1998). Several studies have demonstrated that retention in treatment for opioid dependence was unaffected by the use of cannabis either prior to or during treatment (Saxon et al., 1993; Budney et al., 1998; Epstein and Preston, 2003; Weizman et al., 2004). However, the long-term nature of MMT often renders retention a poor indicator of overall treatment outcome. Among MMT patients, chronic cannabis use also did not alter control of heroin craving and withdrawal signs (Nava et al., 2007). Additionally, no increases in psychological distress, infectious disease, and risk-taking behavior were observed within a cohort of methadone-maintained individuals testing positive for cannabis use (Weizman et al., 2004). Cognitive function and employment were not found to be significantly different between cannabis-users and cannabis-abstinent individuals undergoing MMT (Saxon et al., 1993). Moreover, regardless of cannabis use, disruptions in normal HPA axis function due to opioid abuse were restored to normal following MMT (Nava et al., 2007).

We recently examined the question of cannabis use in a longitudinal fashion in a sample of individuals seeking outpatient medication-assisted treatment. Retrospective chart analysis was used and examined past and present cannabis use and its association with opiate abstinence, dose stabilization, and indices of treatment compliance. Consistent with the literature, objective rates of cannabis use were high during methadone induction, dropping significantly following dose stabilization. History of cannabis use correlated with cannabis use during MMT, but did not appear to negatively impact the methadone induction process. Pilot data also suggested that objective ratings of opiate withdrawal decreased in MMT patients using cannabis during stabilization. The present findings may point to novel interventions to be employed during treatment for opiate dependence that specifically target cannabinoid–opioid system interactions (Scavone et al., 2013).

While much of the existing research finds a lack of evidence for harmful cannabis effects on treatment for opioid-dependence, several studies have revealed detrimental associations across diverse populations. Cannabis use was associated with more rapid lapse to heroin use within a cohort enrolled in MMT (Wasserman et al., 1998). While no impact of cannabis use on treatment outcome was noted within an outpatient buprenorphine treatment trial coupled with behavioral therapy, cannabis use was associated with drug dealing and needle-sharing factors (Budney et al., 1998). Interestingly, following inpatient treatment for substance abuse, post-discharge cannabis use was associated with faster relapse to alcohol and cocaine use, but was unrelated to heroin use (Aharonovich et al., 2005). However, among individuals receiving chronic opioid therapy for pain, the presence of cannabis use was a positive predictor of future opioid misuse (Reisfeld et al., 2009). Within the general population, cannabis use was also strongly associated with increased risk for other substance use and dependence (Degenhardt et al., 2001).

Interestingly, several studies have demonstrated that under certain circumstances, cannabis use can be associated with positive treatment prognosis among opioid-dependent cohorts. For example, Epstein and Preston (2003) found that cannabis abuse and dependence were predictive of decreased heroin and cocaine use during treatment. Intermittent use of cannabis (defined as \( \geq 1 \) but \( \leq 99\% \) positive drug screens) was associated with a lower percentage of positive opioid UDS and improved medication compliance on naltrexone therapy (Church et al., 2001). Similarly, associations of intermittent or occasional cannabis use with improved retention in treatment for opioid dependence have also been reported (Ellner, 1977; Raby et al., 2009). Among opioid-dependent individuals undergoing naltrexone therapy, intermittent cannabis users (with 1–80% of UDS positive for cannabis) fared better than cannabis abstinence or consistent cannabis users in terms of treatment retention and medication compliance (Raby et al., 2009 010 1715, Lopez-Moreno et al., 2010; Robledo, 2010).

An important consideration is the response to cannabinoid therapies in the substance-dependent population, which may differ significantly from drug naïve or recreational substance users. Within adolescents, frequent cannabis use doubles the risk for depression and anxiety, and significantly decreases multiple indices of psychosocial functioning (Brook et al., 1999, 2002; Patton et al., 2002). Indisputably, chronic cannabis exposure in large doses has negative psychological and health consequences (Hollister, 1986; Kendler and Prescott, 1998; Budney and Moore, 2002; Patton et al., 2002; Lundqvist, 2005; Rubino and Parlarlo, 2008). However, obvious differences would be expected in the responses to cannabinoid exposure in the opioid-dependent population given the many physiological adaptations that occur with long-term drug exposure and typical psychiatric co-morbidity. The risks associated with cannabis use in the opioid-dependent population must be weighed against the prospective benefit of successful substance abuse treatment outcomes and the prevention of the much greater risk and harm association with opioid addiction.

**CONCLUSIONS**

Opioid dependence and withdrawal are complex biological processes that appear to be subject to the influence of cannabinoids. The findings from basic and pre-clinical studies in rodent models highlight several potential mechanisms through which cannabinoids may modulate the phenomenon of opioid withdrawal, and call attention to the importance of cannabinoid–opioid interactions within noradrenergic brain circuits such as the coeruleo-cortical pathway. Preclinical studies that continue to explore the safest and most effective means of using cannabinoids to target disrupted noradrenergic circuits will be central to the progress within this field of research. Like many pharmacological therapeutics, the use of cannabinoids does not come without risk and will continue to require assessment of the impact of its use.
to treat conditions such as opioid withdrawal in humans. Determining whether cannabinoids have therapeutic efficacy in clinical populations similar to that reported in animal models will be extremely important. Ultimately, the knowledge gained from the preclinical and clinical research studies described within this review highlights important and exciting new avenues for future research that continue to investigate cannabinoid effects on noradrenergic circuit dysfunction during opioid dependence and withdrawal. Future studies may contribute to the development of novel cannabinoid-based therapeutics that provide clinicians an additional tool to support the recovery of opioid-dependent persons undergoing treatment.

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involved in the asymmetric interaction between cannabinoid and opioid systems. Psychopharmacology 182:527–536.


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Background
A natural experiment is unfolding in California related to the therapeutic use of marijuana as a component of substance abuse treatment for alcohol, methamphetamine, heroin, cocaine, and other drugs of abuse. For up to 13 years now, people have been authorized to use marijuana for recognized medical purposes under California’s “Compassionate Use Act of 1996” (also known as Prop. 215) and, more recently, the “Medical Marijuana Program” (also known as SB 420). Despite U.S. Drug Enforcement Administration refusal to recognize any legitimate medical use of marijuana, counties in California remain accountable to the state government for implementation of medical marijuana laws as passed by voter initiative and legislative action. Most county governments and public social service programs in the state have recognized the legal right of qualified patients to use marijuana in a variety of settings. For some public agencies that provide substance abuse treatment this has included authorization to use marijuana during the course of treatment.

Several studies have linked cannabis to psychosis, schizophrenia, anxiety, depression and other adverse physical, psychological, and social outcomes [1-6]. Meanwhile, marijuana's positive therapeutic effects have
been documented by the U.S. Institute of Medicine [7], the American College of Physicians [8], and other sources [9-12] in relation to psychosis, bipolar disorder, anxiety, pain, anorexia, nausea, and muscle spasticity, including randomized, placebo-controlled, crossover trials [13]. Despite Macleod’s [14] analysis of weaknesses in methodology, analysis, and interpretation of studies linking marijuana use to mental illness, Hall & Room’s [15] comprehensive review of published studies concluded that there is reasonable evidence to suggest that regular cannabis use predicts an increased risk of schizophrenia and psychotic symptoms. They also concluded that the public health harm from cannabis remains substantially lower than from legal substances such as alcohol and tobacco. Consistent answers to questions about marijuana’s social and health effects still allude clinical, scholarly, and legal domains.

Noticeably missing from research literature related to marijuana’s therapeutic potential is any examination of its influence on substance abuse treatment outcomes. Decades old studies on the therapeutic effects of psychedelics on alcoholism are generally regarded with a bit of suspicion, though some researchers attest to their veracity [16]. The National Institute on Drug Abuse sponsored studies in the early 1990s related to ibogaine, the active ingredient in the African iboga plant, for treatment of cocaine addiction [17]. In 2002, the FDA approved research on MDMA for PTSD treatment [18]. Reiman’s [19] surveys of medical marijuana consumers at cannabis dispensaries in the San Francisco Bay area demonstrated nearly half of respondents had “substituted cannabis for alcohol and illegal drugs,” including 74% who reported using marijuana instead of prescription drugs (p. 31).

Experimental research on marijuana’s role in addiction treatment presents legal and political difficulties. Even as the American College of Physicians recommends “programs and funding for rigorous scientific evaluation of the potential therapeutic benefits of medical marijuana and the publication of such findings” ([8], p. 3), clinical trials that would administer marijuana to people undergoing substance abuse treatment are highly unlikely to receive approval. Therefore, any examination of marijuana’s effect on treatment outcomes must necessarily make use of existing data.

Demonstrating the impact of marijuana use on treatment outcomes is important for developing an expansive evidence-base for treatment alternatives. Examining the negative, positive, or neutral consequences of marijuana use is also critical for evaluating abstinence-only and harm reduction models for addiction treatment. Harmful social, psychological, and behavioral effects of marijuana use pale in comparison to other common drugs of abuse, including alcohol, methamphetamine, cocaine, and heroin [20]. Clear evidence that people who enter substance abuse treatment for problematic use of more harmful drugs can exhibit equal or better outcomes when using marijuana during their treatment offers a compelling case for further research on this particular dimension of marijuana as medicine. Findings that suggest marijuana use during treatment serves as an obstacle to treatment, compromises treatment integrity, or increases the prevalence or severity of relapse may similarly influence legal and clinical decisions.

Just as legal pharmaceutical substances are routinely prescribed in the course of substance abuse treatment, marijuana may provide a less harmful alternative to the drug problems bringing people in. Substitution of a lower risk psychoactive substance for a more harmful psychoactive substance has been regarded as legitimate clinical practice for at least half a decade [21]. Clinical communities will be impacted by findings as they will need to develop proper treatment protocols for current medical marijuana users. Treatment outcomes of authorized marijuana users may suggest that use of marijuana instead of riskier substances is an important step toward abstinence for some treatment clients, while it may serve as a long-term solution for others, much like pharmaceutical opiates such as methadone and buprenorphine [21]. Contrarily, studies that reveal poorer outcomes for medical marijuana users in treatment may push public agencies to revise protocols that currently allow for continued medical use of cannabis during substance abuse treatment. The aim of the study presented here was to demonstrate an ethical and legitimate methodology for engaging in such research.

**Methods**

Data was collected from a nonprobability, convenience sample composed of all clients in one California county identified as authorized medical marijuana users who were admitted to substance abuse treatment during the study time period. The comparison group consisted of all other county treatment clients with similar admission dates and primary drug use reported. While this could be considered a quasi-experimental comparison group design with no controlled randomization and a limited sample size, the study is best described as an exploratory pilot investigation due to the final sample size.

All publicly funded substance abuse treatment agencies in California must report admission and discharge data to the State Department of Alcohol and Drug Programs via the California Outcomes Measurement System (CalOMS). While CalOMS has some limitations, noticeably in relation to specificity of treatment outcomes, it is the best available database for cohort comparisons across a range of domains. Access to county level CalOMS data was provided by the participating...
The medical marijuana users in this study was referred to substance abuse treatment by the criminal court, and received such authorization. The Attorney General of California has defined a qualified medical marijuana patient as someone “whose physician has recommended the use of marijuana to treat a serious illness, including cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief” ([22], p. 4). The Attorney General’s guidelines also note that “criminal defendants and probationers may request court approval to use medical marijuana while they are released on bail or probation” (p. 6). Each of the medical marijuana users in this study was referred to substance abuse treatment by the criminal court, sought permission to use medical marijuana during treatment, and received such authorization.

Treatment staff identified 18 clients as medical marijuana users engaged in treatment at the beginning of the study. Staff were aware of clients’ medical marijuana use and had documented it in clients’ files. While the identities of these clients were never shared with the researcher, they were confirmed by multiple staff on repeated occasions. Though this substantially weakens the study’s sampling protocol, no other option is currently available. Existing substance abuse treatment data systems do not record the status of a client as a medical marijuana user, so there is no independent way to establish who is a medical marijuana user in treatment and who is not other than through multiple substantiations from program staff. Of the initial set of 18 one died during the course of treatment and was excluded. Cause of death could not be determined from data collected, as client data files were not included in the study. Similarly, specific diagnoses could not be ascertained. In order to strengthen the research design, only those clients receiving outpatient drug free treatment in the county’s substance abuse treatment program were included (“drug free” means they did not participate in an opiate maintenance or titration program). This resulted in the exclusion of one residential treatment client and three day treatment clients, leaving an experimental group size of 13. While including the day treatment and residential treatment clients would have increased the sample size, the significant variation in treatment protocols weakened the comparison to non-medical marijuana users. Admission dates for the 13 medical marijuana using clients were used as the basis for generating comparative data. Since they all indicated marijuana or methamphetamine as their primary drug of choice, the comparison group was limited to those treatment admissions where marijuana or methamphetamine was noted as the primary drug. In order to generate the comparison data set, county level reports on all adult treatment admissions between July 3, 2006 and November 16, 2007 (the admission dates for the medical marijuana group) who received Outpatient Drug Free treatment from the same treatment programs as the medical marijuana group, and who indicated marijuana or methamphetamine as their primary drug used were generated using CalOMS. These constitute separate reports in CalOMS, so ns were combined. From this combined data set, the ns for the medical marijuana group were subtracted leaving a comparison group composed of non-medical marijuana using treatment clients admitted in the same time period, receiving the same treatment services, and using the same primary drugs.

Results

Table 1 presents major characteristics of the group of clients authorized to use marijuana during the course of substance abuse treatment (MM). As noted, the only group for which complete outcome data is available is the group that successfully completed treatment (n = 8). Though clinicians vary in their recommendations for the optimal length of treatment, it is generally accepted that the longer clients are engaged in treatment, the better their outcomes [23]. A very high percentage of the MM group who received at least four months of treatment complete or were discharged successful (80% [n = 8]), with a mean length for those completing treatment of five months. 8.4 days.

The catchment area for the public substance abuse treatment agency is not particularly ethnically diverse. The ethnic breakdown of the MM group (84.6% White, 15.4% American Indian) reflects disproportionate involvement of Native Americans in treatment. However, Native Americans represent one of the largest non-White populations in the region. Native Americans composed 10.3% of the control group. White clients were 71.9%.

Sixty-six point seven percent (n = 8) of the MM group reported having a disability and each person could indicate multiple disabilities. The most common disabilities reported include Mental, Mobility, and Visual.

Because 92% (n = 12) of the MM group reported poly-drug use at admission, Table 1 also presents the percentage of clients reporting use of alcohol, methamphetamine, or marijuana. While 38.5% (n = 5) of the MM group indicated primary use of methamphetamine at admission, 84.6% (n = 11) reported primary or secondary use of methamphetamine. Sixty-one point five percent (n = 8) of the MM group indicated primary use of marijuana at admission and 100% (n = 13) of clients in the MM group reported primary or secondary use of marijuana. Five people in the MM group indicated use of alcohol in the last 30 days, including four people for whom alcohol was not noted as a primary or secondary drug of use at admission.
Table 1 Medical Marijuana (MM) Client Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>%</th>
<th>n</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-25</td>
<td>23.1%</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>26-35</td>
<td>23.1%</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>36-45</td>
<td>38.5%</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>45&lt;</td>
<td>15.4%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>84.6%</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>15.4%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Completed tx or made satisfactory progress at discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed tx</td>
<td>61.5%</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Unsatisfactory discharge</td>
<td>30.8%</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Received at least 4 months of tx</td>
<td>76.9%</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Waitlist before admission</td>
<td>15.4%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Prior tx episodes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>53.8%</td>
<td>7</td>
<td>Mean of 1 prior tx episode (Range = 0-5) Mean of 1.86 (Range = 1-5) amongst those with prior tx episode(s)</td>
</tr>
<tr>
<td>1</td>
<td>30.8%</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>15.4%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3&lt;</td>
<td>7.7%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>84.6%</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>American Indian</td>
<td>15.4%</td>
<td>2</td>
<td>All Non-white clients identified as American Indian</td>
</tr>
<tr>
<td>Disability(^a)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>66.7%</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>33.3%</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Disabilities reported(^a)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mental</td>
<td>37.5%</td>
<td>3</td>
<td>Mean of 1.73 disability categories per person</td>
</tr>
<tr>
<td>Mobility</td>
<td>37.5%</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Visual</td>
<td>37.5%</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Hearing</td>
<td>12.5%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Speech</td>
<td>12.5%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>25.0%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Primary drug at admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>38.5%</td>
<td>5</td>
<td>Mean use of 13.3 days in last month (Range = 0-30, Median = 10)</td>
</tr>
<tr>
<td>Marijuana</td>
<td>61.5%</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Age of 1st use of Primary drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-14</td>
<td>30.8%</td>
<td>4</td>
<td>Mean of 164 years old (Range = 12-25)</td>
</tr>
<tr>
<td>15-17</td>
<td>46.2%</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>18-20</td>
<td>7.7%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>21&lt;</td>
<td>15.4%</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Primary or Secondary drug at admission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No 2nd drug</td>
<td>7.7%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>7.7%</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>84.6%</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td>100.0%</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Alcohol use in last 30 days at admission (alcohol is not Primary or Secondary)</td>
<td>33.3%</td>
<td>4</td>
<td>Mean of .75 drinks/day in last month</td>
</tr>
<tr>
<td>Needle use in last year</td>
<td>7.7%</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) = Declined To State, Not Sure, and/or Don’t Know not included

Table 2 presents complete admission data for the 13 MM clients included in the data set, as well as the subset of clients who successfully completed treatment. Client outcomes are presented only for those who successfully completed treatment. Amongst those successfully completing treatment, use of all drugs other than marijuana had ceased in the month before discharge. This represents a drop in alcohol use from 50% (n = 4) to zero amongst those completing treatment when all clients who reported alcohol use at admission (primary, secondary, or other) are included. Of the 38.5% (n = 5) reporting methamphetamine use at
admission, none reported methamphetamine use in the 30 days before discharge. Mean days of primary drug use in the last month stayed roughly the same at 16.1 (from 16.3). One client who reported needle use in the last year did not report intravenous drug use in the last 30 days.

In relation to social outcomes, one client went from not looking for employment to “not in the labor force.” Though one client went from looking for employment to not looking for employment and one moved from full time employment to part time employment, the mean number of days worked in the last 30 days went up from 4.0 to 5.5. Other notable changes include enrollment in school and enrollment in job training for distinct clients. No criminal justice involvement (arrests, jail, or prison) was reported in the 30 days before discharge. This is worth mentioning when considering that one client was in prison in the 30 days before admission and another client had been arrested and spent time in jail in the 30 days before treatment. One client who had visited an emergency room in the 30 days prior to admission did not return in the 30 days prior to discharge. Similarly, one client who had been hospitalized in the 30 days prior to admission was not re-hospitalized in the 30 days prior to discharge. In total, the number of clients reporting medical problems in the last 30 days dropped from 37.5% (n = 3) to 12.5% (n = 1) amongst those completing treatment. The three that had indicated medical problems in the 30 days before admission went from a mean of 4.375 days with medical problems to zero. One person discontinued use of psychiatric medication. Reiman [19] reported that many medical cannabis users sought marijuana as a less debilitating method of controlling psychiatric difficulties than traditional psychiatric medications. Further research into treatment outcomes of medical marijuana users might offer further insight into those findings.

Table 3 offers a comparison between medical marijuana using clients and the control group. Some of the data from Table 1 is repeated in Table 3 to highlight the areas where differences are apparent. Successful completion or satisfactory progress at discharge was 28.1 percentage points higher in the MM group than in the Non-MM group, while successful completion alone was 30.7 percentage points higher. The MM group stayed in treatment for at least four months at twice the rate as the Non-MM group (76.9% [n = 10] to 37.7% [n = 55]). 84.6% (n = 11) of the MM group and 71.8% (n = 112) of the Non-MM group reported methamphetamine as a primary or secondary drug. This suggests that methamphetamine use was at least equally problematic in the MM cohort. 100% (n = 8) of the MM group reported marijuana as a primary or secondary drug. This suggests that marijuana use was at least equally problematic in the MM cohort. 100% (n = 8) of the MM group reported marijuana as a primary or secondary drug. This suggests that marijuana use was at least equally problematic in the MM cohort.

**Table 2 Medical Marijuana (MM) Client Outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Admission - All</th>
<th>Admission-Completers</th>
<th>Discharge-Completers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol use in last 30 days (alcohol is not Primary or Secondary)</td>
<td>33.3% 4</td>
<td>42.9% 3</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Needle use in last year</td>
<td>7.7% 1</td>
<td>12.5% 1</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>IV drug use in last 30 days</td>
<td>0.0% 0</td>
<td>0.0% 0</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Employed (includes FT &amp; PT, excludes NILF)</td>
<td>54.5% 6</td>
<td>50.0% 3</td>
<td>50.0% 3</td>
</tr>
<tr>
<td>Worked in last 30 days</td>
<td>33.3%* 4</td>
<td>28.6% 2</td>
<td>37.5% 3</td>
</tr>
<tr>
<td>Currently enrolled in school</td>
<td>7.7% 1</td>
<td>0.0% 0</td>
<td>12.5% 1</td>
</tr>
<tr>
<td>Currently enrolled in job training</td>
<td>0.0% 0</td>
<td>0.0% 0</td>
<td>12.5% 1</td>
</tr>
<tr>
<td>Any criminal justice involvement in last 30 days</td>
<td>30.8% 4</td>
<td>37.5% 3</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Arrested in last 30 days</td>
<td>15.4% 2</td>
<td>12.5% 1</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Jailed in last 30 days</td>
<td>15.4% 2</td>
<td>12.5% 1</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Prison sentence in last 30 days</td>
<td>7.7% 1</td>
<td>12.5% 1</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>ER visit in last 30 days</td>
<td>23.1% 3</td>
<td>12.5% 1</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Hospitalized in last 30 days</td>
<td>15.4% 2</td>
<td>12.5% 1</td>
<td>0.0% 0</td>
</tr>
<tr>
<td>Medical problems reported in last 30 days</td>
<td>38.5% 5</td>
<td>37.5% 3</td>
<td>37.5% 3</td>
</tr>
<tr>
<td>MH diagnosis</td>
<td>45.5%* 5</td>
<td>50.0% 3</td>
<td>50.0% 3</td>
</tr>
<tr>
<td>MH medication</td>
<td>38.5% 5</td>
<td>37.5% 3</td>
<td>25.0% 2</td>
</tr>
</tbody>
</table>

* = Declined To State, Not Sure, and/or Don’t Know not included
before admission nor in the 30 days before discharge. The categories of “increase,” “reduction,” and “no change” only relate to those who were actively using alcohol or other drugs in the 30 day period before treatment admission. “Abstinence” numbers are 25% (n = 2) for the MM group and 72.4% (n = 42) for the Non-MM group, suggesting that many more of the Non-MM group were abstinent before treatment ever began. Amongst those that reported drug use at admission, the MM group showed a greater percentage of clients who reported an increase in number of days of primary drug use (25% [n = 2] to 13.8% [n = 8]). However, this group shows a proportionately greater percentage of clients who reported a reduction in primary drug use in the 30 days before discharge (12.5% [n = 1] to 5.2% [n = 3]). This seemingly contrary outcome (higher level of increase and higher level of reduction) is possible because of the smaller number of MM clients who were abstinent before admission. The MM group also demonstrated a greater percentage of clients with no change in their drug use (37.5% [n = 3] to 8.6% [n = 5]). As a large percentage of the MM group reported marijuana as their primary drug of use, it ought not be surprising that they continued to use marijuana regularly or even increased it. Since CalOMS data are presented in aggregate, it is not possible to determine the number of days of methamphetamine use in the 30 days prior to discharge amongst the Non-MM group. However, 26.5% (n = 9) of the Non-MM group reported some level of methamphetamine use at discharge, compared to none for the MM methamphetamine users.

A higher percentage of the MM group demonstrated preferred outcomes in relation to employment, school enrollment, job training enrollment, criminal justice involvement, ER visits, and hospitalizations, but the ns are too small to warrant significant attention. In fact, at the .05 level the small sample size of the MM group prevents meaningful statistical analysis altogether. If similar results were found in a proportionately larger sample size, the following differences likely would have been significant: treatment completion, at least 4 months of treatment, employed at discharge, and alcohol use at discharge. Clearly more research is warranted to answer questions about treatment effects raised here.

### Discussion

#### Limitations

This research project is notably limited. Primarily, MM group members were identified by persons working in the treatment setting, not through official documentation. Unfortunately, California does not require treatment providers to indicate the medical marijuana status of a client when CalOMS data is reported. MM group identities were confirmed on multiple occasions and by more than one program staff member (though the identities were not shared with the researcher).

| Table 3 Medical Marijuana Client (MM) and Non-Medical Marijuana (Non-MM) Client Outcomes |
|-------------------------------------------------------------|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
|                                                               | Medical Marijuana Clients       | %               | n               | Non-Medical Marijuana Clients | %               | n               |
| Completed tx or made satisfactory progress at discharge       | 69.2%                          | 9               | 41.1%           | 60                           |
| Completed tx                                                | 61.5%                          | 8               | 30.8%           | 45                           |
| Unsatisfactory discharge                                    | 30.8%                          | 4               | 58.9%           | 86                           |
| Received at least 4 months of tx                             | 76.9%                          | 10              | 37.7%           | 55                           |
| Primary drug use - no changeabc                             | 37.5%                          | 3               | 8.6%            | 5                            |
| Primary drug use - reductionabc                              | 12.5%                          | 1               | 5.2%            | 3                            |
| Primary drug use - increaseabc                               | 25.0%                          | 2               | 13.8%           | 8                            |
| Employed at dischargeabc                                     | 50.0%                          | 3               | 33.9%           | 20                           |
| Enrolled in schoolabc                                        | 12.5%                          | 1               | 8.5%            | 5                            |
| Enrolled in job trainingabc                                  | 12.5%                          | 1               | 0.0%            | 0                            |
| Any criminal justice involvement in last 30 daysabc          | 0.0%                           | 0               | 1.7%            | 1                            |
| Arrested in last 30 daysabc                                  | 0.0%                           | 0               | 1.7%            | 1                            |
| Jailed in last 30 daysabc                                    | 0.0%                           | 0               | 1.7%            | 1                            |
| ER visit in last 30 daysabc                                  | 0.0%                           | 0               | 3.4%            | 2                            |
| Hospitalized in last 30 daysabc                              | 0.0%                           | 0               | 3.4%            | 2                            |
| Medical problems reported in last 30 daysabc                 | 12.5%                          | 1               | 8.5%            | 5                            |
| MH diagnosisabc                                              | 50.0%                          | 3               | 22.0%           | 13                           |
| MH medicationabc                                             | 25.0%                          | 2               | 23.7%           | 14                           |

a = For Medical Marijuana clients this only includes those who completed treatment. For Non-Medical Marijuana Clients this only includes a completed “AOD treatment services set” (a matching admission and discharge-excluding administrative discharges).

b = Thirty day use prior to admission compared to 30 day use prior to discharge.

c = Includes Full-time and Part-time, excludes Not in Labor Force.
Aside from the small sample size, data gaps presented the other main limitation. CalOMS data for the control group is presented in aggregate, while the data for the MM group is much richer. This allows for more accurate representation of treatment outcomes for the MM group, but hinders the rigor of comparisons. So, for example, CalOMS reports client characteristics and treatment outcomes for all treatment episodes (service counts), while the MM group is only for the most recent treatment episode (unduplicated individuals). This means that CalOMS includes data on clients who moved in and out of treatment on multiple occasions. Also, CalOMS reports data on categories of discharge besides treatment completion, while the MM group only reports discharge information for treatment completers. Since the MM group ns were subtracted from the CalOMS reports for the entire county, this potentially included duplicated clients. There were 53 cases of "completed treatment" in the Non-MM group. The data comparing admission indicators to discharge indicators for this group included 67 cases. This suggests that discharge data were reported for 14 people who did not successfully complete treatment.

Another limitation in the study relates to its quasi-experimental nature. The quantity of marijuana used by members of the MM group is unknown, as are other important factors including frequency of use, potency of product, level of contamination, and method of ingestion. So, for example, while the bulk of marijuana consumed in the United States is produced in Mexico [24] it is more likely that the marijuana used in this study was secured from a regional source owing to the setting's geography. The American College of Physicians notes, "examining the effects of smoked marijuana can be difficult because the absorption and efficacy of THC on symptom relief is dependent on subject familiarity with smoking and inhaling. Experienced smokers are more competent at self-titrating to get the desired results. Thus, smoking behavior is not easily quantified or replicated" ([8], p. 35).

Cannabidiol (CBD) content is as important for ascertaining the effect of marijuana use as tetrahydrocannabinol (THC). The lack of illness specific data limits the study's ability to draw powerful conclusions about marijuana's potential in addictions treatment. We know, for example, that CBD has some anti-psychotic and anti-anxiety properties [25-27]. Yet the percentage of clients who used medical marijuana for psychiatric difficulties rather than, for example, chronic pain is unknown. The data does indicate that 50% (n = 3) of MM group treatment completers had a mental health diagnosis compared to 22% (n = 13) of the Non-MM group.

**Suggestions for further research, practice, and policy**

Expanded data collection is necessary while the "natural experiment" of authorized marijuana use continues in California. A very simple policy change, adding an additional question (i.e., Are you an authorized medical marijuana user? Yes/No) to the State of California's Outcomes Measurement System (CalOMS), would make rigorous data analysis possible by significantly increasing sample size. Clearly there are other questions related to marijuana use that would aid in any research project as well, such as frequency of use, potency of product, method of ingestion, and medical condition for which marijuana has been recommended. Though treatment clients currently participate in a lengthy interview at admission that generates data points for client characteristics, demographics, and patterns of behavior, introduction of too many additional questions would likely prevent requisite legislative action.

Sample size could be increased by involving additional counties at a higher level of engagement than that described here. Medical marijuana users themselves could also be recruited to participate in the research (for examples of medical marijuana user surveys see [19,28,29]).

Most importantly, the study described here demonstrates a beginning methodology for determining medical marijuana's effects on substance abuse treatment outcomes. Research can be done even within legal and ethical constraints posed by cannabis research.

**Concluding considerations**

The American College of Physicians position paper on "Supporting Research into the Therapeutic Role of Marijuana" references marijuana's analgesic qualities [8] while other sources address marijuana's potential in the context of mental illnesses, anorexia, nausea, and muscle spasticity [7,9-13]. How the findings described here relate to other studies on marijuana's potential as a therapeutic aid remains inconclusive. It is clear, however, that cannabis use did not compromise substance abuse treatment amongst the medical marijuana using group. In fact, medical marijuana users seemed to fare equal to or better than non-medical marijuana users in every important outcome category.

Movement from more harmful to less harmful drugs is an improvement worthy of consideration by treatment providers and policymakers. The economic cost of alcohol use in California has been estimated at $38 billion [30]. Add to this the harm to individuals, families, communities, and society from methamphetamine, heroin, and cocaine, and a justification can be made for medical marijuana in addictions treatment as a harm reduction practice. As long as marijuana use is not associated with
poorer outcomes, then replacing other drug use with
marijuana may lead to social and economic savings.

There are differences in public and professional
perceptions about marijuana use. Thirty-two percent of
Americans believe that addiction to marijuana is a dan-
ger to society [31]. However, the Institute of Medicine is
quite clear in saying, “Marijuana has not been proven to
be the cause or even the most serious predictor of ser-
ious drug abuse” ([7], p. 10). Marijuana dependence may
very well be problematic, but the Institute of Medicine
also concluded “compared with alcohol, tobacco, and
several prescription medications, marijuana’s abuse
potential appears relatively small and certainly within
manageable limits for patients under the care of a physi-
cian” (p. 58). Further research on marijuana’s effects on
treatment outcomes can help address the disparity in
disciplinary perceptions and decision-making.

Hardly pro-marijuana lobbies, the National Institute
on Drug Abuse, the Office of National Drug Control
Strategy, and the State of California’s Little Hoover
Commission on California State Government Organiza-
tion and Economy all make recommendations about
substance abuse treatment services that are consistent
with studying the potential for medical marijuana use in
addictions care.

For at least a decade the National Institute on Drug
Abuse has maintained that drug addiction is a brain dis-
ease [32]. California’s Compassionate Use Act of 1996
(Section 11362.5 of California’s Health and Safety Code) is
equally clear that people “have the right to obtain and use
marijuana for medical purposes where that medical use is
deemed appropriate and has been recommended by a phy-
sician who has determined that the person’s health would
benefit from the use of marijuana in the treatment of can-
cer, anorexia, AIDS, chronic pain, spasticity, glaucoma,
arthritis, migraine, or any other illness for which marijuana
provides relief” (emphasis added). Expanding the evidence-
base for effective addiction treatments through a variety of
treatment protocols continues to be worthy of attention
from research and clinical communities.

While it may sound contrarian to suggest that the fed-
eral government’s National Drug Control Strategy might
support research into the potential therapeutic effect of
marijuana on problematic use of other drugs, the docu-
ment emphasizes “the need for customized strategies
that include behavioral therapies, medication, and con-
sideration of other mental and physical illnesses” ([24],
p. 31). Considering marijuana in a medicinal context,
the research described here offers a novel customized
strategy. The National Drug Control Strategy goes on to
note, “Experience with methamphetamine abusers has
shown that recovery can be achieved by focusing on sobriety, pharmacological intervention for any associated
depression and anxiety that appear with sobriety, and
the establishment of routines” (p. 31). Marijuana has
already shown therapeutic potential for anxiety symp-
toms [10]. Just as anti-depressant medications are used
in substance abuse treatment, marijuana may show pro-
mise as an additional pharmacological intervention for
methamphetamine users, if the data presented here are
replicated in larger-scale studies.

California’s Little Hoover Commission on California
State Government Organization and Economy has stud-
ied the state’s system of substance abuse treatment
twice in the last five years [33,34]. In their most recent
analysis, the commission concluded that “the state
should transform programs for nonviolent drug offen-
ders by tying funding to outcomes, requiring drug court
models where appropriate, and requiring counties to tai-
lor programs to offenders’ individual risks and needs.”
Supporting the use of marijuana during treatment fol-

dows from this recommendation unless such use demon-
strates poorer outcomes, which is not indicated in the
research described here.

From the perspective of abstinence-only treatment, 30
day drug use at discharge may be a key measure of
treatment success or failure. With 87.5% (n = 7) of
the MM group having used marijuana in the 30 days
discharge, the question could certainly be asked whether
the overwhelming percentage of successful treatment
completions noted in Table 1 ought really be considered
positive. Furthermore, those indicating marijuana use in
the 30 days before discharge had used cannabis any-
where from 14-30 days. This is clearly not abstinence.
However, marijuana was the only substance with
reported use in the 30 days before discharge, including
amongst those who had reported use of alcohol and
methamphetamine previously. Social, health, and beha-
vioral outcomes for the MM group did not appear to be
any worse than the Non-MM group.

Drug abuse screening tools do not tend to focus on fre-
quency or quantity of use as an indicator of drug-related
problems, nor do the diagnostic criteria for substance
abuse or substance dependence. If clinical, moral, and
legal concerns about marijuana use during treatment are
set aside, we are left with measurable outcomes as the
only meaningful indicators of success. Preliminary find-
ings presented here lay out a systematic methodology
for examining marijuana’s effect on treatment outcomes.

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NIH Studies on How Cannabis kills Tumor cells:

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1576089


Cannabis Cures Colorectal Cancer:


Cannabis Cures Uterine, Testicular, and Pancreatic Cancers:

http://www.cancer.gov/.../cannabis/healthprofessional/page4
Cannabis-derived substances in cancer therapy and anti-tumor properties:


Cannabis Cures Brain Cancer:

http://www.plosone.org/.../info%3Adoi%2F10.1371%2Fjournal.pon...
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Cannabis Cures Mouth and Throat Cancer:


Cannabis Cures Breast Cancer:


Cannabis Cures Lung Cancer:


Cannabis Cures Prostate Cancer:
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3339795/…
Cannabis Cures Blood Cancer:


Cannabis Cures Skin Cancer:


Cannabis Cures Liver Cancer:


Cannabis Cures Cancer in General:


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Targeting CB2 cannabinoid receptors as a novel therapy to treat malignant lymphoblastic disease

Marijuana kills cancer cells:

http://cancer.gov/.../p.../cam/cannabis/healthprofessional/page4

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Cannabinoids and the immune system:


Cannabis partially/fully induced cell death in Cancer:

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By Ashley C. Bradford and W. David Bradford

Medical Marijuana Laws Reduce Prescription Medication Use In Medicare Part D

ABSTRACT Legalization of medical marijuana has been one of the most controversial areas of state policy change over the past twenty years. However, little is known about whether medical marijuana is being used clinically to any significant degree. Using data on all prescriptions filled by Medicare Part D enrollees from 2010 to 2013, we found that the use of prescription drugs for which marijuana could serve as a clinical alternative fell significantly, once a medical marijuana law was implemented. National overall reductions in Medicare program and enrollee spending when states implemented medical marijuana laws were estimated to be $165.2 million per year in 2013. The availability of medical marijuana has a significant effect on prescribing patterns and spending in Medicare Part D.

In the past twenty years, the drive in many states to legalize medical marijuana has gained widespread public attention, though there has been no corresponding change to federal marijuana laws. In the late 1980s evidence began to emerge that the use of marijuana has a positive effect on the lives of many people suffering from a variety of ailments. Nevertheless, marijuana is still federally classified as a Schedule I drug (the most restrictive category, according to the Controlled Substances Act of 1970), which means that it is deemed to have "no currently acceptable medical use in treatment in the United States," a high potential for abuse, and "a lack of accepted safety for use...under medical supervision." This classification imposes significant barriers not only to obtaining marijuana products for clinical use but also to conducting primary research on the pharmacological and behavioral impacts of marijuana use.

Despite such barriers, twenty-four states and the District of Columbia have adopted laws legalizing the use of marijuana for medical purposes. Surprisingly, although there is a rapidly growing literature about many indirect effects of medical marijuana laws, almost nothing is known about how these state health policies affect clinical care or spending in the health care sector. In this article we investigate how implementing state-level medical marijuana laws changes prescribing patterns and program and patient expenditures in Medicare Part D for prescription drugs approved by the Food and Drug Administration (FDA).

There is significant variation across state medical marijuana policies. Every state that currently allows the use of medical marijuana requires a licensed physician to recommend that use and requires that the recommendation be made only if a patient presents with one or more illnesses from a state-approved list. Home cultivation of marijuana is sometimes permitted, though every state that passed a medical marijuana law since 2009 has included some form of regulated dispensary program. Some states allow caregivers to distribute marijuana. In addition, the legal possession limit differs greatly across states.

The findings from research on the effects of the medical use of marijuana have been extremely mixed. Historically, opponents of medical marijuana legalization have cited addiction, criminal
activity, marijuana’s status as a so-called gateway drug, and marijuana’s lack of demonstrated medical value as reasons for keeping the drug illegal. However, the causal link between the use of marijuana and the use of harder drugs has never been proven definitively, nor has the link between medical marijuana and criminal activity.

In a 2013 study Mark Anderson and coauthors reported that traffic fatalities dropped 8–11 percent following the passage of state medical marijuana legislation. Sarah Lynne-Landsman and coauthors analyzed data from the Youth Risk Behavior Survey using a difference-in-differences design to estimate the effects of medical marijuana laws on adolescent marijuana use. That study found no effect on self-reported prevalence or frequency of use. In contrast, Melanie Wall and colleagues reported that states that passed a medical marijuana law had significantly higher rates of marijuana use and abuse among adolescents, compared to states with no such law, though the estimated effects were largely associations.

In a later study that attempted to replicate the results of Wall and colleagues, Sam Harper and coauthors found that when researchers used statistical methods that identified causal effects, the effect of medical marijuana laws on drug use largely disappeared.

These findings are representative of an unsettled literature. Earlier studies did not generally use statistical methods such as those of Harper and coauthors, but later studies did—and the later studies tended to find only insignificant effects or a mix of significant and insignificant ones.

One issue that has received surprisingly little attention is the question of whether medical marijuana is being used clinically to any significant degree. To the extent that physicians recommend the use of marijuana to their patients to manage conditions that it can treat, according to clinical evidence, one would expect marijuana to be primarily a substitute for existing prescription medications (for patients who did not respond to previous therapy or who respond better to marijuana than to previous treatment). Nonetheless, there are no published studies that investigate whether states’ approval of medical marijuana changes the prescriber’s patterns for pharmaceuticals approved by the FDA.

In this study we asked two straightforward questions. First, does implementing a medical marijuana law change prescriber patterns in Medicare Part D for traditional (FDA-approved) drugs that treat conditions marijuana itself might treat? Second, if it does, what is the effect on overall spending—both by Medicare and by enrollees out of pocket—of such changes?

**Conceptual Framework**

Two competing forces can drive prescription behavior when a medical marijuana law is implemented. The primary effect one expects is that prescribing for FDA-approved drugs will fall when a medical marijuana law is put in place, because marijuana is often a substitute for existing therapies. For most FDA-approved prescription drugs for which medical marijuana can serve as a replacement, we hypothesized that prescribing would decline.

However, this substitution effect model does not account for the secondary effect from demand expansion that might result from the introduction of a new product. When new products are made available, information sets change because of influences such as discussion of the treatment option in the media. Media coverage may draw new patients into physicians’ offices, much as direct-to-consumer advertising does. If not all new patients are diverted to marijuana, then prescription drug use might rise, even if those drugs and marijuana are clinical substitutes for each other.

Glucoma is a notable condition for which demand expansion might swamp substitution. Clinical evidence is very strong that while marijuana sharply reduces intraocular pressure, the effect lasts only about an hour. As a result, new patients who seek glaucoma treatment after learning about the potential benefits of marijuana are likely to receive a prescription for an FDA-approved drug. The prognosis for untreated glaucoma is very ominous. Thus, we expected that prescribing for glaucoma drugs would remain unchanged or even rise with the implementation of a medical marijuana law.

**Study Data And Methods**

**DATA** Our data came from the Medicare Part D Prescription Drug Event Standard Analytic File for the period 2010–13. These data contain information on all prescription drugs paid for under Medicare Part D. Each record in the data represents a specific drug prescribed by a physician in a given year and contains information on the total number of daily doses filled and the total expenditures (the amount paid by Medicare, patients’ out-of-pocket expenditures, and any low-income subsidies for deductibles and copayments under the Affordable Care Act). We linked these data to basic information on the prescribing physicians, including sex, specialty, and location of home and business addresses. The baseline data contained more than eighty-seven million physician-drug-year observations.

We restricted the analysis to drugs that treat conditions for which marijuana might be an al-
ternative treatment. We obtained guidance on which conditions were in that category from the states’ medical marijuana legislation, which explicitly mentions certain conditions; from summaries of the clinical evidence in a 1999 Institute of Medicine review; and from a recent comprehensive meta-analysis. We selected nine broad clinical condition categories to study, based on the intersection of this reviewed clinical evidence and the list of conditions mentioned in state medical marijuana laws. A list of these condition categories and information about the clinical evidence for the use of marijuana in treating them appear in Exhibit 1.

Once the relevant condition categories were selected, we had to determine which drugs to study. In clinical practice, patients may be prescribed drugs that have been formally approved by the FDA to treat their diagnosed conditions (an on-label prescription) or drugs that do not have such formal approval (an off-label prescription). If we chose only drugs that were on label, we might have overlooked a large number of drugs that were used to treat the condition categories listed in Exhibit 1.

For our analysis, we extracted data on all drugs that were in a drug class that had at least one on-label option to treat one or more of the condition categories.

---

**EXHIBIT 1**

Nine medical condition categories with at least one drug approved by the Food and Drug Administration for on-label use, and level of evidence for marijuana as a treatment for conditions in the category

<table>
<thead>
<tr>
<th>Condition category</th>
<th>Anxiety</th>
<th>Depression</th>
<th>Glaucoma</th>
<th>Nausea</th>
<th>Pain</th>
<th>Psychosis</th>
<th>Seizures</th>
<th>Sleep disorders</th>
<th>Spasticity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLINICAL EVIDENCE OF MEDICAL MARIJUANA EFFECT ON CONDITIONS IN EACH CATEGORY</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Institute of Medicine (1999)</td>
<td>Present</td>
<td>—</td>
<td>Insufficient</td>
<td>Present</td>
<td>—</td>
<td>Insufficient</td>
<td>—</td>
<td>Insufficient</td>
<td>Insufficient</td>
</tr>
<tr>
<td>Whiting et al. (2015)</td>
<td>Very low</td>
<td>Low</td>
<td>—</td>
<td>Moderate</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low or very low</td>
<td>Low to moderate</td>
</tr>
</tbody>
</table>

**DRUG CLASSES WITH AT LEAST ONE ON-LABEL OPTION FOR TREATING CONDITIONS IN EACH CATEGORY**

- Adrenal cortical steroids
- Analgesics
- Antiarrhythmic agents
- Anticonvulsants
- Antidepressants
- Antidiarrheal agents
- Antiemetic or antivertigo agents
- Antimalarial agents
- Antipsychotics
- Antirheumatics
- Anxiolytics, sedatives, and hypnotics
- Central nervous system stimulants
- Functional bowel disorder agents
- Immunostimulants
- Muscle relaxants
- Ophthalmic preparations
- Proton pump inhibitors
- Respiratory inhalant products
- Sedatives and hypnotics
- Smoking cessation agents

**SOURCE** Authors’ analysis of principal findings in Institute of Medicine. Marijuana and medicine (Note 13 in text); and Whiting PF, et al. Cannabinoids for medical use (Note 16 in text).

**NOTES**

- The nine condition categories were selected based on their inclusion in at least four states’ medical marijuana laws and the two comprehensive clinical studies cited in the exhibit.
- Classifying evidence of effect as either present (without rating the strength of the evidence) or insufficient.
- No review of the effects of marijuana were provided for conditions in these categories.
- Classifying evidence of effect on a scale from moderate to very low.
Our research suggests that more widespread state approval of medical marijuana could provide modest budgetary relief.

categories listed in Exhibit 1. This resulted in a set of both on- and off-label drugs used to treat each of our study condition categories, while excluding off-label drugs that were pharmacologically far removed from the on-label options.

We saved these prescription data in separate analytic data sets, one for each condition category listed in Exhibit 1. We aggregated the data to the physician-year level, so that each line in the data represented the number of daily doses (and associated Medicare program and enrollee out-of-pocket costs) that were filled for all prescriptions written by each physician in the particular condition category each year. The final physician-level analytic data sets, which were aggregations of all Medicare Part D prescriptions for our selected drugs, ranged in size from 588,808 observations for the spasticity diagnosis sample to 2,496,608 observations for the pain diagnosis sample.

More details on the data and data construction methods can be found in the online Appendix.18

**BASIC MODELS** The key variable of interest was an indicator of when prescriptions were filled in a state and year with an effective medical marijuana law in place—that is, where it was legal for state residents either to use home-grown marijuana or to purchase marijuana in a dispensary and where such a dispensary was open. Covariates included physician and state characteristics. We also included county-level demographic variables from the Area Health Resources Files that were expected to influence the aggregate demand for drugs dispensed under Medicare Part D.19

We used a simple difference-in-differences regression framework estimated separately for each of the nine condition categories listed in Exhibit 1. All models were estimated with least squares regressions. Each of the estimated models was corrected for clustering at the physician level. Details of the model variables are included in the Appendix.18

In addition to estimating changes in prescribing patterns with the implementation of a medical marijuana law, we estimated changes in Medicare Part D payments (including government low-income subsidies for copayments and deductibles) and patients’ out-of-pocket spending. Details of how we conducted this analysis can be found in the Appendix.18

**LIMITATIONS** Our study had several limitations. First, previous studies have suggested that Medicare patients may make up a relatively small percentage of people who use medical marijuana and that only 13–27 percent of people who used medical marijuana were ages fifty and older.20,21 Thus, while our study illuminated the behaviors of a generally older population in response to implementation of medical marijuana laws, future research is needed to understand the prescription drug use responses of younger people.

Second, our study of prescribing behavior at the physician level could not explore important remaining questions about the mechanism of the response. It is certainly plausible that forgoing medications with known safety, efficacy, and dosing profiles in favor of using marijuana (despite its reasonably favorable safety profile) could be harmful under some circumstances. In addition, patients who switch from a prescription drug that requires regular physician monitoring to marijuana, which requires no monitoring, may interact with the health care community less often overall than they did before switching to marijuana, and adherence to other important treatment regimens could be compromised. Again, we leave exploration of these important issues to future research.

**Study Results**

Our simple bivariate comparisons demonstrated that, with the exception of glaucoma, fewer prescriptions were written for any of our study condition categories when a medical marijuana law was in effect (Exhibit 2). When we controlled for other factors that might have been driving differences in prescribing across states that did and did not have medical marijuana law in effect, we found similar results.

The results for our difference-in-differences models of daily doses filled were extremely consistent across condition categories (Exhibit 3). For seven of the categories—all but glaucoma and spasticity—we found that implementing an effective medical marijuana law led to a reduction of between 265 daily doses (for depression) and 1,826 daily doses (for pain) filled per physician per year. The effects of a medical marijuana law on those seven categories were all significant \((p < 0.01)\), with magnitudes that were econom-
ically important. We found no statistically or economically significant effect on glaucoma or spasticity.

To confirm that these effects were causally related to implementing a medical marijuana law, and not due to some unobserved characteristic of the states that affected general prescribing and adoption of a medical marijuana law, we selected drugs from four classes—blood-thinning agents, phosphorous-stimulating agents, antivirals used to treat influenza, and antibiotics—in which there is no evidence of any beneficial (or harmful) effect from the use of medical marijuana.

We found no changes after implementation of a medical marijuana law in the number of daily doses filled in condition categories with no medical marijuana indication. This provides strong evidence that the observed shifts in prescribing patterns were in fact due to the passage of the medical marijuana laws. Results from these models are presented in the Appendix.18

Our analysis suggested that prescription drug spending in Medicare Part D—that is, both program and enrollee spending—fell by $104.5 million in 2010 and that cost savings had risen to $165.2 million by 2013 (Exhibit 4). The savings accrued from only seventeen states and the District of Columbia—jurisdictions that had implemented a medical marijuana law by 2013. Assuming the remaining states are of similar size, we forecast that if all states were to have adopted a medical marijuana laws by 2013, total spending by Medicare Part D would have been $468.1 million less in that year than it would have been had no state adopted such a law. That amount would have represented just under 0.5 percent of all Medicare Part D spending in 2013.

Discussion
As of June 2016 twenty-four states and the District of Columbia had passed a medical marijuana law (though not all states had fully implemented their laws by that time), and there is a growing academic literature on the effects of these laws. Researchers have investigated negative externalities associated with medical marijuana, such as spillovers from medical marijuana to recreational use of the drug among adults and youth, and changes in the number of traffic fatalities following the implementation of a medical marijuana law, among other topics.

Remarkably, there is no literature that investigates the extent to which marijuana is used medically as a result of implementing medical marijuana laws at the state level. In this article we provide the first, albeit somewhat indirect, evidence on the clinical impact of medical marijuana availability by examining the impact of medical marijuana laws on the use of all FDA-approved prescription drugs paid for by the Medicare Part D program.

Generally, we found that when a medical marijuana law went into effect, prescribing for FDA-approved prescription drugs paid for by the Medicare Part D program fell in all states with the exception of glaucoma and spasticity.
approved prescription drugs under Medicare Part D fell substantially. The only exceptions were for spasticity- and glaucoma-related drugs. Ultimately, we estimated that nationally the Medicare program and its enrollees spent around $165.2 million less in 2013 as a result of changed prescribing behaviors induced by seventeen states and the District of Columbia—the jurisdictions that had legalized medical marijuana by then.

Policies surrounding the appropriate use of medical marijuana are the subject of intense and ongoing debate, and the research we have presented here has direct implications for multiple aspects of the evolution of those policies. State reforms to medical marijuana policies are constrained by the current status of marijuana as a Schedule I drug under the Controlled Substances Act. That status prohibits any sale of marijuana under federal law because the drug is defined to have a high potential for abuse and no medical benefit; thus, many state laws now contradict federal law. Our findings and existing clinical literature imply that patients respond to medical marijuana legislation as if there are clinical benefits to the drug, which adds to the growing body of evidence suggesting that the Schedule I status of marijuana is outdated.

Additionally, at a time when Medicare is under increased fiscal pressure, our research suggests that more widespread state approval of medical marijuana could provide modest budgetary relief. Although some of the savings are likely to be a transfer of costs from the Medicare program to beneficiaries who would have purchased marijuana out of pocket, saving $468.1 million annually is not trivial. As noted above, that would represent about 0.5 percent of total Part D spending for 2013.

Finally, while we did not directly test the impact on governmental programs other than Medicare—most importantly, Medicaid—finding significant cost savings for Medicare suggests that other programs might also enjoy budgetary reductions when medical marijuana laws are implemented. Lowering the costs of Medicare and other programs is not a sufficient justification for approving marijuana for medical use, a decision that is complex and multidimensional. Nonetheless, these savings should be considered when changes in marijuana policy are discussed.

The authors thank seminar participants at the University of North Carolina at Chapel Hill and Texas A&M University for comments on an earlier presentation of this research.
NOTES

3. Frequently accepted illnesses include chronic pain, nausea, cachexia (weakening or wasting of the body), wasting syndrome resulting from HIV, glaucoma, AIDS, and cancer. For more details on specific state policies, see ProCon.org. 24 legal medical marijuana states and DC: laws, fees, and possession limits [Internet]. Santa Monica (CA): ProCon.org; 2016 [cited 2016 May 25]. Available from: http://medicalmarijuana.procon.org/view.resource.php?resourceID=000881.
14. For the years 2010–12, when the data originated from a request by Propublica under the Freedom of Information Act of 1966, only physician National Provider Identifier (NPI) numbers appeared in the public use Medicare Part D Prescription Drug Event Standard Analytic File data. We merged information on physician characteristics and practice location and the analysis file according to the NPI number and the National Plan and Provider Enrollment System of the Centers for Medicare and Medicaid Services. For more details on state laws with links to legislative language, see Note 3.
16. Whiting PF. Surapproach. Beta-blockers have been used for decades to treat hypertension, cardiac dysrhythmias, and other related diagnoses. Researchers have noted that beta-blockers also control physical sensations associated with anxiety (such as rapid heartbeat, tightness in the chest, and trembling) and that when patients do not feel these sensations, their psychological experience of anxiety is significantly reduced. As a result, these drugs are widely prescribed for situational and other forms of anxiety, even though they are not officially approved for that indication by the FDA. An estimated 52 percent of prescriptions for beta-blockers in the period 1999–2002 were for off-label use. See Lin HW, Phan K, Lin SJ. Trends in off-label beta-blocker use: a secondary data analysis. Clin Ther. 2006;28(10): 1736–46; discussion 1710–1.
17. To access the Appendix, click on the Appendix link in the box to the right of the article online.
How I Treat

Medical use of cannabis: an addiction medicine perspective
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Key words
medical marijuana, medicinal cannabis, THC, therapeutic use.

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Abstract
The use of cannabis for medical purposes, evident throughout history, has become a topic of increasing interest. Yet on the present medical evidence, cannabis-based treatments will only be appropriate for a small number of people in specific circumstances. Experience with cannabis as a recreational drug, and with use of psychoactive drugs that are prescribed and abused, should inform harm reduction in the context of medical cannabis.

The use of cannabis for medical purposes, evident throughout history, has become a topic of increasing media interest in recent months. A formal evidence base for several medical indications is gradually building and pharmaceutical cannabis preparations are being produced.1 Major changes in the legal status of cannabis in the United States have occurred, with several states legalising possession of small amounts of marijuana for medical purposes, chronic pain being the most prominent indication.2 There are calls for similar legislation in Australia. Legal cannabis production and its marketing is fast emerging as a major new industry.

In Australia, a 2013 New South Wales parliamentary committee was generally supportive of medical cannabis, but noted that ‘on the present medical evidence, cannabis based treatments will only be appropriate for a small number of people in specific circumstances’.3 Announcement of a trial of medical marijuana in New South Wales has now received support of the Council of Australian Governments. A strong evidence base for assessing the balance between therapeutic benefits and potential harms is however lacking. The wealth of experience in addiction practice and policy can offer an important contribution to the debate about medical cannabis.

Cannabis and cannabinoids
Cannabis is a generic term used for drugs that are made from any of the genus cannabis plants, most commonly Cannabis sativa. Cannabis is a heterogeneous product, containing over 400 chemicals and 60 cannabinoids, with two major constituents: Δ9-tetrahydrocannabinol (Δ9-THC or THC) and cannabidiol.4,5 THC is responsible for most of the psychoactive effects of cannabis, including the ‘high’. Cannabidiol has antipsychotic and anxiolytic properties and may offset some of the psychoactive effects of THC; the ratio between THC and cannabidiol is likely to be important.5 Both THC and cannabidiol content vary considerably between different sources and preparations of cannabis, making cannabis a very variable drug with unpredictable pharmacological and psychological activity.5

Understanding of the endogenous cannabinoid system is relatively new, with cannabinoid receptors first isolated in the last 25 years.6 The endocannabinoid system is involved in analgesia, cognition, memory, locomotor activity, appetite, vomiting and immune control.4 Two separate cannabis receptors have to date been identified: CB1 and CB2, and the endocannabinoids anandamide and 2-arachidonoyl glycerol have been isolated.4,6 Most of the effects of cannabis preparations, including the well-known psychotropic effects, are based on the agonistic action of THC on the CB1 receptors.

Several cannabis preparations are now being produced.7 Nabiximols, an oromucosal spray of botanical cannabis extract, containing 2.7 mg THC and 2.5 mg CBD
per 0.1 mL, was registered by the Therapeutic Goods Administration (TGA) in 2012 for use in multiple sclerosis. Dronabinol, a synthetic THC oral capsule, has been licensed in the USA for the treatment of nausea and vomiting caused by cytostatic therapy and for loss of appetite in human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS)-related cachexia. Nabilone capsules, a synthetic analogue of THC, has been registered for treatment of the side-effects of chemotherapy in Britain.1,9

Therapeutic indications

A recent review of data from randomised controlled trials reported evidence for medical cannabis for several indications.1 Cannabis extract in multiple sclerosis significantly reduced spasticity and the frequency of spasms and significantly improved sleep quality compared with placebo. Numerous studies have demonstrated that cannabinoids were just as effective against chemotherapy-related nausea and vomiting as standard anti-emetics, and may be as effective as ondansetron. All seven studies examining anorexia in HIV and AIDS patients have shown a positive effect of dronabinol and cannabis cigarettes in the treatment of poor appetite. Chronic neuropathic pain and pain in multiple sclerosis have been shown to respond to cannabinoids, though the magnitude of effect is modest.1,10 Small controlled studies have indicated that cannabinoids may also be effective against chronic pain of other causes including tumour pain, rheumatism and fibromyalgia.1,16 Little or no effect has been found in patients with acute pain.1

In Australia, TGA approval has only been obtained for use of nabiximols in multiple sclerosis, and only for the narrow indication of ‘symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy’.8 Pharmaceutical Benefits Scheme listing for this indication was rejected in 2013 as it was not shown to be superior to standard care and is inferior to standard care in terms of safety.11

While cannabinoids have been shown to be effective in nausea and vomiting, they have not been shown to be more effective than other safer medication. A role in HIV was questioned in a recent review,12 and has lessened with the advent of effective and better tolerated retroviral medication. TGA approval has not been obtained for these indications.

The potential role of cannabis in the treatment of chronic pain is an area attracting increasing interest, as chronic pain is common, debilitating and lacking in therapeutic options.10 Interest particularly lies in developing CB1 and CB2 receptor agonists that act outside the blood-brain barrier.9 This is on the basis that many of the ‘unwanted effects’ of cannabinoid receptor agonists are caused by their activation of CB1 receptors located within the brain, and beneficial effects such as pain relief occur outside the central nervous system. CB2-specific agonists may have roles in certain types of cancer, cardiovascular, immunological and inflammatory conditions.9

There is also interest in potential therapeutic effects of cannabidiol, currently in trial in the USA for use as a treatment for Dravet syndrome – a form of severe childhood epilepsy.

Risks and harms

Cannabis use has not been directly associated with toxic deaths, although the emergence of synthetic cannabinoids may change this observation.13 Notwithstanding this, cannabis use can cause significant harms.14 Cannabis are widely used recreationally for the pleasurable and relaxing effects, but unwanted psychotropic effects including anxiety and panic attacks can occur even in the context of deliberate intoxication.6 A strong link exists between early onset cannabis and later mental health; a study of 1600 Australian school students 14–15 years old followed for 7 years found those who used cannabis regularly had increased risk of depression.15 There is strong epidemiological evidence that early onset cannabis is associated with subsequent psychotic disorder in young adulthood.16,17 A 2007 meta-analysis pooling 35 longitudinal, population-based studies demonstrated an elevated odds ratio of 1.41 for psychosis in individuals who had ever used cannabis, with findings consistent with a dose–response effect.16 Cannabis is also shown to result in a poor prognosis for those with an established vulnerability to psychosis.17

Cannabis use can lead to dependence syndrome, with well-documented withdrawal symptoms including restlessness, insomnia, anxiety, aggression, anorexia, muscle tremor and autonomic effects.6,18 Adult lifetime prevalence rates suggest that 9% of cannabis users develop cannabis dependence,19 with higher rates in young people.20 Cannabis is the most common substance after alcohol for which admission for detoxification is sought.21 Presentations to hospitals following ingestion or inhalation of illicit synthetic cannabis are also on the rise.13

There is growing evidence linking cannabis use with cognitive impairment. Cannabis acutely impairs cognitive and psychomotor performance, with effects including slowing of reaction time, motor incoordination, defects in short-term memory, difficulty in concentration and impairment in complex tasks.5 Impairment due to
cannabis is increasingly recognised as a factor in road trauma;\textsuperscript{23} acute cannabis consumption is associated with an increased risk of a motor vehicle accident, especially for fatal collisions.\textsuperscript{21} Ongoing cannabis use is associated with poor academic achievement and a below expected performance in measures of intelligence in adulthood.\textsuperscript{24} Further, cessation of cannabis use did not fully restore neuropsychological functioning among adolescent-onset cannabis users.\textsuperscript{24}

Other general health effects of cannabis that have been described include airway injury with regular use leading to symptoms of chronic bronchitis.\textsuperscript{25} Cannabis use also has implications for fertility, immunosuppression, cardiac health and psychomotor performance.\textsuperscript{14,26}

**Perspective**

Our experience with use of psychoactive drugs that are prescribed and abused can inform harm reduction in the context of medical cannabis. There are valuable lessons to heed from the exponential rise in use of prescription opiate and other pharmaceuticals and associated deaths,\textsuperscript{27,28} the increasing rates of alcohol and drugs (both illicit and prescribed) in road trauma,\textsuperscript{29} and the heavy burden of disease of mental health disorders, especially in young people.\textsuperscript{30,31}

The history of morphine as medicine, with varying levels of medical and recreational use, regulation and criminalisation, offers insight into the challenges now faced with medical cannabis.\textsuperscript{32} Absence of regulation of laudanum and morphine in the 19th and early 20th century resulted in widespread inappropriate use, including for infantile diarrhoea, with resultant infantile deaths. Conversely government and media condemnation of opioid use in the context of a flourishing illegal market can lead to underutilisation of opioids and inadequate management of pain.\textsuperscript{32,33}

The substantial appeal of cannabis to the community is clear, it being the most commonly used illicit drug. The number of Australians using cannabis increased from 1.6 million in 2007 to 1.9 million in 2010.\textsuperscript{34} This level of appeal perhaps in part explains the apparent incongruity between the high level of interest in cannabis as medicine and the limited therapeutic role that can be recommended on current evidence. Recreational use of cannabis and its criminalisation and decriminalisation fall outside the scope of this article, but blurring of the line between recreational and medical use of cannabis is recognised, and creates confusion around advocacy for its use as medicine.\textsuperscript{35} The implications of availability of cannabis beyond the clinical context therefore need careful consideration.

The therapeutic potential for medical cannabis cannot be ignored and the commencement of therapeutic trials is to be applauded. As with any other pharmacological agent, the underlying neurobiological mechanisms of action, clinical efficacy, dose-response, clinical pharmacokinetics, efficacy and toxicity in special population groups such as the elderly, cost-effectiveness and rigorous controls around production of high quality pharmaceuticals need to be systematically addressed. Such exploration should occur as a priority for those indications where no other therapeutic avenue is available, such as severe childhood epilepsy. Formulations that have greater cannabidiol content such as nabiximols are particularly appealing given that cannabidiol appears to attenuate paranoia and euphoria and produces little intoxication, tolerance or withdrawal.\textsuperscript{36} Strategies to reduce diversion and public harms such as permits, authority scripts and regular review should also be considered. As the medical role for cannabis becomes clear, thought is required into preventing predictable associated harms.

**References**

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Impact of Cannabis Use during Stabilization on Methadone Maintenance Treatment

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Background and Objectives: Illicit drug use, particularly of cannabis, is common among opiate-dependent individuals and has the potential to impact treatment in a negative manner. Methods: To examine this, patterns of cannabis use prior to and during methadone maintenance treatment (MMT) were examined to assess possible cannabis-related effects on MMT, particularly during methadone stabilization. Retrospective chart analysis was used to examine outpatient records of patients undergoing MMT (n = 91), focusing specifically on past and present cannabis use and its association with opiate abstinence, methadone dose stabilization, and treatment compliance. Results: Objective rates of cannabis use were high during methadone induction, dropping significantly following dose stabilization. History of cannabis use correlated with cannabis use during MMT but did not negatively impact the methadone induction process. Pilot data also suggested that objective ratings of opiate withdrawal decrease in MMT patients using cannabis during stabilization. Conclusions and Scientific Significance: The present findings may point to novel interventions to be employed during treatment for opiate dependence that specifically target cannabinoid-opioid system interactions. (Am J Addict 2013;22:344–351)

INTRODUCTION

Methadone maintenance treatment (MMT) is an opiate agonist pharmacotherapy prescribed for opiate-dependent individuals as a means of extinguishing illicit opiate use and reducing associated risk behaviors.1,2 Initiation on MMT is a federally regulated process that requires slow and careful titration of methadone dosing to avoid risk of overmedication. Dose titration proceeds through initiation, induction, and stabilization phases prior to reaching a maintenance phase.3–5 The initial period of methadone dose stabilization is one of particular vulnerability to relapse due to the persistence of low-moderate grade opiate withdrawal and associated stress during dose titration.6–10 Non-opiate illicit drug use often persists during the early phases of treatment for opiate dependence,11–18 promoted at least in part by the experience of withdrawal and craving. There is a limited amount of research focused on the impact of continued non-opiate substance use on methadone dose titration and overall treatment compliance.

Cannabis (marijuana) is commonly used in combination with heroin or oral opiates, in addition to other substances such as cocaine and benzodiazepines.19–21 In several studies of non-opiate illicit drug use in opiate-dependent individuals, rates of cannabis use were shown to remain high during treatment for opiate dependence.15,22–25 Several groups have investigated the impact of cannabis use on various measures of treatment outcome and success, such as retention in treatment or compliance.16,23–28 However, very limited research has focused specifically on the impact of cannabis exposure during the process of methadone dose titration (referred to herein as methadone induction) and the early stabilization phase. The present study sought to examine the trends in cannabis use of individuals during the early phases of MMT initiation in order to test the hypothesis that cannabis use may impact illicit drug use, and subsequently methadone stabilization. Based on findings from experimental models of opiate dependence, it is hypothesized that the use of cannabinoids, via its interaction with the opioid system, may impact opioid signaling in the brain.29–36 Multiple groups have reported synergy between cannabinoids and opiates when administered concurrently.10,37–40 The present study attempted to investigate whether similar evidence of cannabinoid-opioid interactions can be found in the clinical setting among treatment-seeking opiate-dependent individuals. The authors hypothesized that cannabis use may increase during dose titration, and that this elevated use may impact methadone induction and stabilization on MMT. Additionally, associations between pre-treatment history of opiate and cannabis use were examined as they relate...
to methadone dosing and titration, and illicit drug use during treatment.

MATERIALS AND METHODS

The data presented in this retrospective study were collected from outpatient charts belonging to individuals enrolled in the Narcotic Addiction Rehabilitation Program (NARP) at Thomas Jefferson University in Philadelphia, PA. This urban, publicly funded, and university-sponsored clinic offers medication-assisted treatment and intensive outpatient programs for opiate dependence. Criteria for admission to treatment included a minimum of 1-year documented history of opiate use, being at least 18 years of age, and a positive opiate urine drug screen (UDS) at admission. Approximately 365 individuals were enrolled in NARP at any given point in time over the past decade. This study was approved by the Institutional Review Board of Thomas Jefferson University.

Sample Criteria

Criteria for study inclusion were a minimum of 9 months in treatment and the presence of the following data in the outpatient chart: monthly urinary drug screen results, treatment compliance (daily attendance), and medical intake evaluation information. In order to capture data from the weeks both prior to and immediately following methadone dose stabilization, the time in treatment criteria was established at a minimum of 9 months. Charts were sampled from individuals that were enrolled in NARP between December 1, 2005 and July 1, 2009 (approximately 500 in total). The authors collected and analyzed data from all criterion-meeting patients that had at least one cannabis-positive urine drug screen (UDS) during treatment (n = 56). An additional random sample of 35 non-cannabis using individuals from the same enrollment period was used as a comparison group. These charts were pulled using a random number generator and were selected for the study if all inclusion criteria were met.

Treatment Enrollment and Structure

As part of the intake process, individuals seeking admission participated in a structured clinical interview and medical evaluation where detailed drug use histories were collected. Individuals were then initiated on methadone maintenance therapy according to federal guidelines, with assigned daily medication times. Dosing was slowly titrated until a blocking dose of methadone was achieved and opiate craving and use were controlled. For the purposes of this project, dose stabilization was defined as a period of 8 weeks at a constant dose of methadone. Acquisition of this dose marked the transition from methadone induction to early stabilization phase in patients. Progress was monitored through regular meetings with counselors and medical staff, as well as UDS performed at least once-monthly on a random basis. During the titration period, in which low to moderate-grade opiate withdrawal symptoms were typically experienced, the clinical opiate withdrawal scale (COWS) was administered by the medical staff as needed to help assess the need for dose increases, and periodically thereafter when dose changes were requested or needed.

Plan of Analysis

Study data was analyzed as follows using SPSS 16.0 Graduate Pack software. The authors first examined whether a history of pre-treatment cannabis use was associated with proxy measures of opiate addiction and severity (ie, daily opiate expenditure, number of previous opiate dependence treatment episodes, and cumulative years of opiate use). Next, the patterns and effects of both pre-treatment and in-treatment cannabis use on methadone induction and opiate use were studied. Recent cannabis history (dichotomized as yes/no) referred to any self-reported history of cannabis use in the month prior to enrollment in treatment. Data on in-treatment cannabis use was recorded from urinalyses conducted during the initial 9 months of MMT enrollment. To test the hypothesis that cannabis use impacts the process of methadone induction, a series of ANOVAs were conducted using either recent cannabis history or cannabis use during methadone induction as independent variables. Because illicit drug use during stabilization could have potentially complicated the dose titration process, the dependent measures included: (i) rates of cannabis and opiate drug use during the methadone induction phase and early stabilization phase, (ii) the number of weeks required to complete methadone dose titration (induction), (iii) the methadone blocking dose upon stabilization, and (iv) medication compliance (attendance for daily methadone administration). Parallel ANCOVAs were conducted for each operationalization of the independent variable, using daily opiate expenditure as a covariate to control for pre-treatment opiate use/severity of dependence. In this manner, it was possible to study how the patterns of cannabis use interact with opiate dependence prior to treatment, and also the possible impact of cannabis use on MMT and opiate use during two critical phases of treatment: methadone induction and early stabilization.

RESULTS

Sample Statistics

Data from a total of 91 individuals were recorded. Due to the limited availability of certain data in the clinical record, some analyses were performed on a smaller subset of cases. Average age at admission was 39 ± 11 years, and ranged from 20 to 62 years of age. Sixty percent (n = 55) of subjects were male. Almost 18% (n = 70) of subjects were Caucasian, the remainder were African American (n = 12, 13.5%) and Hispanic (n = 6, 6.7%). The majority of the sample were intravenous drug users (n = 61, 67.0%), but oral narcotic (n = 44, 50%) and intranasal administration (n = 43, 49.4%) was also commonly reported. In the month prior to entering
treatment, almost half of the individuals (46.6%) were using multiple substances (benzodiazepines, cannabis, or stimulants) in addition to opiates (see Table 1).

Analysis of stabilization involved examination of two distinct treatment phases during the time period from enrollment through month nine of treatment. “Methadone induction phase” was used to refer to the period of time during which an individual’s methadone dose was titrated to a stable blocking dose, while “early stabilization phase” denoted the remainder of the 9-month study period following acquisition of a blocking dose. Almost all subjects \((n = 85)\) were able to achieve a stable blocking dose of methadone \((x = 112.42 \pm 61.03 \text{ mg})\) within an average of \(11 \pm 9.4\) weeks. For a variety of reasons, 6 of the 91 subjects were unable to achieve a stable blocking dose during the study time frame. In the 9 months following enrollment, subjects on average missed daily dosing \(18.5 \pm 24.6\) times. Stabilization on MMT, operationalized in this study as 8 weeks on a stable methadone dose, was associated with a significant decrease in the percentage of opiate-positive UDS. A within-subjects comparison of opiate use between methadone induction and early stabilization treatment phases revealed an approximately 50% decrease in the mean percentage of opiate-positive UDS \([57.4–28.2\%], t(82) = 6.58, p < .001\]. Cannabis use during stabilization on MMT was examined next (see Table 1).

### Table 1. Descriptive characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>(N)</th>
<th>Values</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>91</td>
<td>39.37 ±11.29</td>
</tr>
<tr>
<td>Stable methadone blocking dose</td>
<td>85*</td>
<td>111.98 mg/day</td>
</tr>
<tr>
<td>Weeks to stabilization</td>
<td>91</td>
<td>11.01 ±9.38</td>
</tr>
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<td>Gender</td>
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<td></td>
</tr>
<tr>
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<td>Race/ethnicity</td>
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<tr>
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</tr>
<tr>
<td>Opiate route of administration(^\d)</td>
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<tr>
<td>Intravenous</td>
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<tr>
<td>Oral</td>
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<tr>
<td>Intrasanal</td>
<td>49.4</td>
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</tr>
<tr>
<td>Combination of (\geq 2) of the above</td>
<td>38.9</td>
<td></td>
</tr>
</tbody>
</table>
| History of illicit drug use: lifetime\(^\d\)\(^\d\)\)
- Marijuana                                    | 71.5  |                         |
- Stimulants                                    | 64.8  |                         |
- Benzodiazepines                               | 70.3  |                         |
- Combination of \(\geq 2\) of the above        | 80.2  |                         |
| History of illicit drug use: recent\(^\d\)\(^\d\)\)
- Marijuana                                    | 42\(^\d\)\) |                      |
- Stimulants                                    | 39.3  |                         |
- Benzodiazepines                               | 51.7  |                         |
- Combination of \(\geq 2\) of the above        | 46.6  |                         |

\(^\d\)Six individuals did not stabilize within the initial 9-month period; \(^\d\)Only data from those that stabilized within the initial 9-month period were considered; \(^\d\)Values do not sum to 100% due to poly-drug use; \(^\d\)In addition to opiates; \(^\d\)Values may be biased by purposeful sampling for cannabis use while in treatment.

### Cannabis Use: Pre-Treatment History and Use during Methadone Induction

Data on self-reported pre-treatment cannabis use was gathered from information recorded during the intake medical evaluation. Within the sample, 28.6% \((n = 26)\) individuals reported no history of cannabis use, past or recent (ie, 30 days prior to enrollment). While 31.9% \((n = 29)\) of subjects reported past but no recent cannabis use, almost 40% \((n = 36)\) reported past and recent cannabis use. During the 9-month study period, 38.5% were cannabis-abstinent \((n = 35)\), while 61.5% \((n = 56)\) used cannabis at least once.

Not surprisingly, when examining the relationship between pre-admission reports of marijuana use and urine results in the first 9 months of treatment, a strong positive effect was observed \((r = .736, p < .001)\). Evidence of ongoing cannabis use was also examined. Based on monthly UDS results during the first 9 months of enrollment, cannabis using individuals were classified as \textit{occasional users} (1–3 months cannabis-positive, \(n = 27\)) or \textit{frequent users} (>3 months cannabis, \(n = 29\)). There was a positive correlation between rates of cannabis use and illicit benzodiazepine use during the initial 9 months in treatment: \(r(91) = .374, p < .01\) (see Table 2).

### Role of Drug Use History and Proxy Measures of Addiction Severity in Cannabis Use

Opiate addiction history and severity of dependence at treatment intake was assessed via several proxy measures reported in the intake medical evaluation: years of opiate abuse, number of previous treatment episodes for opiate dependence (excluding Narcotics Anonymous), and daily opiate expenditure. The following analyses included data from all individuals in the sample providing complete information. In addition to having \(2.42 \pm 1.70\) \((n = 51)\) previous episodes in treatment, individuals had an average of \(15.68 \pm 10.71\) \((n = 71)\) year history of opiate abuse upon presentation to the clinic for treatment, and spent an average of \(\$108.00 \pm 65.00\) \((n = 49)\) per day on opiates.

To test the hypothesis that cannabis users may actually use less opiates and possibly constitute a unique subset of opiate-dependent individuals, analyses were performed to examine
whether pre-treatment cannabis use was associated with any of the proxy measures of opiate addiction severity. Neither years of opiate abuse nor number of previous treatment episodes differed based on history of recent cannabis use \( t(71) = .026, p = .796, \) and \( t(51) = 1.360, p = .178, \) respectively. Interestingly, decreased daily opiate expenditure spent on opiates (ie, pre-treatment opiate use) was associated with a history of recent cannabis use (Mn = $85.00) when compared to those with no recent cannabis use (Mn = $126.25) \( t(49) = 2.373, p = .022 \) (Fig. 1). These data indicate that cannabis users appear to spend less per day on the purchase of opiates, and may in turn use a lesser amount of opiates daily.

Subsequent analyses included daily opiate expenditure as a covariate in an attempt to control for variation based upon the amount of pre-treatment opiate use. For all subsequent analyses involving daily opiate expenditure (Mn = $107.65 ± 64.56, n = 51), imputation with the mean was performed in cases where this information was missing in patient records. To verify that this procedure did not alter the findings of associations with cannabis use, analyses were repeated using the imputed form of daily opiate expenditure (Mn = $107.65 ± 48.12, n = 91). A recent history of cannabis use was again associated with decreased daily opiate expenditure \( t(89) = 2.368, p = .020 \) (Fig. 1).

**Effect of Cannabis Use History on Methadone Induction**

ANOVA was next used to determine whether a history of cannabis use was associated with changes in rates of drug use during the methadone induction phase and early stabilization phase. Analyses first examined whether past cannabis use was associated with increased cannabis use during methadone induction or early stabilization. There was a significant interaction between treatment phase (methadone induction/early stabilization) and cannabis history on rates of cannabis use during treatment \( F(1, 80) = 14.669, p < .001 \). Those with a history of recent cannabis use decreased from an average of 75/38% cannabis-positive UDS during methadone induction to 49/38% during early stabilization. However, individuals with no recent cannabis use history increased from an average of 9/23% cannabis-positive UDS during induction to 13/28% during early stabilization. A parallel

<table>
<thead>
<tr>
<th>Cannabis use history</th>
<th>n</th>
<th>Percentage</th>
<th>Frequency of cannabis use in-treatment</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No lifetime/no recent</td>
<td>26</td>
<td>28.6</td>
<td>Abstinent</td>
<td>35</td>
<td>38.5</td>
</tr>
<tr>
<td>Yes lifetime/no recent</td>
<td>29</td>
<td>31.9</td>
<td>Occasional</td>
<td>27</td>
<td>29.7</td>
</tr>
<tr>
<td>Yes lifetime/yes recent</td>
<td>36</td>
<td>39.6</td>
<td>Heavy</td>
<td>29</td>
<td>31.9</td>
</tr>
</tbody>
</table>

**TABLE 2.** Patterns of cannabis use in the sample

<table>
<thead>
<tr>
<th>Cannabis use history</th>
<th>Change and SD</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals with lifetime cannabis history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone induction phase</td>
<td>48.8</td>
<td>(-11.2 ± 42.9%)</td>
</tr>
<tr>
<td>Early stabilization phase</td>
<td>37.6</td>
<td>(p = .055)</td>
</tr>
<tr>
<td>Individuals with recent cannabis history</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Methadone induction phase</td>
<td>74.6</td>
<td>(-25.3 ± 45.2%)</td>
</tr>
<tr>
<td>Early stabilization phase</td>
<td>49.3</td>
<td>(p = .003)</td>
</tr>
</tbody>
</table>

Correlations

| Cannabis use: prior to and during treatment | \(r(80) = .736\) | \(p < .001\) |
| Pre-stabilization cannabis use and unfavorable discharge status | \(r(80) = .069\) | \(p = .567\) |
| Pre-stabilization cannabis use and MMT attendance | \(r(65) = .151\) | \(p = .230\) |
| Rate of cannabis use and opiate use (during treatment) | \(r(82) = .018\) | \(p = .873\) |
| Cannabis use during treatment and age | \(r(91) = -.210\) | \(p = .047\) |
| Rate of cannabis use and daily opiate expenditure | \(r(49) = -.313\) | \(p = .028\) |

*Percentage of UDS that were positive for cannabis during the specified treatment phase. The cutoff for a cannabis-positive result was 50ng/ml.

whether pre-treatment cannabis use was associated with any of the proxy measures of opiate addiction severity. Neither years of opiate abuse nor number of previous treatment episodes differed based on history of recent cannabis use \( t(71) = .026, p = .796, \) and \( t(51) = 1.360, p = .178, \) respectively. Interestingly, decreased daily opiate expenditure spent on opiates (ie, pre-treatment opiate use) was associated with a history of recent cannabis use (Mn = $85.00) when compared to those with no recent cannabis use (Mn = $126.25) \( t(49) = 2.373, p = .022 \) (Fig. 1). These data indicate that cannabis users appear to spend less per day on the purchase of opiates, and may in turn use a lesser amount of opiates daily.

Subsequent analyses included daily opiate expenditure as a covariate in an attempt to control for variation based upon the amount of pre-treatment opiate use. For all subsequent analyses involving daily opiate expenditure (Mn = $107.65 ± 64.56, n = 51), imputation with the mean was performed in cases where this information was missing in patient records. To verify that this procedure did not alter the findings of associations with cannabis use, analyses were repeated using the imputed form of daily opiate expenditure (Mn = $107.65 ± 48.12, n = 91). A recent history of cannabis use was again associated with decreased daily opiate expenditure \( t(89) = 2.368, p = .020 \) (Fig. 1).
ANOVA controlling for daily opiate expenditure yielded similar results \[F(1, 79) = 12.973, p = .001\] (Fig. 2).

Analogous mixed-effects analyses crossing recent cannabis history and early MMT treatment phase (methadone induction/early stabilization) were then conducted employing opiate use as the outcome measure. Supportive of treatment efficacy, a main effect of treatment phase demonstrated that the rates of opiate use declined significantly between the induction and early stabilization phase \[F(1, 81) = 141.338, p < .001\]. To control for severity of pre-treatment opiate abuse, a repeated-measures ANCOVA was performed using daily opiate expenditure as the covariate, and a similar pattern of findings was observed \[F(1, 80) = 9.616, p = .003\]. Additionally, there was no significant interaction observed between treatment phase and cannabis history on in-treatment rates of opiate use \[F(1, 80) = .044, p = .835\].

In addition to rates of illicit drug use, the analyses also sought to uncover any potential associations between recent cannabis history and several other measures of stabilization difficulty such as time required to complete methadone dose titration (methadone induction), methadone blocking dose upon stabilization, and medication compliance. Cannabis use prior to treatment was not associated with any changes in the time required to complete methadone dose titration \[t(80) = .150, p = .881\], blocking dose \[t(79) = .847, p = .399\], or medication compliance \[t(63) = 1.212, p = .230\]. Furthermore, cannabis use did not significantly affect premature discharge status \[\chi^2(1) = 3.009, p = .222\] (Fig. 3).

### Preliminary Data on Cannabis and Opiate Withdrawal Severity
To examine whether cannabis intake during MMT treatment could be related to opiate withdrawal symptoms, associations

### Effects of Cannabis Use during Methadone Induction
To address potential detrimental effects of cannabis on MMT stabilization, in-treatment cannabis use was examined in several ways to reveal any potential associations with illicit opiate use or measures of stabilization difficulty. Rates of cannabis-positive UDS and opiate-positive UDS did not correlate during either phase of treatment [methadone induction: \(r(82) = .104, p = .332\); early stabilization: \(r(82) = .038, p = .734\)]. Dichotomized (yes/no) in-treatment cannabis use was not associated with change in opiate use during any treatment phase \[F(1, 81) = .999, p = .321\], and ANCOVA controlling for daily opiate expenditure yielded similar results \[F(1, 80) = .087, p = .769\]. cannabis use during methadone induction was not associated with any significant differences in time required for dose titration \[t(80) = .150, p = .881\], blocking dose \[t(79) = .847, p = .399\], or medication compliance \[t(63) = 1.212, p = .230\]. Furthermore, cannabis use did not significantly affect premature discharge status \[\chi^2(1) = 3.009, p = .222\] (Fig. 3).
between cannabis use and severity of opiate withdrawal were investigated using data from the clinical opiate withdrawal scale (COWS), an index designed to serve as an objective measure of opiate withdrawal. Effective in January of 2007, the COWS was added as an additional clinical assessment tool, administered in response to patients’ complaints of opiate withdrawal symptoms and craving. While induction COWS data were only available for a subset of the sample \((n = 40)\), when subjects were categorized as either low \((n = 29)\) or moderate withdrawal severity \((n = 11)\), a significant relationship with cannabis use was observed. Specifically, a 2 \(\times\) 2 contingency table revealed that cannabis users preferentially fell into the low-severity withdrawal category while those that abstained from cannabis were more often in the moderate-level withdrawal category \([X^2(1) = 7.54, p = .006]\). When further characterizing in-treatment cannabis users as abstinent, occasional, or frequent use, 3 \(\times\) 2 chi-square analysis demonstrated an inverse association between frequency of cannabis use and opiate withdrawal severity \([X^2(2) = 6.71, p = .035]\). Further prospective studies are needed to assess this effect in a more controlled manner (Fig. 3).

DISCUSSION

Association between Cannabis and Opiate Use in Treatment-Seeking Individuals

Cannabis-using opiate-dependent individuals presenting for MMT reported significantly less daily expenditure on acquisition of opiates. When considering this observation, note that the proxy measures of opiate addiction severity used in this study were selected based on available information in the patient record, and therefore lack the control of prospective assessment of addiction severity. Nonetheless, these findings highlighted a potentially interesting trend associated with concurrent cannabis and opiate use. A possible explanation for this finding may be that cannabis users in this study were less “severe” opiate addicts, or required lesser opiate intake. However, cannabis-using individuals did not differ from cannabis-abstinent individuals based on other proxy measures of severity of opiate dependence that included one’s cumulative years of opiate use and number of previous treatment episodes. Interaction between the molecular targets of opiates and cannabis in the brain may underlie the observation that those concurrently using both cannabis and opiates actually purchase and use less opiates. 

While cannabis users appeared to purchase (and presumably used) less opiates than cannabis-abstinent individuals at the time of program enrollment, rates of persistent illicit opiate use during MMT were not found to differ based on cannabis use. Data from this sample demonstrated no cannabis effects on dose titration, induction time, attendance, or unfavorable early discharge. These findings were in agreement with several previous studies concerning cannabis effects on MMT. In a large retrospective analysis of MMT, cannabis use was not associated with treatment retention, opiate/cocaine use, or any measure of treatment outcome. Similarly, no risk or harm to treatment outcome was associated with cannabis use in additional studies of patients on MMT or buprenorphine. Intermittent cannabis users were found to have improved retention and outcomes in antagonist treatment for opiate dependence. In a study examining post-discharge cannabis use following inpatient treatment, using cannabis was associated with relapse to alcohol and cocaine use, but not with relapse to heroin use. However, negative aspects of cannabis use on treatment for opiate dependence have also been reported. Several groups have demonstrated the association of cannabis use with likelihood of poly-drug use and increased risk for heroin relapse. Overall, studies of cannabis use on heroin intake in clinical populations did not support this trend. 

Decreased Cannabis Use upon Completion of Methadone Induction

Interestingly, upon acquisition of a blocking dose of methadone, there was a concurrent decline in cannabis use in the sample as a whole. Although this could possibly have been a direct effect of methadone, methadone dose was not found to be related to cannabis use rates in our sample. In a study comparing detection of substance use over the first year of heroin-maintenance and MMT, similar but less dramatic decreases in cannabis use were observed among methadone-maintained patients. Both heroin and methadone-maintenance resulted in dramatic reduction of illicit opiate use despite common cannabis use. Although our group has demonstrated the decline in multiple types of illicit drug use with long-term MMT in the past, the present findings were to our knowledge the first to specifically examine patterns of cannabis use over time during the critical early stages of MMT.

Potential Role for Cannabis in Reduction of Opiate Withdrawal

The transition from methadone induction to the early stabilization phase of treatment was expected to be accompanied by a decline in opiate craving and withdrawal. Decreases in the rate of cannabis-positive UDS were also observed during this transition, but it is unknown if this decline in cannabis use was related to diminished withdrawal symptoms, as clinical data regarding this phenomenon is limited. One group found that cannabis use was positively associated with lower plasma methadone concentrations, and while cannabis use could have caused metabolic changes that resulted in this finding, it is also possible that “cannabis use may be a compensatory response to opioid withdrawal symptoms in some individuals with more rapid methadone clearance.” In a study on the efficacy of non-opioid drugs for opiate withdrawal, cannabis was reported by patients to be less effective in reduction of symptoms than benzodiazepines, but more effective than cocaine, alcohol, and nicotine. There was a positive correlation between rates of cannabis and benzodiazepine use (based on monthly UDS results) in our sample. Further studies will be required to determine how the effects of...
benzodiazepine may interact with those of cannabis during methadone induction. However, numerous studies of cannabinoid–opioid interactions in animal models of opiate addiction have provided strong evidence for an ameliorative effect of cannabinoids on opiate withdrawal symptoms.30,34,51–54

The current study used objective measures (COWS and UDS) to examine this relationship in a pilot data set, where increased cannabis use was found to be associated with lower severity of withdrawal in a subset of the sample with available chart data. These results suggested a potential role for cannabis in the reduction of withdrawal severity during methadone induction, however prospective studies will be required to verify these initial findings.

Limitations and Prospective Studies

Due to the study design, the information gleaned from this retrospective chart analysis was descriptive in nature and interpretation of its findings must be cautiously considered. The challenges presented by the nature of the data included lessened control over inherent confounds in studies of drug use, and missing or limited chart information reduced the sample size for certain analyses. While UDS data provided an objective view of drug use during treatment, tests were required to be administered only once a month. Weekly quantitative drug screens detailing the specific amount of drug use would have been optimal and should be employed in prospective studies. Additionally, the study data on substance use history prior to treatment was limited to self-reported information present in the medical record. Optimally, more detailed objective analysis of pre-treatment substance use would be undertaken.

More extensive studies will be necessary to elucidate whether cannabis does indeed alleviate withdrawal signs during stabilization and whether it may be associated with treatment prognosis. Additionally, many individuals within this sample concurrently used cannabis and illicit benzodiazepines during MMT. Unfortunately, the nature of the data made it impossible to control for benzodiazepine use. Therefore, carefully controlled studies will be essential to determine whether concurrent use of cannabis and benzodiazepines during methadone induction results in additive, subtractive, or synergistic decreases in opiate withdrawal signs. Additionally, further studies will be necessary to examine the specific patterns and effects of cannabis use in individuals on other types of therapeutic interventions for opiate dependence, such as antagonist or buprenorphine treatment.

Although the retrospective data presents limitations, this approach offered the opportunity to uncover patterns of cannabinoid–opiate associations in the existing data, so that this information may be used to guide the design of future prospective studies. Poly-drug abuse is extremely common among opiate-dependent individuals, and use of multiple substances often persists during substance abuse treatment. By maintaining a particular focus on the stabilization process during initiation of MMT, it was possible to examine whether cannabis use affected progress during initiation on to MMT, a critical time point in the treatment for opiate dependence.

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Declaration of Interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

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Intermittent Marijuana Use Is Associated with Improved Retention in Naltrexone Treatment for Opiate-Dependence

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Division on Substance Abuse, Department of Psychiatry, Columbia University, New York State Psychiatric Institute, New York, New York

INTRODUCTION

Opioid dependence is a serious public health problem, with endemic opioid dependence having been joined over the past decade by a growing epidemic of prescription opioid dependence.1 Fortunately, effective treatments are available, but the majority of opioid dependent patients are not engaged in any treatment, while rates of dropout from treatment and relapse are high. Opioid substitution treatments, with methadone or buprenorphine, have consistent evidence of efficacy from multiple clinical trials, but even there rates of dropout and relapse are substantial.2 Dropout is usually associated with relapse. Treatment failure and ongoing opioid use have serious consequences, including morbidity and mortality from overdose and infectious diseases.3,4 Thus, factors that may improve retention deserve close scrutiny. Factors associated with better retention in methadone maintenance include demographic characteristics of patients, such as older age, being employed, being married, having effective social supports and good health.5,6 Importantly, features of methadone treatment programs are also associated with better outcome, including adequate methadone dosage, adequate counseling, presence of ancillary psychosocial services, emphasis on abstinence, and patient satisfaction.7–15

Naltrexone is a theoretically promising treatment for opioid dependence with a different mechanism of action, opioid antagonism, and potential advantages including lack of agonist effects or abuse potential. However, in practice the effectiveness of naltrexone has been severely limited by poor adherence. The ease with which naltrexone pills can be discontinued, the need for patients to be fully detoxified before starting naltrexone, and potential for precipitated withdrawal symptoms are likely contributing factors. Severity of opioid dependence and recent use of methadone have been associated with greater likelihood of dropout from naltrexone treatment.16 Coupling of naltrexone with enhanced behavioral interventions has been shown to improve retention, but dropout rates are still high.17–22
We previously reported a surprising finding that opioid dependent patients with intermittent cannabis use during naltrexone treatment showed better retention than patients with either heavy cannabis use, or no cannabis use, suggesting an inverted U-shaped function. This analysis was prompted by clinical observations that some opioid dependent patients on naltrexone reported benefit from cannabis use. However, this finding goes against conventional wisdom that other substance use during treatment would be associated with poor outcome, perhaps reflecting greater overall severity of addiction, or by functioning as a conditioned cue prompting return to opioid use. Other substance use is common among patients during treatment for opioid dependence, but studies of its impact on treatment outcome have been mixed. Interestingly, a number of studies have found the impact of concurrent cannabis use on outcome of treatment for opioid dependence to be neutral. One study found concurrent cannabis use associated with poorer psychosocial functioning, but not with dropout among naltrexone treated opioid dependent patients. A further study found concurrent cannabis use associated with poorer outcome for alcohol and cocaine dependence, but not for opioid dependence.

In this report, we sought to replicate the association between intermittent cannabis use and treatment retention in a different sample of opioid dependent patients undergoing naltrexone treatment, and to examine its impact on other outcomes. Since this was a randomized trial comparing intensive behavioral treatment, and to examine its impact on other outcomes. Since this was a randomized trial comparing intensive behavioral treatment (Behavioral Naltrexone Therapy, BNT) reported previously. One hundred and five patients that might confound an observed relationship between cannabis use and outcome. We also searched for demographic and clinical differences between patients under study in this report. As part of the screening procedure, potential participants were evaluated with the Structured Clinical Interview for DSM-III-R Substance Abuse Comorbidity version (SCID-I/SAC), and by a psychiatric, medical and laboratory examination. Patients were eligible if they met DSM-IV criteria for current opiate dependence, were seeking treatment voluntarily, and had an abstinent significant other who could commit to participate in the treatment. Exclusion criteria included any unstable medical or psychiatric disorder that could make participation hazardous. After giving consent, patients were detoxified in hospital for up to 10 days, and then entered outpatient naltrexone maintenance lasting six months. Following the detoxification, patients were randomly assigned to one of two therapies: BNT or compliance enhancement (CE). All patients received oral naltrexone, titrated up to a dose of 50 mg a day, encapsulated with riboflavin to estimate compliance by urine fluorescence.

**Psychosocial Therapy**

Behavioral Naltrexone Therapy, described in detail elsewhere, is a manual-guided intervention that combines evidence-based approaches, including Motivational Interviewing, Cognitive Behavioral Relapse Prevention, Voucher Incentives, and Network Therapy with a significant other monitoring medication-taking, and Compliance Enhancement is also a manual-guided intervention intended to control for professional attention, and to simulate standard medical management. It consists of two appointments per week, one with a psychiatrist for counseling and another for clinical monitoring. The counseling consists of psychoeducation, emphasis on compliance with daily naltrexone intake, problem-solving, and 12-step principles.

**Urine Collection and Analysis**

During the six months of the BNT trial urine samples were collected under supervision at each twice-weekly visit. All collected urine samples were tested for illicit opiates, cocaine, benzodiazepines, and cannabis using Abbott//MDTX and scored as positive or negative using standard NIDA cutoffs, and viewed under ultraviolet light for riboflavin fluorescence, a marker of compliance with naltrexone treatment.

**Data Analyses**

Participants in the study were divided into three groups, based on how the proportion of cannabis positive urines collected during the trial was distributed. The abstinent cluster demonstrated no cannabis positive urines during their treatment (0% cannabis positive). For the intermittent use cluster between 1% and 79% of their urine samples were positive for cannabis. The consistent use cluster showed greater than 80% cannabis positive urines. Differences among the Cannabis Use groups on baseline demographics, baseline drug use, and continuous treatment outcomes were tested with chi-square or ANOVAs.

Treatment retention was the primary outcome measure. Retention was defined as the numbers of days to dropout. Patients who relapsed (reverted back to opiate dependence) or did not attend the clinic at least once within a 14-day period were rated as treatment dropouts. The day on which the patient relapsed and was removed from the trial, or the 14th day of treatment absence was designated as the time of dropout. For those completing the trial, the 182nd day was the
Changes in Pattern of Cannabis Use Before vs. After Treatment Entry

The pattern of cannabis use before treatment entry was classified into abstinent, intermittent, or consistent use based on self-reported use frequency at baseline and was compared to the during-treatment pattern based on urine toxicology. Sixty percent of abstinent cannabis users at baseline remained abstinent, 31% became intermittent users, and 9% became consistent users during the trial. Thirty-three percent of intermittent users at baseline remained intermittent, 11% became abstinent, and 56% became consistent cannabis users. All consistent users at baseline remained so during the trial. These data are imprecise since serial urine toxicology data were not available pre-treatment, necessitating reliance on self-report to classify pre-treatment levels. Bearing that caveat in mind, the overall pattern was for patients to either remain at the same use level, or advance to a higher level of use.

Effect of Cannabis Use on Treatment Outcome

Treatment outcome for the three cannabis use groups is summarized in Table 2, and the survival curves describing treatment retention across the groups are displayed in Figure 1. Intermittent cannabis users demonstrated longer treatment retention (median = 133 days) relative to those who were either abstinent (median = 35 days), or consistent (median = 35 days) users in either BNT or CE groups (log rank = 12.2, df = 2, p = .002). Cocaine use increased in proportion to the level of cannabis use, while the cannabis use groups did not differ on measures of opiate or benzodiazepine use during the treatment program. The Cox proportional hazards regression model, summarized in Table 3, yields a significant main effect of intermittent cannabis use on treatment retention, consistent with the descriptive data and the unadjusted log-rank test. Results modeling cannabis use (% THC positive urine toxicology) as a continuous variable yielded similar findings, supporting an inverted U shaped association between cannabis use and retention. There were no significant effects of baseline opioid use or during-treatment cocaine use. The model also yields a significant interaction of cannabis use level with randomized treatment condition. The interaction is driven by the heavy cannabis use group where treatment retention was better in the BNT treatment condition compared to the CE condition (see Figure 2), such that intensive behavioral therapy (BNT) appears to mitigate the adverse prognostic effect in the heavy cannabis use group, but not in the cannabis abstinent group. Compliance with naltrexone, assessed by the proportion of urine samples with riboflavin fluorescence differed by level of cannabis use (F(2,60) = 3.4; p < 0.03): intermittent users (mean = 0.86, SD = 0.22), abstinent users (mean = 0.56, SD = 0.41), consistent users (mean = 0.69, SD = 0.39).

DISCUSSION

The present study replicates a previous surprising finding that intermittent cannabis use is associated with improved retention in naltrexone treatment among opioid dependent patients.
TABLE 1. Baseline demographic, drug use, treatment condition by cannabis use

<table>
<thead>
<tr>
<th>Variable</th>
<th>Abstinent (n = 24)</th>
<th>Intermittent (n = 18)</th>
<th>Consistent (n = 21)</th>
<th>Test statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>37.9 (9.23)</td>
<td>35.9 (13.4)</td>
<td>34.8 (9.4)</td>
<td>F(2,60) = 1.0; p &lt; .36</td>
</tr>
<tr>
<td>Female (%)</td>
<td>3 (12.5%)</td>
<td>6 (33.3%)</td>
<td>2 (9.5%)</td>
<td></td>
</tr>
<tr>
<td>Relationship (%)</td>
<td>7 (29.2%)</td>
<td>1 (5.6%)</td>
<td>4 (19.0%)</td>
<td>X^2(2) = 3.7; p &lt; .16</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>4 (16.7%)</td>
<td>1 (5.6%)</td>
<td>5 (23.8%)</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>7 (29.2%)</td>
<td>4 (22.2%)</td>
<td>8 (38.1%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>13 (54.2%)</td>
<td>13 (72.2%)</td>
<td>8 (38.1%)</td>
<td></td>
</tr>
<tr>
<td>Pretreatment Depression (HAM-D)</td>
<td>15.0 (7.3)</td>
<td>17.7 (6.8)</td>
<td>15.3 (9.8)</td>
<td></td>
</tr>
<tr>
<td>% with anxiety or depressive disorder DX</td>
<td>54% (n = 13)</td>
<td>44% (n = 8)</td>
<td>43% (n = 9)</td>
<td>X^2(2) = 4.5; p &lt; .109</td>
</tr>
<tr>
<td>% with antisocial PD DX</td>
<td>88% (n = 21)</td>
<td>94% (n = 17)</td>
<td>86% (n = 18)</td>
<td>X^2(2) = 0.82; p = .66</td>
</tr>
<tr>
<td>Administration Route</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IN</td>
<td>15(62.5%)</td>
<td>9 (50.0%)</td>
<td>15 (71.4%)</td>
<td>X^2(2) = 1.1; p &lt; .598</td>
</tr>
<tr>
<td>IV</td>
<td>9 (37.5%)</td>
<td>8 (44.4%)</td>
<td>6 (28.6%)</td>
<td></td>
</tr>
<tr>
<td>Smoke</td>
<td>0 (0.0%)</td>
<td>1 (5.6%)</td>
<td>0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>Tx Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BNT</td>
<td>11(45.8%)</td>
<td>8 (44.4%)</td>
<td>13 (61.9%)</td>
<td>X^2(2) = 1.6; p &lt; .46</td>
</tr>
<tr>
<td>CE</td>
<td>13(54.2%)</td>
<td>10 (55.6%)</td>
<td>8 (38.1%)</td>
<td></td>
</tr>
</tbody>
</table>

Note: Administration route was tested as IV versus other routes; Racial differences as Caucasian versus other.

patients, while both abstinence from cannabis and regular cannabis use during naltrexone treatment are associated with high dropout. Inspection of the retention curves (Figure 1) shows that most of this effect occurs during the first 30 days after completion of inpatient detoxification and induction onto naltrexone, when dropout is steepest, and when patients may continue to experience protracted withdrawal that may be promoted by antagonist or inverse agonist effects of naltrexone. Intermittent cannabis use was also associated with improved adherence to naltrexone pill-taking. The data comparing cannabis use levels before versus after treatment entry suggest patients either stay at the same level, or advance to a higher level of cannabis use after starting naltrexone, consistent with a process of self-medication. These findings are of interest, because they suggest the hypothesis that moderate cannabis use may be exerting a beneficial pharmacological

TABLE 2. Clinical outcome measures by cannabis use group

<table>
<thead>
<tr>
<th>Variable</th>
<th>Abstinent (n = 24)</th>
<th>Intermittent (n = 18)</th>
<th>Consistent (n = 21)</th>
<th>Test statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion of cocaine positive urines</td>
<td>.07 (.23)</td>
<td>.25 (.28)</td>
<td>.39 (.43)</td>
<td>F(2,60) = 5.2; p &lt; .009</td>
</tr>
<tr>
<td>Proportion of benzodia-zepine positive urines</td>
<td>.07 (.21)</td>
<td>.06 (.15)</td>
<td>.10 (.21)</td>
<td>F(2,60) = 0.2; p &lt; .85</td>
</tr>
<tr>
<td>Proportion of treatment weeks opiates were used</td>
<td>0.37 (0.39)</td>
<td>0.25 (0.31)</td>
<td>0.39 (0.42)</td>
<td>F(2,60) = 0.8; p &lt; .46</td>
</tr>
<tr>
<td>Median Days in treatment</td>
<td>35</td>
<td>133</td>
<td>35</td>
<td>Diff log rank = 12.2, df = 2, p = .002</td>
</tr>
</tbody>
</table>
effect improving the tolerability of naltrexone in the early weeks after induction, and that cannabinoid agonists might have promise for improving the effectiveness of naltrexone treatment for opioid dependence.

A beneficial effect of cannabinoid agonism early in the course of naltrexone treatment is biologically plausible. Rapid naltrexone induction during a 7 to 10 day hospitalization involves substantial withdrawal discomfort, which can be partially relieved by attenuating adrenergic activity with the alpha-2 autoreceptor agonist clonidine.47,48 During the early weeks after naltrexone induction, protracted withdrawal symptoms may persist, again likely driven in part by sympathetic nervous system activation.47,48 Data from a variety of preclinical models suggest that exogenous cannabinoids can attenuate sympathetic nervous activation, especially with intermittent rather than sustained administration.49–63 Thus, intermittent cannabis use might improve tolerability of naltrexone in the early weeks after induction by attenuating sympathetically driven withdrawal symptoms such as insomnia and agitation.

Cannabis also stimulates appetite and has antiemetic, anti-spasmodic and analgesic effects that have been clinically useful during cancer chemotherapy and wasting syndromes.64,65 This might be useful in helping relieve the gastrointestinal distress and other physical discomfort associated with opioid withdrawal.

Finally, cannabis might improve the tolerability of naltrexone maintenance by furnishing an indirect dopaminergic agonist effect at the brain reward system, countering the lethargy and anhedonia that are typical of opioid withdrawal and that might be worsened or prolonged by antagonist or inverse agonist effects of naltrexone. Naltrexone has not generally been associated with anhedonia among normal controls or alcohol dependent patients.66,67 However, preclinical evidence suggests naltrexone functions as an inverse agonist in the setting of prior exposure to mu agonists,44–46 as in opioid dependence. Cannabinoid (CB1) and mu opiate receptors are both G protein coupled receptors with overlapping neuroanatomical localization,68 and both CB1 and mu agonists stimulate dopamine release from the meso-limbic dopamine neurons and function as positive reinforcers. Thus, cannabis might compensate for a deficit in dopaminergic tone related to naltrexone.

The hypothesis of a beneficial pharmacological effect of cannabis for naltrexone maintenance would need to account for the inverted U-shaped function, namely that heavier cannabis use was associated with worse treatment retention than intermittent use. It may be that heavy cannabis use identifies a subgroup with greater overall addiction severity and worse prognosis that overwhelms any beneficial pharmacological effect of cannabis. This would be consistent with the significant association between cannabis use level and baseline level of opioid use (bags per day) (see Table 1), which has been shown to be a predictor of poor outcome for naltrexone maintenance.69 In prior analyses, the intensive behavioral

---

**TABLE 3.** Final Cox Regression Model testing the effect of marijuana use by treatment interaction on treatment retention

<table>
<thead>
<tr>
<th>Variables</th>
<th>B (SE)</th>
<th>Wald Chi-Square</th>
<th>Sig</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>−0.390 (.36)</td>
<td>1.17</td>
<td>0.761</td>
<td>0.68 (.33; 1.37)</td>
</tr>
<tr>
<td>Baseline opioid use (Bags per day)</td>
<td>0.045 (.05)</td>
<td>.83</td>
<td>0.30</td>
<td>1.05 (.95; 1.15)</td>
</tr>
<tr>
<td>Cocaine Use during treatment</td>
<td>0.030 (.50)</td>
<td>0.00</td>
<td>0.95</td>
<td>1.03 (.39; 2.72)</td>
</tr>
<tr>
<td>Intermittent cannabis use during-treatment</td>
<td>−1.46 (.46)</td>
<td>10.24</td>
<td>0.001</td>
<td>.23 (.09; .57)</td>
</tr>
<tr>
<td>Consistent cannabis use during treatment</td>
<td>0.351 (.54)</td>
<td>0.65</td>
<td>0.516</td>
<td>1.42 (.49; 4.1)</td>
</tr>
<tr>
<td>Treatment × Consistent Use</td>
<td>−1.32 (.65)</td>
<td>4.1</td>
<td>0.044</td>
<td>—</td>
</tr>
</tbody>
</table>
therapy (BNT) was shown to have its greatest beneficial effect among patients with the higher levels of opioid dependence (more bags per day) at baseline. Similarly here, the interaction of treatment assignment with level of cannabis use suggests that BNT partially counteracts the adverse prognosis in the heavy cannabis use group (Table 3, and Figure 2).

It is possible that regular or heavy cannabis use induces tolerance, perhaps through down regulation of CB1 receptors, diminishing any beneficial effects. The inverted U pattern might also reflect individual differences in sensitivity to the putative beneficial effect of cannabis. Since patients would be self-medicating, in effect adjusting their own dosages, those who are most responsive to the beneficial effects might select a modest dosage level sufficient to provide substantial relief, whereas those who are less responsive may advance to more regular or heavy use without sufficient response to impact retention.

The present findings are observational, and it is also possible that the association between intermittent cannabis use and improved retention on naltrexone is accounted for by unmeasured confounds or other mechanisms, rather than a causal pharmacological effect. Baseline level of heroin use (bags per day), the most consistent predictor of naltrexone treatment in our hands, was controlled for in the Cox model, suggesting severity of opioid dependence at baseline is not a confound. Another approach is to consider why patients without any concurrent cannabis use would have poor outcome. For example, it has been theorized that complete abstinence early in treatment may be stressful for patients who have long relied on substance use as a coping mechanism. It is also possible that the cannabis abstinent group differs in their response to cannabis, experiencing it as either not reinforcing or aversive, based on constitutional or neurobiological factors that also might be associated with poor response to naltrexone.

Experimental studies are needed to determine whether cannabinoid agonists may exert a beneficial effect on opioid withdrawal or naltrexone maintenance. Haney and colleagues examined the impact of naltrexone (versus placebo) on cannabis effects, finding that naltrexone at 50 mg, but not 12 mg, increased the intoxicating effects of cannabis in established smokers, while in participants without a history of cannabis use, 12 mg of naltrexone enhanced the effect of cannabis. Such a mechanism might explain the inverted-U pattern if naltrexone caused excessive and aversive cannabis effects among the heavy users. In any case, it suggests there may be meaningful pharmacological interactions between cannabinoid and opioid systems, and that these may be conditioned by the prior history of use.

Experimental, placebo-controlled studies are needed to directly examine whether cannabinoid agonists are effective as adjuncts to opioid detoxification or naltrexone maintenance treatment and to delineate the mechanism. Oral THC (Dronabinol) is FDA approved to counteract appetite suppression and wasting syndromes and would be available in the U.S. for study. Sativex, which includes both THC and cannabidiol, is available in Canada. Other cannabinoid agonists or partial agonists might be considered as they become available for study in the future. Small, within-subjects crossover studies in the human laboratory could examine effects of cannabinoid agonists on acute opioid withdrawal, or naloxone precipitated withdrawal. Larger placebo-controlled clinical trials should examine cannabinoid effects as adjuncts to opioid detoxification or naltrexone maintenance treatment. Success in these efforts could advance the field by improving the viability of naltrexone in the treatment armamentarium for opioid dependence. Issues regarding exposing patients to a medication with its own addictive potential would also need to be carefully addressed.

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The authors thank Dr. Mary Bonjiovi and her clinical staff for clinical support throughout this study. Gratitude is expressed to Lisa Sanfilippo for editorial assistance.
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CONCURRENT SUBSTANCE USE AND OUTCOME IN COMBINED BEHAVIORAL AND NALTREXONE THERAPY FOR OPIATE DEPENDENCE

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New York State Psychiatric Institute, Division of Substance Abuse, Substance Treatment and Research Service, and Columbia University, College of Physicians and Surgeons, Department of Psychiatry, New York, New York

ABSTRACT

The effect of concurrent nonopiate drug use on outcome of treatment for opiate dependence. Method: Forty-seven opiate-dependent patients received a 6-month course of outpatient treatment with naltrexone and cognitive-behavioral therapy (behavioral naltrexone therapy, BNT) at a university-based research clinic. Opiate-negative urines and naltrexone ingestion were rewarded with monetary vouchers. Abstinence from other drugs was encouraged verbally, but no contingencies were placed on nonopiate drug use. The proportions of all urines (collected twice weekly) positive for cocaine, cannabis, and benzodiazepines over the course of treat-

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ment were evaluated as predictors of outcome of opiate dependence treatment, as measured by proportion of opiate-positive urines, days retained in treatment, and proportion of naltrexone doses taken, using Pearson product moment correlations and one-way analysis of variance (ANOVA).

Results: The majority of patients (78%) used a nonopiate drug at least once during the trial. There were no significant correlations between concurrent drug use measures and opiate dependence treatment outcomes, indicating no simple linear relationship between these measures. However, when concurrent drug use was trichotomized into abstinent, intermittent, and heavy use groups, groups with intermittent use had superior outcome compared to both abstinent and heavy use groups in several contrasts. Conclusions: Intermittent use of non-opiate drugs is common during outpatient treatment for opiate dependence and may be a favorable prognostic indicator. This may support a ‘harm reduction’ approach as opposed to a strict abstinence-oriented approach. Further research is needed to identify the optimal therapeutic stance toward other drug use during treatment for opiate dependence.

INTRODUCTION

Polydrug abuse is common among treatment-seeking opiate-dependent patients. The most commonly abused substances within this population are marijuana, cocaine, and benzodiazepines (1, 2). Researchers exploring patterns of nonopiate drug use during methadone maintenance treatment have generally demonstrated a decrease in nonopiate substance use over time (3–5). Despite this reduction in concurrent drug use, there is frequent concern when patients are not completely abstinent from all substances during treatment (6, 7).

There are two main concerns associated with continued use of nonopiate substances. First, other drugs might function as substitutes in the absence of opiates, potentially leading to increased nonopiate drug use. Second, nonopiate drug use could lead to treatment failure, including premature dropout, total relapse to opiates, or both. The first concern, the possible substitution of other drugs for opiates, has not been supported by empirical findings from methadone-maintained populations as patients have been found to decrease their use of nonopiate substances over the course of treatment (2, 3). This paper addresses the effect of nonopiate drug use on treatment retention and outcome in a naltrexone maintenance program.

Clinical approaches to the treatment of concurrent nonopiate drug use in
opiate-dependent patients have varied widely. In the past, patients who consistently used illicit drugs while in methadone maintenance were often discharged from treatment. More recently, treatment programs continue to work with patients even when they are noncompliant due to the high risk of contracting human immunodeficiency virus (HIV) through intravenous substance use (8). Therefore, several interventions have been developed to address the problem of concurrent drug use, including contingency management and limit-setting approaches (9–11).

Contingency management and limit-setting techniques typically target a single substance rather than attempting to address all substances simultaneously. For example, in alcohol treatment programs, clinicians often recommend that patients do not attempt smoking cessation at the outset of treatment, and patients will receive vouchers or other reinforcement only for abstinence from alcohol. It is unclear whether this approach, which targets a single substance, is superior to one in which the contingencies are extended to reinforce abstinence from nicotine and other drugs as well. In part, this ambiguity is fueled by a lack of empirical evidence to clarify these issues. There is some data that indicate that complete abstinence is not always associated with the best outcomes (5, 12–14). However, other research has demonstrated mixed or negative results of concurrent substance use, including evidence that cocaine and benzodiazepine use may predict relapse to opiates, while marijuana does not (1), and evidence that benzodiazepine and cocaine use predict opiate use during treatment (e.g., 15, 16).

The effects of nonopiate drug use have been explored during opioid agonist treatment (e.g., methadone maintenance) (12), but not during opiate antagonist treatment (e.g., naltrexone maintenance). The purpose of this study was to examine the relationship of nonopiate drug use to outcome during treatment of opiate dependence in a naltrexone maintenance program. Outcome was defined as the number of days in treatment, level of compliance with naltrexone maintenance, and amount of opiate use during treatment.

METHOD

Participants

Forty-seven treatment-seeking opiate-dependent patients between the ages of 18 and 65 years were recruited through advertisements and word of mouth. After giving informed consent, participants were detoxified and entered into a 6-month outpatient naltrexone maintenance treatment program located in an urban university medical center. Participants were primarily male (77%), and Caucasian (64% Caucasian, 11% African-American, and 25% Latino), and their mean age
was 33.6 ± 9.3 years (range 20–54). The majority were employed (n = 32, 68%), and about a third were married (n = 17, 36%). All patients met DSM-IV criteria for opiate dependence. Route of administration varied, with 17 (37%) using heroin intravenously, 29 (63%) using heroin intranasally, and 1 patient using methadone exclusively.

Exclusion criteria included unstable medical conditions (e.g., active liver disease), psychosis, bipolar mood disorder, and significant suicidal or homicidal ideation.

**Procedures**

Participants entered a 24-week trial of behavioral naltrexone therapy (BNT) and naltrexone maintenance, the details of which have been described elsewhere (17). Briefly, this treatment integrates a manual-based voucher incentive program that rewards both naltrexone compliance and opiate abstinence with aspects of four different empirically validated psychosocial treatments: motivational enhancement therapy (MET), community reinforcement approach (CRA), network therapy (NT), and relapse prevention (RP). Each week, participants were required to attend one individual session and one session with a significant other trained to monitor naltrexone compliance. Two urine toxicology screenings were performed each week. Each patient was maintained on 50 mg of naltrexone per day. This medication was administered in the clinic for the first 2 weeks and was monitored by the patient’s significant other thereafter. In addition, patients earned $2 in vouchers for each opiate-free urine they provided and for each pill they ingested. Therefore, they were able to earn up to $672 in vouchers during the 6-month trial. Patients could exchange these vouchers for goods or services consistent with an opiate-free lifestyle (e.g., books, compact discs, and food).

No contingencies were placed on nonopiate drug use. Concurrent drug use was addressed during psychotherapy by providing a clinical rationale for the discontinuation of this behavior. Patients were encouraged to add abstinence from nonopiate drugs to their treatment goals. Patients who indicated a desire to decrease other drug use were taught to utilize the same strategies they used to decrease their opiate use.

**Data Analysis**

For each patient, the proportion of total urines collected over the total positive for cocaine, cannabis, and benzodiazepines was computed. These data were evaluated as predictors of opiate treatment outcome, which was measured by the proportion of urines positive for opiates, number of days retained in treatment,
and proportion of naltrexone doses taken. Linear associations between predictors and outcome measures were evaluated with Pearson product moment correlations. Further, the level of use for each nonopiate drug was trichotomized into abstinent, intermittent use, and heavy use groups, and outcome across these groups was contrasted with one-way analysis of variance (ANOVA).

RESULTS

Twenty-nine patients (71%) tested positive for opiates at least once during the trial. The mean percentage of opiate-positive urine samples was 43% (SD = 44%, range 0%–100%). Nonopiate drug use was common in this population: 21 (51%) tested positive for benzodiazepines, 21 (51%) tested positive for cocaine, and 28 (68%) tested positive for cannabis at least once. The mean percentages of positive urine tests for cocaine and benzodiazepines were 27% (SD = 36%) and 9% (SD = 24%), respectively; the mean percentage for cannabis was 47% (SD = 42%). Table 1 shows the correlation matrix of all the predictor and outcome measures.

As would be expected, the three principle treatment outcome measures (e.g., weeks in treatment, medication compliance, and opiate-positive urines) were highly intercorrelated. Percentages of urines positive for cocaine and benzodiazepines were also significantly correlated. However, there were no significant correlations between nonopiate drug use and any of the principal outcome measures.

Because the distributions of nonopiate substance use were not normal, the percentages of nonopiate-positive urines were trichotomized for each of the three drugs into abstinent, intermittent use, and heavy use groups. For cocaine and benzodiazepines, the percentages for the groups were abstinent 0%, intermittent use 1%–50%, and heavy use 51%–100%. For marijuana, the percentages for these categories were abstinent 0%, intermittent use 1%–99%, and heavy use 100%. Marijuana was coded differently from the other substances because it has the longest half-life and remains in the urine for approximately 1 month. Therefore, any patient obtaining a negative result for marijuana use had to abstain for at least a month, demonstrating intermittent use.

For each of the nonopiate drugs, an ANOVA was conducted to compare means of abstinent, intermittent, and heavy users on the outcome variables (see Table 2). Significant differences across groups were detected in treatment retention for both cocaine and benzodiazepine use. Post hoc comparisons demonstrated that intermittent users of cocaine and benzodiazepines remained in treatment longer than did participants who were abstinent from these substances. In addition, although the results were not significantly different, there was a trend for treatment retention for intermittent cocaine and benzodiazepine users to ex-
Table 1. Correlations Between Substance-Positive Urines (%) and Outcome Variables (n = 41)

<table>
<thead>
<tr>
<th>Concurrent Drug Use Variables</th>
<th>Outcome Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Cocaine-Positive Urines</td>
<td>No. of Days in Treatment</td>
</tr>
<tr>
<td>% Marijuana-Positive Urines</td>
<td>1.00</td>
</tr>
<tr>
<td>% Benzodiazepine-Positive Urines</td>
<td>.200</td>
</tr>
<tr>
<td>% Cocaine-positive urines</td>
<td>.312&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>% Marijuana-positive urines</td>
<td></td>
</tr>
<tr>
<td>% Benzodiazepine-positive urines</td>
<td></td>
</tr>
<tr>
<td>No. of days in treatment</td>
<td>- .054</td>
</tr>
<tr>
<td>% Heroin-positive urines</td>
<td>- .164</td>
</tr>
<tr>
<td>% Pill compliance</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>p < .05.
<sup>b</sup>p < .001.
### Table 2. Association Between Levels of Ancillary Drug Use Severity and Outcome of Treatment for Opiate Dependence

#### Level of Cocaine Use During Treatment

<table>
<thead>
<tr>
<th>Treatment Outcome</th>
<th>No Use ($N = 20$)</th>
<th>Intermittent Use ($N = 11$)</th>
<th>Heavy Use ($N = 10$)</th>
<th>$F$</th>
<th>df</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of days in treatment</td>
<td>44.4 ± 63.0</td>
<td>120.4 ± 64.8&lt;sup&gt;a&lt;/sup&gt;</td>
<td>59.6 ± 70.5</td>
<td>4.924</td>
<td>38</td>
<td>.013</td>
</tr>
<tr>
<td>% Heroin-positive urines</td>
<td>55.0 ± 46.7</td>
<td>30.1 ± 34.9</td>
<td>33.3 ± 46.4</td>
<td>1.459</td>
<td>38</td>
<td>.245</td>
</tr>
<tr>
<td>% Pill compliance</td>
<td>43.0 ± 46.7</td>
<td>68.8 ± 34.6</td>
<td>61.6 ± 41.5</td>
<td>1.487</td>
<td>38</td>
<td>.239</td>
</tr>
</tbody>
</table>

#### Level of Benzodiazepine Use During Treatment

<table>
<thead>
<tr>
<th>Treatment Outcome</th>
<th>No Use ($N = 30$)</th>
<th>Intermittent Use ($N = 9$)</th>
<th>Heavy Use ($N = 2$)</th>
<th>$F$</th>
<th>df</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of days in treatment</td>
<td>57.1 ± 64.5</td>
<td>120.1 ± 77.4&lt;sup&gt;a&lt;/sup&gt;</td>
<td>7.0 ± 0.0</td>
<td>3.994</td>
<td>38</td>
<td>.027</td>
</tr>
<tr>
<td>% Heroin-positive urines</td>
<td>46.9 ± 45.2</td>
<td>28.6 ± 38.7</td>
<td>50.0 ± 70.7</td>
<td>0.600</td>
<td>38</td>
<td>.554</td>
</tr>
<tr>
<td>% Pill compliance</td>
<td>48.4 ± 43.9</td>
<td>75.8 ± 32.0</td>
<td>50.0 ± 70.7</td>
<td>1.443</td>
<td>38</td>
<td>.249</td>
</tr>
</tbody>
</table>

#### Level of Marijuana Use During Treatment

<table>
<thead>
<tr>
<th>Treatment Outcome</th>
<th>No Use ($N = 13$)</th>
<th>Intermittent Use ($N = 18$)</th>
<th>Heavy Use ($N = 10$)</th>
<th>$F$</th>
<th>df</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of days in treatment</td>
<td>48.0 ± 57.1</td>
<td>92.7 ± 74.6</td>
<td>51.6 ± 75.5</td>
<td>1.932</td>
<td>38</td>
<td>.159</td>
</tr>
<tr>
<td>% Heroin-positive urines</td>
<td>60.0 ± 44.8</td>
<td>15.0 ± 25.7&lt;sup&gt;b&lt;/sup&gt;</td>
<td>71.4 ± 43.8</td>
<td>9.381</td>
<td>38</td>
<td>.000</td>
</tr>
<tr>
<td>% Pill compliance</td>
<td>32.8 ± 38.0</td>
<td>81.2 ± 32.5&lt;sup&gt;c&lt;/sup&gt;</td>
<td>34.6 ± 42.4</td>
<td>8.454</td>
<td>38</td>
<td>.001</td>
</tr>
</tbody>
</table>

Results of one-way analysis of variance. Values in this table are mean ± standard deviation of the treatment outcome measures.

<sup>a</sup> Intermittent use > no use, $p < .01$.

<sup>b</sup> Intermittent use < no use and heavy use, $p < .01$.

<sup>c</sup> Intermittent use > no use and heavy use, $p < .01$. 
ceed the retention rate for heavy users. Comparisons between abstinent and heavy use groups did not differ significantly.

For concomitant marijuana use, the groups differed on both percentage of heroin-positive urines and naltrexone compliance. Post hoc comparisons revealed that the percentage of positive opiate urines was significantly lower for intermittent marijuana users than for those who abstained and for heavy users. For medication compliance, intermittent marijuana users were significantly more compliant than abstainers. Again, although not significant, intermittent users tended to be more compliant than heavy users. There were no significant differences between the abstinent and heavy use groups.

DISCUSSION

The results of the current study generally replicate previous findings of high rates of polysubstance abuse in treatment-seeking opiate-dependent populations. The majority of patients (78%) used at least one illicit substance during the study, underscoring the necessity of understanding the effect of concurrent drug use on treatment outcome of opiate-dependent patients.

These data indicate that there is no straightforward relationship among marijuana, benzodiazepine, and cocaine use on the major indicators of outcome in a naltrexone-maintained population. Thus, use of any of these three substances was not associated in a linear fashion with treatment retention, medication compliance, or opiate use. However, when patients were grouped based on their level of use of each of these three different substances, intermittent substance use was associated with better overall outcome. Intermittent marijuana use was associated both with a reduction in opiate-positive urines and with increased medication compliance, while intermittent cocaine and benzodiazepine use were both associated with enhanced retention in treatment.

Although these findings may seem counterintuitive at first glance, there have been similar findings in the literature. For example, Budney and colleagues found no difference in outcome for methadone-maintained patients who smoked marijuana and those who abstained from marijuana (12). In addition, Shaffer and LaSalvia found that, during 1 year of methadone maintenance treatment (5), opiate use in the third month of treatment and benzodiazepine use during the seventh month of treatment predicted less drug use at the end of the year. Finally, Saxon et al. (18) and Nirenberg et al. (1) both failed to find an effect of marijuana use on opiate or other drug use in a methadone-maintained population. These data suggest that the relationship between treatment outcome and concurrent substance use may be complex.

There are several possible explanations for these findings. Past research (14) has indicated that both patients who immediately relinquish all substances
and patients who continue to abuse substances excessively throughout treatment may be less psychologically healthy than patients who occasionally use illicit substances to tolerate and continue in treatment. Khantzian (19) suggests that intermittent patterns of drug use may indicate that the patient is employing a self-medicating technique to tolerate difficult moments and crises during treatment that might otherwise be too stressful to withstand. In addition, it is possible that heavy use of substances indicates a total loss of control over use, while intermittent use of substances indicates an ability to utilize nonopiates as a coping mechanism in the struggle to abstain from opiates. In this case, abstainers may have worse outcomes than intermittent users because they do not possess the same coping skills (i.e., self-medication) that the intermittent users have.

In our treatment program, several patients have reported that they used marijuana or other substances in the early phases of treatment to cope with their opiate craving. Although nonchemical means of coping with craving were recommended, it may not be feasible for patients to learn new methods of coping with their difficulties instantly after detoxification. It is possible that opiate-dependent patients may use other substances as transitional coping mechanisms while blocked with naltrexone. Employing a risk reduction or "harm reduction" approach, although controversial, might allow patients time to participate in the psychosocial treatment and to learn new methods of coping with their craving. In addition, patients would have more time to increase the number of alternatively reinforcing experiences in their lives without the fear of becoming dependent again on opiates. Ellner (13) reported that baseline marijuana use was a predictor of retention in an outpatient narcotic rehabilitation center, and Grinspoon (20) actually proposed the use of marijuana in the treatment of opiate addiction. Although the use of marijuana as a treatment tool is not advocated, it is important to consider whether risk reduction techniques or abstinence-only models will retain patients longer and provide better results.

Recent findings have demonstrated similarities between the neurochemical effects of heroin and marijuana. Tanda and colleagues found that both marijuana and heroin increase dopamine transmission through the opioid receptor system in an animal model (21). In addition, this research group also determined that naloxone, an opiate antagonist similar to naltrexone, prevented the action of both marijuana and heroin on dopamine transmission. Marijuana was also found to have separate psychoactive effects that were mediated through the cannabinoid system and that were unaffected by naltrexone. In the present study, intermittent marijuana use was associated with increased naltrexone compliance and opiate-negative urines, while heavy marijuana use and abstinence from marijuana were associated with poorer outcomes. It is possible that the intermittent marijuana users were able to obtain a satisfactory self-medicating effect from the effect of the marijuana on the cannabinoid receptors, whereas the heavy marijuana users were unable to obtain a satisfactory effect without the addition of opiates, which
target the opiate receptors. Consequently, the heavy users may have discontinued naltrexone use and reinitiated opiate use to obtain a more complete self-medicating response. It is unclear what effect marijuana has on naltrexone-maintained humans; however, these findings underscore the importance of evaluating each illicit drug separately and in combination with treatment medications as illicit drugs and medications can have both unique and interacting effects that can influence treatment planning and outcome.

There are several important limitations of these findings. First, the data are correlational in nature. Future research could manipulate ancillary drug abuse in opiate addicts, for example, by attaching contingencies to abstinence from both opiates and other drug use for one group, while only linking contingencies to opiate abstinence for a second group. This type of controlled trial would aid in understanding how to manipulate contingencies to obtain the best treatment outcomes.

Second, sample size was modest, and group sizes were unequal, limiting power to detect relationships between opiate outcome and other substance use. Third, it is unclear if these results would generalize to samples with greater representation of female and non-white substance users. In addition, as this was an exploratory study, we chose not to control for experimentwise error rates. Thus, there is the possibility that the data include spurious findings, and it should be interpreted cautiously until the results are replicated.

Third, this study is restricted to simple measures of opiate treatment outcome. Future studies should include a broader range of outcomes, including ancillary outcomes that tap social functioning. Areas of focus should include assessments of the effect of concurrent use on health, legal issues, employment, and other important aspects of lives.

Fourth, longer follow-up periods should be explored to gather further information about how concurrent drug use both during and following treatment for opiate dependence influences long-term outcome. Attention to long-term outcome of both opiate and concurrent substance use is needed, especially as there is some evidence to suggest that therapeutic benefits from cognitive-behavioral treatments may increase during the 1-year period after treatment termination (22). As intermittent users spend significantly more time in treatment, it is therefore possible that this greater exposure to the psychosocial treatment could lead to enhanced outcomes over time, including reduction in all substance use. Follow-up data are needed to explore this possibility.

In conclusion, this study suggests that, for patients seeking naltrexone maintenance treatment for opiate dependence, concurrent drug use did not have a simple detrimental effect on opiate outcome. In fact, some evidence suggests a better outcome for intermittent use of cocaine, marijuana, and benzodiazepines. This may support a harm reduction approach to other drug use during naltrexone maintenance in which concurrent drug use is discouraged, but patients are not
dismissed from treatment for lapses to nonopiate drug use. More research is needed to identify the predictors of long-term outcome based on differing patterns of nonopiate drug use during opiate antagonist treatment.

ACKNOWLEDGMENT

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REFERENCES

Use and effects of cannabinoids in military veterans with posttraumatic stress disorder

KEVIN BETTHAUSER, JEFFREY PILZ, AND LAURA E. VOLLMER

Cannabis and its synthetic derivatives are commonly used around the world to treat a variety of disease states. However, controversy continues to surround cannabis and cannabinoid use as a primary or adjunctive therapy in the treatment of stress disorders. Conflicting results of published studies further blur the distinction between cannabis as a potentially beneficial alternative to conventional pharmacotherapy and behavioral therapies and cannabis as a substance that might worsen patient outcomes when used for self-medication. This article reviews published evidence regarding the use of cannabis to address symptoms of posttraumatic stress disorder (PTSD) among military veterans.

PTSD prevalence and pathophysiology

Prevalence. PTSD is defined as chronic activation of the stress response as a result of experiencing a traumatic event. It has been estimated that 60% of male and 50% of female persons will experience at least one traumatic experience in their lifetime, with a high rate of stress disorders in men caused by traumatic experiences associated with combat. In the United States, PTSD is diagnosed in approximately 5.2 million people annually, and these people suffer a wide range of symptoms. Individuals serving combat tours in the line of military service are particularly vulnerable to PTSD. According to the Department of Veterans Affairs (VA), 11–20% of veterans of Operations Iraqi Free-
Pathophysiology. The pathophysiology of these symptoms, while not fully understood, is thought to be related to increased sympathetic nervous system activity due to a traumatic experience compounded by changes in memory processing. Physical manifestations of PTSD are linked to increased levels of norepinephrine but also activity at α2-adrenergic receptors, which counteractively impede the release of neurotransmitters from adrenergic presynaptic neurons. Alteration in memory processing is hypothesized by several sources to be the cause of psychological reliving and continued response to triggering stimuli. In central processing of fear and anxiety processes as well as sympathomimetic stimulation, the amygdala and hypothalamic structures are thought to be key components of PTSD symptomatology, although their roles are not fully understood.

Cannabinoid pharmacology

Endogenous cannabinoid ligands, or endocannabinoids, exist naturally in the body to stimulate activity at cannabinoid receptors. Drugs delivering cannabinoid compounds also activate these receptors. Specifically, cannabinoid-1 (CB-1) and cannabinoid-2 (CB-2) G-coupled protein receptors are activated by cannabis compounds, leading to the production of secondary messengers that modulate the release of neurotransmitters from presynaptic sites through both excitatory and inhibitory actions. CB-1 receptors are diffusely distributed within the central nervous system, which helps to explain the wide range of effects seen with cannabinoid receptor activation; CB-1 receptors are the primary target for modification of PTSD symptoms. With cannabinoid use, pleasure is increased, while memory and concentration can be inhibited, due to the release of acetylcholine, norepinephrine, dopamine, serotonin, and glutamate neurotransmitters. CB-2 receptors are concentrated in the peripheral nervous system and elicit immunosuppressive and antiinflammatory responses when activated. Cannabinoids are highly lipophilic compounds that rapidly cross lipid membranes and the blood-brain barrier, leading to a fast onset of effect, especially when cannabinoids are inhaled. In murine models, it was demonstrated that correcting a deficiency of endogenous cannabinoids enabled mice subjected to traumatic shock treatments to overcome their conditioned response by allowing removal of the harmful stress-inducing memories through inhibition of γ-aminobutyric acid pathways in the amygdala. This mechanism is thought to explain human responses to cannabinoids as well.

Cannabinoid classification and legal status

Perhaps the most known connotation of the term cannabinoid to the layperson pertains to marijuana, which can deliver cannabinoids via respiratory, transdermal, and oral routes. Formally, marijuana refers to the unrefined leaves and flowers of *Cannabis sativa*, which contain over 460 active substances and no fewer than 60 cannabinoids. Delta-9-tetrahydrocannabinol (δ-9-THC) is the cannabinoid responsible for the majority of effects seen with marijuana use. The active compounds in marijuana produce the same activity in the messenger systems linked to cannabinoid receptors as those produced by endocannabinoids.
ingredients. Marijuana and select synthetic cannabinoids are classified by the Drug Enforcement Administration as Schedule I drugs under the Controlled Substances Act of 1970. This is largely due to the effects of Δ⁹-THC, which causes a “high” sensation and impaired cognition when inhaled or absorbed via the gastrointestinal tract. However, cannabinoids synthesized for specific disease therapies or available in other dosage forms, such as a hard-shell capsule, may be subject to other legal classifications. As of January 2014, 19 states and the District of Columbia allowed medicinal use of cannabis in select patients with certain disease states, most commonly seizure disorders and chronic pain. The addiction potential and stigma of marijuana use are important considerations, and the benefits of cannabinoid therapies for PTSD must be weighed against the associated adverse considerations, and the benefits of cannabinoid therapies for PTSD must be weighed against the associated adverse

The purpose of this review is to analyze current relevant literature surrounding the use of cannabis and cannabinoids for PTSD symptom control by military veterans, with the goal of providing insights on whether these treatments improve or worsen patient outcomes.

Methods and results of literature review

During the period February 10–October 1, 2014, a comprehensive literature search covering the period January 1, 1995, to October 1, 2014, was conducted using PubMed (MEDLINE) and Academic Search Complete (EBSCO Industries, Inc., Ipswich, MA). Both Medical Subject Headings (MeSH) terms and the subheadings feature of PubMed were used. Keywords were searched separately in combination with appropriate Boolean operators.

Keywords in searches included PTSD, post traumatic stress disorder, medical marijuana, cannabis, medical cannabis, marijuana, and combat veterans (appendix). For the purposes of this review, the term cannabinoid was considered to apply to endocannabinoids. On identification of articles that met the inclusion criteria, the references cited therein were analyzed for additional relevant articles not identified in the original keyword and MeSH term searches.

The article/study inclusion criteria that were applied to each item retrieved in the search were as follows:

- Reported outcome(s) related to the general use of cannabinoids among persons with a diagnosis of PTSD associated with military experience or the use of cannabinoids for the amelioration of PTSD symptoms associated with military experience
- Pertained to research in humans
- Was written in the English language
- Pertained to individuals with PTSD diagnosed via a standard scale (e.g., DSM-IV or DSM-5 criteria, Impact of Event Scale—Revised)

Editorials and opinion pieces were excluded from the review.

Each article identified for inclusion in the review was analyzed by the authors individually and collaboratively in order to determine its clinical relevance and relative standing in the realm of data supporting or mitigating against medicinal cannabis use for PTSD symptoms.

A total of 59 articles were identified through PubMed and the EBSCO database. Pursuant to application of the inclusion and exclusion criteria, 11 articles were included in this review. A variety of study designs were represented in the list of selected articles, and all evaluated research supported two general concepts: (1) many people suffering from PTSD use cannabis for symptom alleviation, and (2) some people find it of benefit in that regard.

Cannabinoids and coping mechanisms

Several studies supported the relationship between cannabinoid use and coping behavior, with usage tending to increase with PTSD symptom severity. Bonn-Miller et al. conducted a cross-sectional study that examined the relationship between PTSD symptom severity and motives for marijuana use among 103 young adult marijuana users who reported at least one traumatic event in their lifetime. The study concluded that symptom severity was significantly related to coping-oriented marijuana use motives. Furthermore, levels of post-traumatic stress were not related to other motives for marijuana use, providing evidence of “discriminant validity” (a construct aimed at showing that things that should not be related are, in fact, not related) and empirical evidence of coping motives for marijuana use.

In other research, Bonn-Miller and colleagues used a cross-sectional study design to examine the correlation between difficulty in emotional regulation and use of cannabis as a coping mechanism in patients who have experienced traumatic life events. The study surveyed a fairly homogeneous sample of adults who reported marijuana use within the previous 30 days. A multitude of surveys were used to determine marijuana use, the presence of PTSD symptoms, and each participant’s level of difficulty with emotional regulation. The investigators found that PTSD symptom severity and difficulty in emotional regulation were both significantly predictive of coping-oriented marijuana use. Furthermore, PTSD symptom severity predicted the degree of difficulty in emotional regulation even when the frequency of marijuana use was controlled.

Bonn-Miller et al. subsequently hypothesized that patients with PTSD using medical marijuana for sleep might increase their use in an attempt to cope with more severe symptoms. As in their previous research, the investigators chose a
Cannabinoids, worsening of PTSD symptoms, and substance abuse

Studies included in this review examined the possible link between cannabis use and worsening of PTSD symptoms or concomitant substance abuse. Bonn-Miller et al. used a prospective cohort study design to analyze cannabis use in relation to PTSD symptom severity in a population of 432 male military veterans (mean ± S.D. age, 51 ± 4 years) admitted to a VA residential treatment program for patients with PTSD. Cannabis use four months after the completion of the rehabilitation program was significantly more likely in program participants with lower levels of improvement from intake to discharge in PCL-M scores for avoidance–numbing and hyperarousal symptom clusters (p < 0.05). The researchers concluded that lower improvement in PCL-M scores at program completion was significantly predictive of an increased risk of cannabis use within the four months after discharge.

Although this study lacked generalizability (i.e., it involved only patients seen in a VA residential rehabilitation program), it suggested that specific symptoms have more influence than others on PTSD patients’ desire to use cannabis. A major limitation of this study was that patients in the rehabilitation program were required to quit marijuana use for the duration of their treatment, but the effect of cannabinoid withdrawal was not included in the analysis. Furthermore, the study involved a nonrandomized sample, raising the possibilities of high subjectivity and bias.

Bremner et al. conducted a similar cross-sectional study of Vietnam War military veterans (n = 61) in the northeastern United States. This study aimed to measure the progression of some PTSD symptoms and related alcohol and substance abuse symptoms, as well as the effects of abused substances on those PTSD symptoms. The researchers found that PTSD symptoms were increased among veterans using substances such as alcohol, heroin, cocaine, and marijuana. Further, the study showed that veterans using said substances reported benefits with regard to PTSD symptoms.

Cannabinoids and reduction of PTSD symptoms

Research also has examined the reduction of PTSD symptom severity after treatment with cannabis products. A study by Mashiah examined the use of medical cannabis in Israeli military veterans (n = 29) with diagnosed chronic PTSD. Study participants were given no more than 100 g of cannabis per month and instructed to smoke the cannabis daily at frequencies and amounts of their own choosing. Patients were reassessed three times throughout one year by their psychiatrists. At each reassessment, the study found that the average total Clinician-Administered PTSD Scale (CAPS) score was reduced relative to previously assessed and baseline scores. However, all patients still met the criteria for moderate-to-severe PTSD. This report did not describe the baseline cannabis-use characteristics of the evaluated patients. Additionally, only 10 participants were reassessed after the second follow-up, with no explanation provided by the study author.

Greer et al. performed a chart review–based study of 80 patients with PTSD participating in New Mexico’s Medical Cannabis Program. The total CAPS score and CAPS symptom-cluster scores for reexperiencing, avoidance–numbing, and hyperarousal symptoms were significantly reduced (p < 0.0001) when patients were using cannabis relative to scores obtained under the no-cannabis condition. Overall, patients reported more than 75% reductions in all three areas of PTSD symptoms while using cannabis. It should be noted that participants in this study had already found cannabis to reduce their PTSD symptoms and, partly for that reason, sought entry into the cannabis program (they also sought to avoid criminal penalties for marijuana possession); as a result, they might have been predisposed to report reduced symptoms. Further, it is possible that subjects exaggerated their PTSD symptoms during initial CAPS assessment in hopes of qualifying for the program. While this study
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how-common-is-ptsd.asp (accessed 2013 Feb 20).

Appendix—Keyword strings used in literature search
(medical marijuana OR medical cannabis OR marijuana OR cannabis) AND PTSD
medical marijuana AND PTSD
medical cannabis AND PTSD
marijuana AND PTSD
cannabis AND PTSD
medical marijuana AND PTSD NOT depression
medical marijuana AND combat veterans
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cannabis AND combat veterans
x is a non-profit organization representing over 150 providers of healthcare and other supports including prevention, treatment, and recovery services for individuals with mental or substance use disorders and for their family members. We are grateful for the thoughtful work that is reflected in these draft rules and believe that they go a long way in establishing conditions that promote the health and safety of all Ohioans. To further this goal and to make the practice of recommending medical marijuana consistent with that of prescribed medications in Ohio, the Ohio Council recommends the following changes to the proposed rules for the regulation of medical marijuana through the State Medical Board of Ohio.

DISCUSSION and RATIONALE:

Research indicates that for some people, a combination of risk factors including biological and environmental conditions create the opportunity for the development of substance use disorders when exposed to drugs, including marijuana. For example, the National Institute on Drug Abuse documents that “a study using longitudinal data from the National Epidemiological Study of Alcohol Use and Related Disorders found that adults who reported marijuana use during the first wave of the survey were more likely than non-users to develop an alcohol use disorder within 3 years; marijuana users who already had an alcohol use disorder at the outset were at greater risk of their alcohol use disorder worsening. Marijuana use is also linked to other substance use disorders including nicotine addiction.”

It is also important for us to take into account the research on conditions that create increased risk for the development of substance use disorders and to reflect such science in Ohio’s policies and practices. For example, Ohio did this in 2014 when we passed a law that increased the informed consent requirements for the prescribing of opioids to minors so that parents would have a better opportunity to understand the risk of consuming medications that research indicates can lead to substance abuse, dependency, or addiction.

Sometimes marijuana can be a gateway drug for adolescents and teens, particularly those with conditions identified as connected to early onset of substance use and dependency and addiction later in life. For example, there is a significant body of research that indicates a link between substance use disorders and conditions such as ADHD, anxiety, depression, impulsivity disorder, and childhood trauma. A study published in the Journal of the American Academy of Child & Adolescent Psychiatry [March...
2013 Volume 52, Issue 3, Pages 250–263 documented that teenagers with attention deficit hyperactivity disorder (ADHD) are significantly more likely to have substance abuse issues and to smoke cigarettes, compared with their peers without a history of the disorder. The authors of the research noted the important finding that substance abuse rates were the same in teenagers still taking ADHD medication and in those no longer on medication. They noted that these results suggest a need to identify alternative approaches to substance abuse prevention and treatment for boys and girls with ADHD.

While we recognize that marijuana use is not always interconnected with substance use disorders, it is prudent for those physicians responsible for recommending the medical use of marijuana to be regularly trained in contemporary information and skills needed to identify a person for whom medical marijuana may not be a good option or for a patient who may move from therapeutic to unhealthy or dangerous use of marijuana alone or in combination with other mood-altering substances. It is also wise for us to increase opportunities for parental education on the potential risks of a child under the age of 18 taking medical marijuana. This can only improve the opportunity for parents to make a fully informed choice in the physical and behavioral healthcare of their children. Informed consent is a bedrock in patient care and one that Ohio must prioritize in the recommendation of medical marijuana to minors. Finally, we urge the use of science when considering the addition of qualifying conditions, and we ask that a process be created to remove qualifying conditions should research reach consensus that marijuana is ineffective in the treatment of that condition.

With this research in mind, we make the following recommendations to promote quality medical care that optimizes the health and safety of patients in Ohio, particularly minors.

RECOMMENDATIONS:

1. **4731-32-02(A)(7):** Increase the two hours of continuing medical education requirements to a total of three (3) hours by requiring one hour (1) of education on the signs of diversion, symptoms of substance use disorders including cannabis use disorder, techniques for substance use disorder screening, and strategies for intervention and referral identified in 4731-32-02 (A) (7) (a) and (b).

2. **4731-32-03 (C) (5):** Expand this section on informed consent requirements for recommending medical use of marijuana for minors to reflect those consent requirements for prescribing opioids to minors as found in Sec. 3719.061 of the Ohio Revised Code, including:

   - As part of the prescriber’s examination of the minor, assess whether the minor has ever suffered, or is currently suffering, from mental health or substance abuse disorders or other conditions identified in research as risk factors for the development of a substance use disorder;
   - Provide written educational materials and discuss with the minor and the minor’s parent, guardian, or another adult authorized to consent to the minor’s medical treatment all of the following:
     - The risks of substance use disorders associated with marijuana use; and
     - The increased risk of addiction to controlled substances of individuals suffering from both mental and substance abuse disorders.
4731-32-03 (E): Expand this section to include the requirement that in addition to determining the efficacy of the medical marijuana, the follow up care provided by the physician who recommends marijuana for medical use shall include screening and assessment for substance use disorders including cannabis use disorder as defined by the ICD-10 or its successor.

4731-32-05 (C) (6): Expand this section on the requirements to request additional qualifying disorders to include evidence of the benefits and risks of using medical marijuana for the treatment of the proposed qualifying condition, including any factors related to the benefits and risks for specific populations or co-occurring conditions that may be identified as at-risk for the development of substance use disorders.

We also recommend that 4731-32-05 create a mechanism for removing a qualified disorder should research emerge that documents the use of marijuana is not productive in or is counter-indicated for people with that disorder or condition.

Thank you for this opportunity to comment on the draft rules.
Public input from the Marijuana Policy Project  
— Proposed Physician Regulations —  
January 13, 2017

These comments are submitted in response to the State Medical Board of Ohio’s proposed rules regulating physicians in the medical marijuana program. We wish to thank the board and staff for their efforts in support of an effective and well-regulated program, which is to the benefit of all Ohioans.

Many areas touched on by medical marijuana regulations can be complicated by differences between federal and state laws and policies. One area that requires special consideration is the regulation of physicians who participate in medical marijuana programs. We believe that the imposition of a few of the requirements in the proposed rules could lead to significant, if unintended, consequences that could place doctors — and thus the viability of the entire program — at risk.

Specifically, the requirements found in §4731-32-03(D)(2)(f) and possibly (e) should be reconsidered. We believe that the physician cannot safely be required to provide instructions for medical marijuana use to patients due to federal law. Similarly, the physician must not be required to determine what the 90-day supply amount should be for a patient, if such a determination is implicit in subsection (e). Even though the proposed rules do not mention the term prescription, specifying instructions for consumption for a patient — or specifying an amount to take over a period of time — could be considered aiding and abetting a federal crime (distribution of marijuana) and could therefore result in doctors’ non-participation in the program.

Background
Under the authority of the Controlled Substance Act (“CSA”), the Drug Enforcement Administration issues registration numbers to qualifying doctors who are then permitted to authorize the use of Schedule II, III, IV, and V controlled substances. Doctors may not issue prescriptions for Schedule I substances. Cannabis in nearly every form is classified as a Schedule I drug and therefore may not be prescribed. A physician who violates the provisions of the CSA may have his or her DEA registration revoked, leaving that physician unable to prescribe controlled substances. In addition, it is a criminal offense for a doctor to aid or abet the purchase, cultivation, or possession of cannabis, or to engage in a conspiracy to cultivate, distribute, or possess cannabis.

1 21 U.S. Code § 829.  
Concerns surrounding doctors potentially prescribing medical marijuana surfaced in California as voters were considering the country’s first medical marijuana law in 1996. During that period, federal law enforcement officials sent letters threatening doctors with prosecution for those who might issue a “recommendation” for the use of medical marijuana, claiming that it was tantamount to a prescription, even if the term was not used. In response, a lawsuit was filed on behalf of physicians who had received the letters, seeking clarification under the law. The result was the Conant decision, which offers a roadmap to lawmakers and regulators for guidance in this area of the law — and which found a doctor’s “recommendation” is protected by the First Amendment, but other conduct could still be penalized.

Prescriptions are legally authorized and operative orders. Among other things, they include specific instructions to take the prescribed medicine or treatment; an authorization in the form of a signature; along with instructions telling the patient when and how to take the medicine, and in what quantities. Even the plaintiffs in Conant acknowledged that prescriptions for medical marijuana, which authorize the distribution of that substance to the patient through a third party — a pharmacy, would be illegal.

In Conant, the Ninth Circuit found that “recommending” the use of cannabis for medical purposes is permitted, so long as it did not cross into aiding and abetting. An integral component of the practice of medicine is the communication between a doctor and a patient. Physicians must be able to speak frankly and openly to patients, and such speech strikes at the fundamental interests behind the adoption of the First Amendment.

Avoiding possible conflict
To be sure, the term “prescription” is used nowhere in the current medical marijuana law, nor in the rules proposed by the board. However, the issue raised by the DEA in Conant — and by the Conant court itself — looked to the activities that underpinned prescriptions, not simply the term. The clear implication is that a doctor can run afoul of federal law by engaging in activities that are similar in effect to a prescription, even if the term prescription is not used.

The Conant decision found that “a doctor would aid and abet by acting with the specific intent to provide a patient with the means to acquire marijuana.” As a result, the California Medical Association’s legal staff and other legal experts have advised doctors not to specify dosage or modes of administering cannabis, because it could be inferred from that activity that the doctor has the specific intent that the patient use the recommendation to obtain cannabis.

In addition to the actual risk to physicians — potential prosecution or the revocation of their DEA registration — Ohio’s medical cannabis program itself may be at risk if this language is not removed. Physicians are often already wary of participating in medical marijuana programs due to concerns about federal law. If they are required to engage in federally risky conduct, the rate of physician participation could be catastrophically low, threatening the program’s viability.

Avoid paperwork overload
The rules proposed by the board contain a great deal of information which must be documented in every client file. While the information itself is reasonable, the requirement that it be documented and included for every patient in every instance seems excessive. Our primary concern is that doctors should be not discouraged from helping patients because requirements are so burdensome that family physicians and other doctors would simply prefer to avoid recommendations. Rules related to medical cannabis should be consistent with standards in other areas of medical practice whenever possible. If the requirements here are beyond those expected of physicians in other, comparable areas, the board should reduce the paperwork burden on state doctors.

Conclusion
In reviewing the proposed rules, we believe a requirement that doctors provide patient instructions, and particularly any requirement that a doctor determine the adequate amount of medical marijuana a patient should consume over a period of time, should be removed. Accordingly, §4731-32-03(D)(2)(f) and possibly (e), should be stricken or amended. In addition, while doctors should be aware of critical pieces of information in the course of making recommendations, requirements that physicians document information simply for documentation’s sake should be minimized.

Sincerely,
Dear Medical Board members,

Thank you for taking the considerable time necessary to construct this comprehensive guideline for Physicians to become certified to recommend Medical Marijuana. As a parent of a child with several debilitating disorders that show promise of improvement with the opportunity to trial medical cannabis, our family anxiously awaits the start of this program.

We would like to provide comment on OSMB Proposed Rule 4731-32-03 Standard of Care, Section B, Item 7 which requires the Physician to include ‘Documented review that standard medical treatment has been attempted or considered and one of the following is met:
(a). The patient had inadequate treatment response to standard medical treatment
(b). The patient was unable to tolerate the standard medical treatment
(c). Standard medical approaches are not appropriate in this patient for other documented reasons.’

Due to our son’s complicated medical needs, we are forced to continuously weigh the risks associated with many of his prescribed medications, and this effort often takes not days, not weeks, but months/years before we understand if 1). the medication is effective 2). he is at the proper therapeutic dose and 3). what the long term negative effects will be (which we have discovered, unfortunately, to be far greater than we were told to expect when he began these medications at age 8). This rule suggests that cannabis cannot be used as a first-line medication, but instead is recommended as a last resort. It is known and validated that the toxicity levels of many pharmaceuticals is substantially higher than cannabis. Patients should not be expected to first trial and fail the use of opiates, barbiturates, benzodiazepines or atypical antipsychotics before a medical cannabis recommendation is allowed. Currently, in pain clinics there is a statement required by physicians to disclose to patients that there is “no exit” off of narcotic therapy for chronic pain treatment. Narcotics, which are highly addictive, can instigate severe, sometimes life threatening withdrawal symptoms. There is substantiated evidence that Medical marijuana does not run these same risks. It feels morally abhorrent to place regulations that require a physician to exhaust narcotic options before recommending medical marijuana to their patients. Patients should be afforded the right to trial cannabis therapy as a first option, or at the very least as an immediate option in conjunction with ‘standard medical treatment’.

A second concern involves the same Proposed Rule, section (H): The physician shall submit to the board an annual report describing the physician’s observations regarding the effectiveness of medical marijuana in treating patients:
While we are very encouraged and dedicated to the need for data to be collected and reported regarding the use of medical cannabis, we are concerned that if left as vague, Physicians will face an undue burden in determining what is appropriate to submit. Our request would be that a specific form/report is provided to ensure recommending Physicians have reasonable guidelines to follow, so as to ensure they are not risking loss of certificate for providing inadequate or insufficient information.
And finally, regarding 4731-32-05 Petition to Request Additional Qualifying Condition or Disease, any petition for a condition that has been previously reviewed by the board and rejected will not be considered by the board unless new scientific research that supports the request is offered:

We sincerely hope there will be flexibility and acknowledgment that anecdotal evidence which strongly supports successful cannabis use will be considered for conditions previously rejected. We believe a statement by Ohio Families Cann captures our viewpoints most appropriately:

“While we support and hope for continued advances that point to the scientific evidence of the effectiveness of cannabis therapy, historical context suggests that scientific work may not be rapidly forthcoming. Federal barriers to research, though moving in the right direction, signify that significant barriers to the epitome of research still exist.

In addition to scientific data, our fellow Ohioans with loved ones on the Autism Spectrum, with Tourette’s syndrome, anxiety and depression, for example, deserve the right for policy changes at state and federal levels to positively impact greater treatment options.”

Thank you so much for your time, attention, and consideration to these critical recommendations that could make a difference between an inaccessible, impossible program for patients and doctors to reasonably implement and a successful Medical Marijuana program in our great state of Ohio.
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January 13, 2017

Medical Marijuana Advisory Committee

Delivered Via Email to: medicalmarijuana@med.ohio.gov

Re: Comments on Physician Certificate to Recommend Medical Marijuana and Petition for Added Qualifying Condition Draft Rules OAC 4731-32-01 through OAC 4731-32-05

Dear Members of the Medical Marijuana Advisory Committee,

On behalf of over 15,000 Ohio physicians, residents and medical students, we are providing our comments on Ohio Administrative Code Draft Rules 4731-32-01 through 4731-32-05.

OSMA appreciates the opportunity to provide comments on the medical board’s initial draft of the provider medical marijuana rules. While largely supportive of the rules, the OSMA is offering the following comments:

**Ohio Administrative Code Draft Rule 4731-32-03, Standard of Care**

**Section B(3)**

OSMA suggests adding the following change as indicated in CAPS/bold:

(3) Documented assessment of the patient’s medical history, including **RELEVANT** prescription history and any history of substance use disorder;

**Section B(9)**

OSMA suggests adding the following change as indicated in CAPS/bold:

(9) The physician’s performance of a physical examination, **OR REVIEW OF A RECENT PHYSICAL EXAMINATION**, relevant to the patient’s current medical condition;
Section D(2)(c)

In an effort to discourage fraud and misuse of physician credentials, physicians are often advised to avoid adding medical license numbers and Drug Enforcement Administration (DEA) numbers on documents unless they are absolutely necessary. It is unnecessary to include the physician’s license number and DEA number on the patient’s medical marijuana recommendation. A physician who issues a recommendation would have already provided that information to the medical board to obtain his or her Certificate to Recommend. Therefore, only the physician's Certificate to Recommend number should be needed on the recommendation.

Ohio Administrative Code Draft Rule 4731-32-05, Petition to Request Additional Qualifying Condition or Disease

Section C (5)

As written, this section implies that the petitioner must provide evidence that conventional medical therapies are insufficient to treat or alleviate the disease or condition. Ohio Revised Code 4371.302 (B)(3) states that, when submitting a petition to add a qualifying disease or condition, the petitioner shall “consider whether conventional medical therapies are insufficient to treat or alleviate the disease or condition”. Therefore, in keeping with the statutory intent, the OSMA recommends the following change as indicated in CAPS/bold/strikeout:

(5) Evidence that CONSIDERATION OF WHETHER conventional medical therapies are insufficient to treat or alleviate the disease or condition;

x appreciates the opportunity to comment on the rules. If you have any questions,
To the State Medical Board of Ohio,

Hello,

I am Deb Chany, executive director of Sylvania Community Action Team in Sylvania, Ohio. We are a community coalition that has served as the voice of prevention since 1985. Our mission is to prevent at-risk youth behavior including drug and alcohol use and to provide support for positive youth, family and community development.

In reviewing the proposed physicians’ rules in regards to the passage of “medical marijuana” our concerns continue to raise red flags as the minimal requirements for the proposed physician rules have been shared. We have learned so much about the importance of protecting the unique process of “brain development up until the age of 25” and the impact of the interruption of this process with substances such as marijuana, alcohol etc. The physicians’ requirement to receive the license to recommend marijuana, should include studies and research that share this information. The brain is the target organ for any substance use/abuse. It is the responsibility of all health professionals to “do no harm”. This need to be taken into consideration. The minimal requirement for a physician to receive the license should be no less than 8 hours with a 4 hour recertification requirement.

In reference to the proposed physician rules regarding medical marijuana in Ohio, I ask that the State Medical Board of Ohio require a sufficient amount of education to physicians seeking to recommend marijuana or renew their license. At present, only two hours of education are identified in the proposed rules. This is insufficient for doctors to truly learn about the risks associated with marijuana. In order for a physician to recommend marijuana or apply for renewal, I ask that the number of required continuing medical education hours be increased to a total of eight hours. Those CME hours should include training on addiction, substance misuse prevention, and the mental and physical health risks associated with marijuana. Renewal requirements will help doctors stay informed as further studies are conducted on its effects on patients.

“Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study,” published in The Lancet Psychiatry in 2015, found a disturbing link between higher frequency use of high-potency marijuana and an increased risk of psychosis.

“Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015,” published in the Journal of the American Medical Association Pediatrics in 2016, found that marijuana poisonings of young children, many of them toddlers, have almost doubled at one hospital since Colorado began its legalization program. The study also suggested that legalization increased the rate of these exposures.

“Effect of Marijuana Use in Pregnancy on Fetal Growth,” published in 1986 by the American Journal of Epidemiology found that use of marijuana during pregnancy correlated with a significant decrease in birth weight and number of pre-term births in white women. More recently, “Birth outcomes associated with cannabis use before and during pregnancy” published in 2012 by Pediatric Research found an increase in the occurrence of low birth weights and faced a number of other adverse birth outcomes compared to babies born to mother who did not use marijuana. The latter study even adjusted for confounding factors found in the women who reported to be marijuana users but found that it did not materially change the findings.

The above research demonstrates that the potential negative health effects of marijuana are still being researched. For doctors to do more good than harm, they must remain up to date on marijuana research. Increasing the number of CME hours doctors who recommend marijuana must attend will help foster that education.
I also ask that doctors be required to recommend dosage and strength when they recommend marijuana, just like they do with any other medicine, and I ask that pregnant women not be allowed to receive a recommendation for medical marijuana due to the risks to fetuses.

Doctors should not be allowed to advertise that they will or can recommend marijuana. Instead, it should come up during regular patient-doctor interactions. Prohibiting advertising will prevent youth exposure and help ensure that this program remains concerned about patient health and safety rather than profit and greed.
To the State of Ohio Board of Pharmacy,

[Introduce yourself, your community role or affiliation, and the nature of your interest.]

In reference to the proposed dispensary rules regarding medical marijuana in Ohio, I ask that the State of Ohio Board of Pharmacy prohibit advertising in order to protect communities, patients, and children.

Countless studies have shown that tobacco advertising, for instance, exposes youth and ultimately causes youth to take up smoking (Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, Centers for Disease Control and Prevention, 2012). If dispensaries are allowed to advertise marijuana, youth will be exposed to those ads and may begin using marijuana without a doctor’s recommendation. As such, marijuana advertisements should be strictly prohibited or at least heavily controlled across all possible mediums.

In states that have legalized marijuana for medical or recreational use, billboards, print ads, Internet ads, and a number of other advertisements have exposed more youth to marijuana than ever before. Unfortunately, many of these ads are also in poor taste and contain medically dubious information.

Examples of misleading advertisements:

- www.doc420.com advertises clothing, including hats and T-shirts, that advertise a marijuana dispensary, complete with a picture of a marijuana leaf.
- www.grassrootsmedical.com advertises that it will help you become a medical marijuana patient and that you can get a pre-rolled joint for just $1.
- www.mmjdoctoronline.com, which offers to help you “Get your Medical Marijuana Card NOW,” features an article claiming that marijuana “is firmly established to be among the safest and least addictive of all medicinals” and encouraging readers to call them for a marijuana recommendation if their doctor won’t do it.

If the board will not prohibit advertising, then I ask that the board strictly control it and adopt the following measures:

- Coupons, discount programs, and purchasing clubs (except for indigent and veterans as outlined by the law) should be prohibited.
- Broadcast ads of any kind should be prohibited.
- Ads should not be placed on vehicles, clothing, or hand-held signs.
- No marijuana leafs should be placed on advertisements.
- Ads should only refer to marijuana as marijuana, not through nicknames or slang.

I also ask that home delivery of marijuana be prohibited. Patients or their caregivers may pick up marijuana at a dispensary and, as such, home delivery isn’t necessary. In fact, it risks diversion by removing marijuana from controlled environments.

I also ask that the board maintain the proposed fee schedule to ensure resources are available to properly regulate marijuana.

I also ask that the board define what a 90-day supply of marijuana is appropriately for each condition. If we’re going to treat marijuana like medicine, we should require doctors and dispensaries to provide specific supplies based on need.

[Signature Line]
Public comments: Physician certificate to recommend medical marijuana

Continuing Medical Education

I ask that the State Medical Board of Ohio require physicians to attend 8 hours of Continuing Medical Education in order to begin recommending marijuana and to complete 4 hours of CME with each renewal to continue recommending marijuana. I also request that the hours require education in prevention and understanding of marijuana addiction, mental health considerations related to the use of marijuana, effects of marijuana on pregnancy, effects of marijuana on youth, marijuana's interactions with other drugs, and on dosing marijuana.

Two hours of education, as was proposed, is insufficient for doctors to truly learn about the risks associated with marijuana as well as how to prevent a recommendation from becoming a lifelong disease, as has happened with opiates. As marijuana is used more frequently and further studies are conducted, physicians recommending marijuana to their patients will need to stay informed.

“Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study,” published in The Lancet Psychiatry in 2015, found a disturbing link between higher frequency use of high-potency marijuana and an increased risk of psychosis.

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The above research demonstrates that the potential negative health effects of marijuana are still being researched. For doctors to do more good than harm, they must remain up to date on marijuana research. Increasing the number of CME hours doctors who recommend marijuana must attend will help foster that education.

Additionally, in a recent survey conducted by the board (http://www.medicalmarijuana.ohio.gov/Documents/advisory-committee/December%202016/Physician%20Survey%20-%20Handout.pdf), more than 40 percent of doctors said they would be more likely to recommend marijuana if they had additional CME, and they expressed interest in substance use disorder, diversion, and mental health events.
Standard of Care
I ask that the State Medical Board of Ohio require physicians to recommend a specific dose of marijuana when recommending marijuana to a patient in order to protect patients from using too little or too much.

Sadly, at least one person’s suicide has been possibly linked to ingesting too much tetrahydrocannabinol in a THC-infused edible, resulting in a marijuana overdose (http://www.philly.com/philly/blogs/healthy_kids/The-lows-of-edible-marijuana.html). Without a doctor’s guidance, patients may use marijuana that is ineffective for their treatment or risk an overdose.

Doctors prescribe specific doses of medications in order to best match the medication to the patient and do more good than harm. I believe the same standard should be applied to marijuana and ask the State Medical Board of Ohio to require it.

Advertising
I ask that the State Medical Board of Ohio expressly prohibit doctors from advertising that they will or can recommend marijuana.

State that have medical marijuana programs have also seen billboards, Internet ads, websites, social media apps, and more advertisements where doctors say they will recommend marijuana for a patient even when other doctors won’t. These ads expose our children and, if allowed, would taint the intent of Ohio’s medical marijuana program by commercializing what’s supposed to be a medicinal program. Unfortunately, many of these ads are also in poor taste and contain medically dubious information.

Tobacco advertising has been shown to cause youth to start smoking (Preventing Tobacco Use Among Youth and Young Adults: A Report of the Surgeon General, Centers for Disease Control and Prevention, 2012). Advertisements featuring images of marijuana along with a doctor saying he would be willing to recommend it will only serve to expose and harm the youth of Ohio.

www.doc420.com advertises clothing that advertise a marijuana dispensary, complete with a picture of a marijuana leaf, and www.grassrootsmedical.com advertises that it will help you become a medical marijuana patient and that you can get a pre-rolled joint for just $1. www.mmjdoctoronline.com, which offers to help you “Get your Medical Marijauana Card NOW,” features an article claiming that marijuana “is firmly established to be among the safest and least addictive of all medicinals” without providing any medical evidence for such a claim. That article also encouraged readers to call them for a marijuana recommendation if their doctor won’t do it.

Already in Ohio, Omni Medical Services is advertising on a website and on social media that it will “get people legal” and directs them towards Michigan dispensaries, effectively encouraging Ohioans to break federal laws. They’re offering discounts, branding themselves as www.420omni.com, and advertising on social media where anyone, including youth, are currently exposed:
Some of the advertisements say, “Kill the pills and get certified for something better!” and urge people to call them “if you’re in Ohio and need relief from pain, discomfort and opioid side effects!” Their website also urges patients to engage in doctor shopping, saying, “your doctor may not feel comfortable prescribing alternative or holistic remedies of this nature, but our doctors will!”

The Holistic Center in Toledo is recommending marijuana to people, giving them medical marijuana cards, offering discounts, branding itself with a marijuana leaf, features prominent photos of marijuana, and is advertising its products as good for nausea, chronic pain, cancer, and several other conditions:

Because businesses in other states have had issues, including lawsuits, over advertisements, and because this is a medical marijuana program that is focused on patients over profits, we believe that implementing rules to eliminate or at least limit advertising by doctors is appropriate and crucial.
If advertising is allowed, we believe it should be limited in order to prevent and limit youth exposure, avoid triggering negative behavior, protect patients and communities, and ensure that advertisements are kept clinical in nature. To that end, we ask that:

- Ads should be limited to the name of the business and its location.
- Broadcast ads should be prohibited; no ads should be circulated in print or online to a general audience, such as in a newspaper or on social media; no ads should be circulated by mail; illuminated signs should be prohibited; ads should not be placed on vehicles, clothing, or handheld signs.
- Coupons and other discounts should be prohibited.
- Visuals used in advertisements should be limited to those that show storefronts, store locations, or a general picture of the store and should not feature images of products, models, actors, or other paid or otherwise compensated representatives.
- No advertisement should depict a marijuana leaf or plant, children, people in a state of undress, illegal activity, cartoons, use of marijuana, or use of paraphernalia, medical devices, or any other substance, including alcohol.
- Advertisements must be medically accurate and shouldn’t make claims that cannot be medically supported or that a preponderance of medical information suggests is false.
- Advertisements should include a warning about the negative health effects of marijuana, including an audio warning if the ad includes any audio element.
- Ads should not include language asking if patients suffer from a qualifying condition and promising relief from those conditions or from other medications’ side effects.
- References to marijuana should be to “marijuana” not to “pot,” “reefer,” “mary jane,” or other terms. Advertisements should not refer to “4/20” or “420” or any variation thereof.
The Risks of Marijuana Use During Pregnancy

Currently, 29 states and Washington, DC, have passed laws to legalize medical marijuana. Although evidence for the effectiveness of marijuana or its extracts for most medical indications is limited and in many cases completely lacking, there are a handful of exceptions. For example, there is increasing evidence for the efficacy of marijuana in treating some forms of pain and spasticity, and 2 cannabinoid medications (dronabinol and nabilone) are approved by the US Food and Drug Administration for alleviating nausea induced by cancer chemotherapy. A systematic review and meta-analysis by Whiting et al found evidence, although of low quality, for the effectiveness of cannabinoid drugs in the latter indication. The antinausea effects of tetrahydrocannabinol (THC), the main psychoactive ingredient in marijuana, are mediated by the interactions of THC with type 1 cannabinoid (CB1) receptors in the dorsal vagal complex. Cannabidiol, another cannabinoid in marijuana, exerts antiemetic properties through other mechanisms. Nausea is a medically approved indication for marijuana in all states where medical use of this drug has been legalized.

However, some sources on the internet are tout- ing marijuana as a solution for the nausea that commonly accompanies pregnancy, including the severe condition hyperemesis gravidarum. Although research on the prevalence of marijuana use by pregnant women is limited, some data suggest that this population is turn- ing to marijuana for its antiemetic properties, particu- larly during the first trimester of pregnancy, which is the period of greatest risk for the deleterious effects of drug exposure to the fetus. Marijuana is the most widely used illicit drug during pregnancy, and its use is increasing. Using data from the National Survey of Drug Use and Health, Brown et al reported in this issue of JAMA that 3.85% of pregnant women between the ages of 18 and 44 years reported past-month marijuana use in 2014, compared with 2.37% in 2002. In addition, an analysis of pregnancy data from Hawaii reported that women with severe nausea during pregnancy, compared with other pregnant women, were significantly more likely to use marijuana (3.7% vs 2.3%, respectively).

Although the evidence for the effects of marijuana on human prenatal development is limited at this point, research does suggest that there is cause for concern. A recent review and meta-analysis found that infants of women who used marijuana during pregnancy were more likely to be anemic, have lower birth weight, and require placement in neonatal intensive care than in- fants of mothers who did not use marijuana. Studies have also shown links between prenatal marijuana ex- posure and impaired higher-order executive functions such as impulse control, visual memory, and attention during the school years.

The potential for marijuana to interfere with neurodevelopment has substantial theoretical justification. The endocannabinoid system is present from the beginning of central nervous system development, around day 16 of human gestation, and is increasingly thought to play a significant role in the proper formation of neural circuitry early in brain development, including the genesis and migration of neurons, the outgrowth of their axons and dendrites, and axonal pathfinding. Substances that interfere with this system could affect fetal brain growth and structural and func- tional neurodevelopment. An ongoing prospective study, for example, found an association between pre- natal cannabis exposure and fetal growth restriction during pregnancy and increased frontal cortical thickness among school-aged children.

Some synthetic cannabinoids, such as those found in "K2/Spice" products, interact with cannabi- noid receptors even more strongly than THC and have been shown to be teratogenic in ani- mals. A recent study in mice found brain abnormalities, eye deformations, and facial disfigurement (cleft palate) in mouse fetuses exposed at day 8 of gestation to a potent full cannabinoid agonist, CP-55,940. The percentage of mouse fetuses with birth defects increased in a linear fashion with dose. (The eighth day of mouse gestation is roughly equivalent to the third or fourth week of embryonic development in humans, which is before many mothers know they are pregnant.) It is unknown whether these kinds of effects translate to humans; thus far, use of syn- thetic cannabinoids has not been linked to human birth defects, although use of these substances is still relatively new.

THC is only a partial agonist at the CB1 receptor, but the marijuana being used both medicinally and rec- reationally today has much higher THC content than in previous generations (12% in 2014 vs 4% in 1995), when many of the existing studies of the teratogenicity of marijuana were performed. Marijuana is also being used in new ways that have the potential to expose the user to much higher THC concentrations—such as the practice of using concentrated extracts (eg, hash oil).

More research is needed to clarify the neurodevel- opmental effects of prenatal exposure to marijuana,

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especially high-potency formulations, and synthetic cannabinoids. One challenge is separating these effects from those of alcohol, tobacco, and other drugs, because many users of marijuana or K2/Spice also use other substances. In women who use drugs during pregnancy, there are often other confounding variables related to nutrition, prenatal care, and failure to disclose substance use because of concerns about adverse legal consequences.

Even with the current level of uncertainty about the influence of marijuana on human neurodevelopment, physicians and other health care providers in a position to recommend medical marijuana must be mindful of the possible risks and err on the side of caution by not recommending this drug for patients who are pregnant. Although no states specifically list pregnancy-related conditions among the allowed recommendations for medical marijuana, neither do any states currently prohibit or include warnings about the possible harms of marijuana to the fetus when the drug is used during pregnancy.8 (Only 1 state, Connecticut, currently includes an exception to the medical marijuana exemption in cases in which medical marijuana use could harm another individual, although potential harm to a fetus is not specifically listed.)

In 2015, the American College of Obstetricians and Gynecologists issued a committee opinion discouraging physicians from suggesting use of marijuana during preconception, pregnancy, and lactation.9 Pregnant women and those considering becoming pregnant should be advised to avoid using marijuana or other cannabinoids either recreationally or to treat their nausea.

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REFERENCES
Ignorance Is Not Bliss!

A Survey of American Medical School’s Acceptance of the Science of the ECS (Endocannabinoid System)

*Nathan Stewart, Sioux Colombe, Ron Mullins, David Allen M.D.*

Medical Cannabis Evaluations, Sacramento, CA

**Summer 2013**

**Introduction**

The discovery of the endocannabinoid system (ECS) is the single most important scientific medical discovery since the recognition of sterile surgical technique. As our knowledge expands, we are coming to realize that the ECS is a master control system of virtually all physiology. The total effect of the ECS is to regulate homeostasis and prevent disease and aging. The more we learn, the more we realize that we are in the infancy of this scientific field of study. The ECS is a control system which involves tissue receptor proteins, cellular communication and control, molecular anatomy and the scavenging of oxygen free radicals. This new field of science will change medicine forever and prove cannabis the *gold standard* for many disease processes. Its effect on scavenging oxygen free radicals is applicable to all disease processes and this is why it has such wide medical application and is considered a cure-all by many.
The discovery of the ECS will replace the current medical system of managing and treating disease. Instead of management of symptoms after disease has occurred, we will prevent disease and cancer by manipulation of the ECS.

Research and education of medical students involving the ECS is being intentionally restricted by politics. No justification can be made for the restriction of the scientific study of cannabis and the endocannabinoid system. What is the danger of providing government-grown and tested cannabis to researchers? Diversion of research cannabis for non-scientific or recreational purposes does not seem to be a serious threat to national security.

**Methods**

The directors of the curriculum of the 157 accredited American medical schools (across all 50 states), were contacted initially by phone, then follow-up email. We asked the following questions:

1. Do you have a department of ECS (Endocannabinoid Science) with a director?
2. Do you teach the ECS as an organized course?
3. Do you mention the ECS in any ancillary classes like pathophysiology, neuroanatomy or pharmacology?

**Resistance to the Survey**

Our surveyors found a lot of resistance to answering questions, and we had to alter our technique for asking these pointed questions. Many people were unaware of what the word endocannabinoid actually meant. We were asking the medical schools if they were teaching a subject that many of them had no knowledge of. We initially called stating Dr. David Allen, a retired cardiothoracic and vascular surgeon, was sponsoring the study. This led to reluctance, suspicion and refusal to answer our questions. We had reactions like, “Who wants to know this?” and “Why do you want to know this information?” We quickly realized there was significant resistance to our questions. We then decided to pose as medical students looking to apply to an institution that specialized in the study of the ECS. This worked well, and we were able to acquire many responses from the office staff of curriculum directors. The directors were frequently not available and often too busy to talk to us. However, this change in technique made data collection easier and curriculum staff more cooperative and affable.
Here are some of the responses to the questions asked in this survey, ranging from passive-aggressive to blissfully ignorant:

- I doubt you will find a school that has a department of endocannabinoid science.
- How do you spell endocannabinoid?
- We have a few lectures that speak to the topic of the cannabinoid system. That is the extent of our curriculum in that area.
- You’re a prospective student? Not with these kinds of questions you aren’t. If you are an applicant you can call the admissions office.
- Are you aware what type of institution we are? Why would we offer that here?
- The topic hasn’t gained enough traction or notoriety on this campus to be fully explored... Y’know what I mean?
- I have no idea what that is.
- You will have some very brief exposure to cannabinoid receptors and their effects in our curriculum.
- No course would touch upon this subject longer than five minutes.
- There are 12 mentions of cannabinoids in the curriculum database but no mention of the endocannabinoid system.
- We don’t teach anything like that at this school.
- If it is mentioned, it is not a particular focus or talking point. I haven’t heard the endocannabinoid system come up in conversation.
- This is a school for people who want to become “doctors.”
- I never heard of it. We probably don’t teach it.
- Why are you asking that question? I don’t believe that’s an appropriate question. I wouldn’t waste other faculty member’s time with that question.

However, a few responses gave our team some hope for the future of this science.

- Yes we touch upon it in some of our biochemistry courses. The benefit of being at a small school is our ability to conduct more specialized research.
- We do not teach the endocannabinoid system, but we do have a research lab dedicated to that issue.
- Three of our physicians include the endocannabinoid system in a lecture.
- VCU (Virginia Commonwealth University School of Medicine) has a leading researcher in the area of cannabinoids. There are numerous possibilities to attend seminars on the latest research in that area.

Some may criticize this study’s accuracy, but the resulting numbers are so overwhelming that, even considering room for error, there is a clear failure of the medical establishment to overcome political repression of scientific knowledge. There is no reason our potential medical doctors should be ignorant of this important physiologic control mechanism. This is similar to ignoring a medical field like neuroanatomy.
The majority of people in the United States have no idea of the remarkable, scientifically-proven medical benefits of cannabis. These cannabinoids are responsible for massive reductions in diabetes, stroke and myocardial scars. Many cancers show significant responses to cannabinoids by

1. Inhibition of growth of the tumor
2. Reduction in metastasis (blood and lymphatic spread of the cancer)
3. Inhibition of VEGF (vascular endothelial growth factor), which inhibits blood vessel growth into tumors (inhibiting vasculogenesis)
4. Induction of apoptosis (normal cell death that cancer cells are immune to)

Glucose and fatty metabolism, pain control and inflammation are all controlled by the ECS. There are many reports of patients with seizures that are unresponsive to all medicines except cannabis extracts. We are learning that even the sperm implantation into the ovum requires endocannabinoids for success. Mother’s milk contains endocannabinoids that stimulate the infant to feed and thrive. (This transfer of cannabinoids from mother to child is the only still legal transfer of exogenous cannabinoids).

Prohibitionists will claim that no political repression of the science exists. They will claim that there are adequate scientific studies being funded, but the application process for scientific study of cannabis is nearly impossible to complete successfully. Dr. Donald Abrams is famous for being rejected for submitting numerous cannabis studies designed to prove benefits from this medication. After many denials, Dr. Abrams changed his tactic and asked to do a study to ascertain if cannabis caused changes in AIDS drugs that would make them less effective or more toxic. This study was approved for government funding because it asked to study the negative effects of cannabis. Fortunately, this study showed cannabis does not make the AIDS drug more toxic or less effective. The Catch 22 for cannabis is that, in effect, the government states, “There are no studies that prove cannabis safety, therefore, it should remain in a class of dangerous drugs that are prohibited from scientific study.” Because cannabis has not been studied, it is a Schedule I drug. Because it is a Schedule I drug, it cannot be studied.

Obviously, there can be no justification for repression of scientific study on any subject, especially the scientific study of a plant with unprecedented medical benefits and a lack of harmful side effects. When scientific knowledge is illegal, the truth does not exist. Americans for Safe Access (ASA) has a very illuminating study on the political repression of the scientific study of cannabis in this country that is well worth reading:

Results

The results of the study are predictable, so no one should be surprised! Not one of the medical schools surveyed had a department of endocannabinoid science or an ECS director. None of them taught the endocannabinoid science as an organized course. Only 21 of the 157 schools surveyed had the ECS mentioned in any course. \[\frac{21}{157} = 13.3\%\]

In the United States of America, only 13% of the medical schools surveyed teach the endocannabinoid science to our future doctors.

Conclusion

The purpose of this study was to point out the absurdity of ignoring a new science. We would hope this study causes medical schools to rethink their position and welcome this new science. We call on the Deans of all medical schools to start organized courses in cannabinoid receptor science and its modulating effects on homeostasis. If the medical schools in your state do not teach the endocannabinoid science, you can discuss ways to incorporate the study of the ECS into their curriculum.

Humans have a hard time believing in things they can’t see. Prior to the invention of the microscope, no medical schools taught sterile technique to their students because bacteria were unseen. You should research the name Ignaz Semmelweis and how the medical community treated his epiphany and scientific medical discovery. Dr Semmelweis referred to the physicians of the day as “ignoramuses.” It may be time for today’s physicians to catch up with the science of the times. The discovery of the ECS is proving it to be a master control system for physiology.

Recent studies show long-term use of cannabis decreases the incidence of diabetes by 66%. US patents prove CBD, a component of cannabis, decreases the size of a stroke by 50%. Other studies show a 66% reduction in the size of a heart scar after a heart attack. The sum of this information means that cannabis augments the body’s own natural endocannabinoid system. Cannabis is not just a pharmaceutical; it is more properly termed a nutraceutical. Your body needs cannabis on a nutritional basis to prevent disease. You don’t need a medical diagnosis to benefit from cannabis, as everyone can benefit from the antioxidant effects. As you can see, this concept will change medicine as we know it, including the distribution of money. The business of medicine will no longer be treatment-based, it will be prevention-based.

The big picture is that the ECS is a control system of physiology that will not be ignored. You can pretend the ECS doesn’t exist or question its importance. People once questioned the significance of handwashing prior to surgical procedures because bacteria are unseen by the naked eye. People may not understand the complex science behind this medicine, but they know
immediately when they use cannabis that it has some beneficial effects. The price that people are willing to pay for cannabis should be a good barometer on how well people think the medicine works. Only organized, double blinded scientific studies of cannabis will prove its true benefits or potential harm. Unfortunately, the politics behind prohibition prevent this from happening to any significant degree.

Ask yourself, “Why is scientific study of cannabis and the ECS restricted in the USA? What possible justification could explain this? Why should the education of medical students exclude this critical control system of physiology and health?” We encourage you to call the Dean of your local medical school and ask if they plan on teaching this science to our future doctors. When will this war end and the healing start? All wars mean big business for somebody. This war is being funded, and that is why it still continues. Stop the funding and the war will end. Jury nullification and education of the public on the truth about cannabis are the best ways to stop this war on us. Read and teach.

David B. Allen M.D. Cali215doc@gmail.com

Resources

US Patent; New use for Cannabinoids;
https://www.google.com/patents/EP2254565A1?cl=en&q=cbd+decreases+diabetes+by&hl=en&sa=X&ei=BU3vUc7oLYa29gS7_oGYBg&ved=0CDsQ6AEwAQ

US Patent: Treating or preventing diabetes with Cannabidiol;
https://www.google.com/patents/WO2005077348A1?cl=en&q=cbd+decreases+diabetes+by&hl=en&sa=X&ei=BU3vUc7oLYa29gS7_oGYBg&ved=0CEIQ6AEwAg

US Patent: Cannabinoids as antioxidants and Neuroprotectants;
https://www.google.com/patents/US6630507?dq=us+cannabinoid+patent&hl=en&sa=X&ei=Ak7vUfuvLsvdqwG8n4GABg&sqi=2&pf=j=1&ved=0CDQQ6AEwAA

https://www.google.com/patents/US20130059018?dq=us+cannabinoid+patent&hl=en&sa=X&ei=Ak7vUfuvLsvdqwG8n4GABg&sqi=2&pf=j=1&ved=0CF4Q6AEwBg

US Patent: Medical use for acidic cannabinoids;
On Feb 4, 2017, TDCANN Institute will host the first in a series of public seminars that will examine the role and impact of cannabis on the local, state, national and international stage. The initial seminar’s objectives are:

1. Examine the key aspects of the cannabis industry being introduced to Ohio
2. The importance of education
3. The history of cannabis in Ohio
4. Review the current state of science and research regarding cannabis and the Endocannabinoid System
5. Identify the risk and benefits of the industry for the patient, businessperson, and governmental officials on a local and statewide level
6. Determine the significance of cannabis in other states and the lessons that have been learned
7. Discuss the needs, opportunities, and barriers for collaboration among, across, and within the governmental role, the healthcare role, the business person role, and the role of the patient.
TDCANN Institute Presents:

The Cannabis Impact:
Opportunities, Issues and Challenges for Ohio

February 04, 2017

The Sheraton Columbus Hotel at Capitol Square
75 E State St, Columbus, OH 43215
8am-5pm

Register Online at Eventbrite.com

Early Bird Registration Ends January 14th
$250

General Registration
$299

Continental Breakfast and Lunch provided

theresaecs@gmail.com
tdcann.com

PRESENTERS

Keynote Speaker Dr. Debra L. Kimless, M.D.
Dr Kimless is an Anesthesiologist, has dedicated the last several years to immersing herself in all aspects of medical cannabis, including participating in the regulatory process of multiple states. She has traveled the world studying under respected experts in cannabis medicine and science, most notably, in the Netherlands and Israel. She is currently working with patients, and collecting case studies that are being presented nationally/internationally at clinical conferences.

Heather Manus, R.N.
International Cannabis Educator, Entrepreneur, and Nurse

Lynn Watchman
Former long term policy maker in Ohio; Senior Government Relations Director at Shumaker, Loop and Kendrick, LLC

Don E. Wirtshafter, Esq.
Pioneer of the Cannabis Industry, Entrepreneur, Director of The Cannabis Museum

Irv Rosenfeld
Federal Compassionate IND Patient and Expert in Cannabis Stocks

Rhory Gould
Award-winning Michigan Dispensary Owner

Tim Johnson
Retired Law Enforcement, Safety/Security Asset Protection Specialist

Panel Moderated by Daisy L. Alford-Smith, PhD

Theresa Daniello
Theresa founded TDCANN Institute in 2014 when she recognized the need for professional, objective education in the cannabinoid sciences and the cannabis industry. As a six year veteran of reform, Theresa has traveled the country collaborating with industry experts while educating policymakers and healthcare professionals in multiple states, including Ohio.
MEMORANDUM

TO: Ohio Medical Marijuana Control

FROM: Program

DATE: January 13, 2017

RE: Comments on proposed Physician Rules

§4731-32-03(A) Consider telemedicine technology to satisfy the “in-person” requirement.

§4731-32-03(A)(5) The dispensary rules seem to talk about providing medical marijuana to adults only and here it talks about minors. Consistency, please. Both should read from minors with the consent of parent or guardian.

§4731-32-03(A)(5)(i) Where is the database housed? With the Board of Pharmacy?

§4731-32-03 (B)(7) Creating a medical marijuana program in Ohio means that marijuana is medicine. Ohio has created a list of qualifying conditions for the state of Ohio. Patients should only have to have a diagnosis from their physician, based on a bona fide physician-patient relationship that the patient has one of the qualified conditions in order to make a recommendation for medical marijuana. What is the “standard medical treatment”? Opioids? Other pharmaceuticals? Patients and doctors should not have to demonstrate that other treatments did not elicit a certain response, or that the treatments were not “tolerable.” If medical marijuana is to be a viable medicine for patients with qualifying conditions, the patients should not have to suffer through these hoops. If the patient determines, with their bona fide physician’s physical examination, that medical marijuana is the appropriate treatment, which should be sufficient.

Colorado’s certification process for physicians and the requirements for recommendations make this medicine more accessible to patients. The following is a passage from the Colorado Medical Marijuana Registry Department of Public Health & Environment Physician Certification.

“To recommend medical marijuana, a physician must:
1. Have an active MD or DO license in good standing with the state of Colorado.
2. Submit a copy of your current DEA Certificate to the Registry. If a copy of the DEA certificate is not already on file, please email it to:
3. Have a bona fide physician-patient relationship with the patient.
4. Conduct a physical examination each year and review patient’s medical history to certify the patient has a **qualifying debilitating medical condition**.
5. Complete a physician certification for the patient. A new physician certification is required each year as part of the patient’s renewal process.
6. Provide a copy of the physician certification to the patient for their application packet.
7. Keep a copy of the completed physician certification in the patient’s medical record.”

(https://www.colorado.gov/pacific/sites/default/files/CHED_MMR_Form_MMR1002_PHYSICIAN_CERTIFICATION_0316.pdf)

The requirements for physician recommendations should model Colorado’s more closely. The rule in Ohio, as written, will severely limit access for patients who may struggle to visit their physician repeatedly to attempt various “standard medical treatment(s)” in order to get their most optimal medicine.

§4731-32-05(C)(5) Again, if medical marijuana is going to be treated, finally, as the medicine it is, patients suffering from additional debilitating diseases and conditions should not have to be excluded from obtaining medicine because physicians are unable to prove in a petition that other “conventional medical therapies are insufficient.” Physicians should be able to petition by showing demanded in 4731-32-05(C)(6) Evidence supporting the use of medical marijuana to treat or alleviate the disease or condition, including journal articles, peer reviewed studies, and other types of medical or scientific documentation; and

§4731-32-05(C)(7) Letters of support provided by physicians with knowledge of the disease or condition. This may include a letter provided by the physician treating the petitioner, if applicable.

For the current list of qualifying conditions, it is doubtful that anyone had to make a showing that “conventional medical therapies are insufficient to treat or alleviate the disease or condition”? Revise this section so that physicians do not have to make this showing, or no additional conditions will ever qualify.
Ohio Families CANN – In Pursuit of Promising Cannabis Therapy

We are a statewide organization of parents of significantly ill children, who have already been prescribed many failed pharmaceutical medications. We appreciate the opportunity to share our perspective as citizens who will be utilizing this program, and as Ohioans who have become quite familiar with many other parents and patients around our country whose state policies allow for various levels of access to a better, safer medicine for their loved ones.

First and foremost, we expect our government officials will create policies that afford us ease of access and regulations that support low cost cannabis therapy.

OSMB Proposed RULE: (7) Documented review that that standard medical treatment has been attempted or considered, and one of the following is met:
(a) The patient had inadequate treatment response to standard medical treatment;
(b) The patient was unable to tolerate the standard medical treatment;
(c) Standard medical approaches are

OFC response: Patients and parents should be afforded the civil right and patient autonomy to trial cannabis therapy as a first option. The above rule seems based in the false notion that non-cannabis therapies are a safer first therapy. It is a false notion that barbiturates, benzodiazepines and/or opiates are known to be safer for babies and young children. Our experience with years of failed pharmaceuticals tells us that traditional therapies come with significant detriment themselves and that cannabis therapy can be positive choice of harm reduction from traditional pharmaceuticals. The long term effects of the former medications have never been tested on children, yet they run the risk of death, need for oxygen, and greater distress from withdrawal, to name a few negative side effects of the failed pharmaceuticals our children have endured.

I hope we can agree that while there is more to know about cannabis therapy. What IS known is that cannabis therapy cannot cause a lethal overdose, withdrawal is considered far less significant than barbiturates, benzodiazepines and/or opiates. And while there is early evidence pointing to necessary risk assessments for developing brains, one cannot state definitively that other heavy hitting epilepsy, cancer, and pain medications that are currently being prescribed, come with less risk for young children.

To therefore require a parent or patient to first fail a barbiturates, benzodiazepines and/or opiates is not acceptable. Parents should be allowed the civil right to choose a promising new option.

The statute suggests that in order to obtain a Medical Marijuana Certification, "a patient must access the risks and benefits of cannabis therapy." This means, "as compared to other existing therapies" and is a sufficient rule.

OSMB Proposed RULE: (f) Any instructions for use of medication marijuana, as determined by the physician.
Will this impact what a person can obtain from a dispensary? If so, it creates an unworkable structure for patients. Patients and caregivers need the ability to shift cannabinoid content in a supportive environment.

We believe a patient should have autonomy to trial a variety of cannabis therapies as it is well understood that each patient will respond differently to cannabinoid therapy.

**OSMB Proposed RULE: (H)** The physician shall submit to the board an annual report describing the physician’s observations regarding the effectiveness of medical marijuana in treating patients. The report shall not contain patient-identifying information.

Will the OSMB create a guide for physicians for determination of effectiveness of MMJ treatment? It doesn’t seem as useful to us, for independent physicians to develop independent and therefore different structures for effectiveness. It would seem to us, that if the powers that be want to collect data, they should develop a system for doing so that does not burden physicians, but assists them in completing the task.

**OSMB Proposed RULE: (G)** Any petition for a condition that has been previously reviewed by the board and rejected will not be considered by the board unless new scientific research that supports the request is offered.

While we understand the logistical reasons for the above decision, the “one shot rule” does seem a harsh reality for any Ohioan with a condition or a loved one with a condition not found on the list. Given the fact that public opinion has driven our state to allow cannabis therapy far more than scientific data, we believe this rule should read “unless new scientific research or public policy that supports the request is offered.”

While we support and hope for continued advances that point to the scientific evidence of the effectiveness of cannabis therapy, we have more historical context suggesting that scientific work may not be rapidly forthcoming. Federal barriers to research, though moving in the right direction, significant barriers to the epitome of research still exist.

In addition to scientific data, our fellow Ohioans with loved ones on the Autism Spectrum, with Tourette’s syndrome, anxiety and depression, for example, deserve the right for policy changes at state and federal levels to positively impact greater treatment options.

**Timelines?** There should designate lengths of processing time for certifying physicians and administer medical cards? A 90 day turnaround time is common place with regard to issuing of Medical Cards for patients. We expect the same to be acceptable for physician certification.

**Research and development?** Where in the structures of rules, can we expect to find explanations of ways in which research will be encouraged? All of our parents wonder how/if you, as the OSMB plan to encourage large hospital systems to allow for cannabis therapies within their establishments?
Comments for Physician Rule

By Colleen Dempsey, Practice Associate for the National Association of Social Workers, Ohio Chapter, colleendempsey@naswoh.org

The National Association of Social Workers, Ohio Chapter (NASW-OH) holds the position that as medical marijuana is made available in the state, consideration should be given to the accessibility of the medication to all Ohioans. This includes low-income patients, the elderly, and persons with disabilities. The current proposed rules could limit accessibility in the following ways.

- Recommendation frequency limited to every 90 days.
  - NASW-OH recommendation: With a commonly abused substance such as marijuana, it is reasonable to have more frequent visits early in a patient’s treatment plan. However, the Advisory Committee could consider some allowance for an extension of time between visits after set goals are met. As an example, a patient could be limited to one recommendation every 90 days for the first year, and in consideration of their compliance and the treatment plan, the patient could then be eligible to receive a recommendation every 180 days.

- Restrictions on delivery of medication.
  - NASW-OH recommendation: Homebound Ohioans and those without transportation are currently able to take advantage of delivery services. While security is certainly a concern, NASW-OH encourages the Advisory Committee to consider delivery options under some conditions such as limited mobility and transportation limitations.

As public comments are considered, NASW-OH would like to propose extensive consideration of cost accessibility during rule revision processes. Because marijuana is illegal under federal law, it is unlikely that Ohio patients will have medical marijuana covered through any available health insurance. As in most other legal states, the cost of medical marijuana will likely be paid for out of pocket by patients, presenting a significant cost barriers for some Ohioans. Many patients qualifying for medical marijuana may often be incapacitated by their illness, making it difficult for them to maintain full-time jobs. Discounts or insurance type programs for low-income patients may be necessary to guarantee access for Ohioans who are eligible for the alternative treatment.

The cost of medical marijuana treatment can quickly add up, as we’ve learned from the experiences of other legal states. Often, patients are required to register with the state, purchase a license or ID card, and attend multiple initial visits with a doctor willing to provide a recommendation for medical marijuana products. In addition to the burden associated with the cost of treatment, the application process can be lengthy and confusing. In Massachusetts for instance, a patient must first visit an evaluation center which is often separate from a primary care office. The patient then must establish a relationship with an evaluation center officer, requiring several visits at a cost of up to $200 a visit, excluding the cost of the drug itself.

To overcome the cost barriers associated with the quasi-legal status of the drug, some legal states and municipalities have crafted mechanisms to provide funding for MM treatment to low-income patients. In Berkley, California, dispensaries are required to set aside 2% of their product for distribution to low-income residents. Similarly, the District of Columbia requires dispensaries to set aside 2% of profits for the same purposes. In other legal states like Washington, New York, and Arizona businesses have taken it upon themselves to develop similar policies and programs to address cost barriers. In addition to funding the purchase of medical marijuana for low-income patients, states have found other ways to reduce costs. New Mexico does not charge any patient registration fee whatsoever. States like Massachusetts and Michigan allow low-income patients to pay a reduced application fee. In Colorado, low-income patients are exempt from paying sales tax on their medicine. Some states only require medical marijuana ID cards to be renewed every two years, as opposed to annually. However it is accomplished, it is imperative that the state of Ohio preemptively address barriers to patient access and ensure equitable access at all income and ability levels.
Q4 Please provide any comments/suggestions on the draft rules.

Answered: 1,105  Skipped: 2,324

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<thead>
<tr>
<th>#</th>
<th>Responses</th>
<th>Date</th>
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<tbody>
<tr>
<td>1</td>
<td>2 hour CME seems excessive</td>
<td>1/17/2017 7:39 AM</td>
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<td>2</td>
<td>If I identified a patient who might qualify for treatment with medical marijuana and has a good likelihood of a beneficial response, I would very likely refer such a patient to a pain management physician who is certified in its use. It is very unlikely that I will prescribe the agent myself.</td>
<td>1/17/2017 5:57 AM</td>
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<tr>
<td>3</td>
<td>I believe in patient autonomy and the right to decide the best treatments for themselves, even non-formulary.</td>
<td>1/17/2017 4:17 AM</td>
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<tr>
<td>4</td>
<td>Why discriminate against fellow Ohioans who live without this goofy list of diagnoses? Thanks, but no thanks. I will not be whoring out my medical license to recommend pot.</td>
<td>1/16/2017 11:00 PM</td>
</tr>
<tr>
<td>5</td>
<td>Treat marijuana like another pharmaceutical. They claim it is for purely medicinal purposes but don't want to put it through the medical scrutiny. Unless someone has cancer and on their death bed then they are most likely burnouts looking for an excuse to get high. Sad part is that everyone knows medical marijuana is a farce but are too afraid to say so. I made an oath like all my peers, primum non nocere, I see contributing to degeneracy as harm and won't be a part of it.</td>
<td>1/16/2017 10:11 PM</td>
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<tr>
<td>6</td>
<td>None</td>
<td>1/16/2017 9:29 PM</td>
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<tr>
<td>7</td>
<td>I am not going to prescribe this no matter what the rules are</td>
<td>1/16/2017 9:17 PM</td>
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<tr>
<td>8</td>
<td>Monitoring may be prohibitive</td>
<td>1/16/2017 8:29 PM</td>
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<td>9</td>
<td>I am primary care and feel this should be followed by specialists.</td>
<td>1/16/2017 6:06 PM</td>
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<td>10</td>
<td>seem like reasonable rules but will have to review once experience accrus</td>
<td>1/16/2017 4:37 PM</td>
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<td>11</td>
<td>Marinol presumably has he same indications (or qualifying conditions) as medical (smokable) marijuana. Why not add language to suggest that marinol be tried first. Have the physician state that marinol was tried and found to be inadequate. Any patient who does not want to try marinol— may be primarily interested in getting high.</td>
<td>1/16/2017 4:37 PM</td>
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<tr>
<td>12</td>
<td>None</td>
<td>1/16/2017 4:15 PM</td>
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<td>13</td>
<td>I know two people who developed schizophrenia after taking marijuana. I am unwilling to risk that.</td>
<td>1/16/2017 4:11 PM</td>
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<tr>
<td>14</td>
<td>None</td>
<td>1/16/2017 2:59 PM</td>
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<td>15</td>
<td>I disagree with the list of qualifying conditions. Fibromyalgia is difficult to diagnose. Most of my patients with Hepatitis C do not even realize they have the disease. I think the list of qualifying conditions should be tightened up considerably.</td>
<td>1/16/2017 2:49 PM</td>
</tr>
<tr>
<td>16</td>
<td>I am not in a position where I would be prescribing medical marijuana. However, I support citizens' rights to use marijuana for medical or recreational purposes as a matter of personal freedom. (I have not used it myself)</td>
<td>1/16/2017 2:43 PM</td>
</tr>
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<td>17</td>
<td>I am not in favor of the legalization of medical marijuana, so have no other comment</td>
<td>1/16/2017 1:00 PM</td>
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<td>18</td>
<td>I really don’t want any further pain management patients in my practice</td>
<td>1/16/2017 12:56 PM</td>
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<td>19</td>
<td>i am not a c fan for medical medical</td>
<td>1/16/2017 11:59 AM</td>
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<td>20</td>
<td>I'm concerned about what a yearly report involves.</td>
<td>1/16/2017 11:24 AM</td>
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<td>21</td>
<td>I worry that we do not have enough data on the safest prescribing practices for medical marijuana</td>
<td>1/16/2017 11:08 AM</td>
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<td>22</td>
<td>I recommend that regardless of the condition, that marijuana not be given to people less than 26 years age since the cerebral development is still occuring until about this age and marijuana consistantly reduces motivation and desire for improvement in one's condition physically and socially. I also think that there needs to be safegards for children in the home of someone using medical marijuana for exposure to second hand smoke and for diversion of the marijuana by pre-teens and teens who live or regulary visit the home (step children or shared parenting children).</td>
<td>1/16/2017 11:03 AM</td>
</tr>
<tr>
<td>23</td>
<td>none</td>
<td>1/16/2017 9:26 AM</td>
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<tr>
<td>24</td>
<td>I am not convinced of the safety and efficacy.</td>
<td>1/16/2017 8:46 AM</td>
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</tbody>
</table>
25 No comment
26 Conditions qualifying could be made more specific
27 The list of so called qualifying conditions include gray areas such as Ulcerative colitis, Crohn's disease, Fibromyalgia, chronic pain conditions, and hence will open up practically every currently addicted patients supported by OAARS documentations.
28 I am practicing in Alabama.
29 It would be nice if the Board provided clinical research studies that have documented the value of marijuana for the conditions currently listed as approved, since the only thing I've seen has been the euphoric response that occurs, and the negative impact as to IQ when used in the teens.
30 at this point they seem reasonable and thoughtful for allowing treatment considerations.
31 Excessive oversight will restrict delivery of quality patient care and will generate nonproductive bureaucratic requirements, especially the annual report. Most physicians will have too few patients to doo all the requirements,
32 there is inadequate scientific study to utilize this chemical in patients
33 They are clear, appropriately constrained, and indicate clear needs for on-going doctor-patient relationships. There is no specific statements regarding pediatric patients and or pediatricians, pediatric oncologists, etc. This may be a prudent addition.
34 No comments
35 I feel very ambivalent about it.
36 A drug screen should be required prior to prescribing medical marijuana.
37 None
38 Marijuana is a Schedule 1 drug, and , as such , has no legitimate medical use. I hope the Trump DOJ prosecutes the State of Ohio, and every doctor who prescribes it. This is unprofessional behavior.
39 marijuana is a drug in search of a condition by and large
40 I work for a federally qualified health center. We will not be able to prescribe medical marijuana in any form - in state or out of state - or write disculpatory letters for employers or the legal system because marijuana remains entirely illegal at the federal level. Your guidelines might make note of the conflict between state and federal statutes.
41 They sound reasonable
42 None at this stage
43 None. Retired Pediatrician.
44 Need to provide easier access for glaucoma patients...we are starving for additional options available for use with patients who are not responsive to other medications.
45 Lengthy and onerous
46 evidence for efficacy in any of these disorders is weak at best
47 If I refer to pain management for treatment, that doctor should be able to decide treatment without my specifically recommending marijuana.
48 none
49 I do not believe PTSD, TBI, fibromyalgia, or Tourette should be included. People with mental health conditions often have co-morbid substance abuse problems and even if they don't, they are much more likely to rely on addictive meds to cope with everyday stress rather than seeking healthier ways to cope or making needed and family lifestyle changes. I've had many patients come to me over the past few years telling me all they need is marijuana. Now I have even more. I don't think 99.9% of these patients need MJ. People who use MJ are 40x more likely to get schizophrenia, which is a chronic severe condition that destroys lives and costs the health care system inordinate amounts of money every year. Using MJ in my opinion will only increase health care costs, deaths from druged driving accidents, and cause more mental illness. If medical MJ is going to be legal, I firmly believe that only a few doctors in the state should be authorized to prescribe it and that at least 3 other doctors must see the patient, agree to recommend MJ, and show that every single other treatment has been tried and failed.
50 No study has proven the effectiveness of Marijuana to treat any condition. Marijuana has very serious negative long term side effects. I do not ask patients to go home and drink beer. Why would I prescribe Marijuana?
51 n/a
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<tr>
<td>52</td>
<td>No comment</td>
<td>1/15/2017 1:41 PM</td>
</tr>
<tr>
<td>53</td>
<td>No comment</td>
<td>1/15/2017 12:20 PM</td>
</tr>
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<td>54</td>
<td>make sure that patients bring adequate documentation by office notes or hospital reports of the supposed diagnosis. A dog bite me at age 7 and I am now 70 years old is not the basis for a diagnosis of PTSD</td>
<td>1/15/2017 11:41 AM</td>
</tr>
<tr>
<td>55</td>
<td>These qualifying patients should be restricted from operating motor vehicles during the duration of their treatment by medical marijuana. Physicians should be required to share this restriction information with motor vehicle licensing and law enforcement authorities.</td>
<td>1/15/2017 11:23 AM</td>
</tr>
<tr>
<td>56</td>
<td>I have researched medical marijuana in depth and believe the physicians should be allowed to use it for any conditions they deem appropriate. It is very safe.</td>
<td>1/15/2017 10:35 AM</td>
</tr>
<tr>
<td>57</td>
<td>Podiatrists should be able to provide prescriptions for medical marijuana as they see multiple patients with chronic pain and fibromyalgia.</td>
<td>1/15/2017 10:04 AM</td>
</tr>
<tr>
<td>58</td>
<td>I care less about the Draft rules, and more about the fact that there is no real evidence to support the medical use of marijuana.</td>
<td>1/15/2017 8:52 AM</td>
</tr>
<tr>
<td>59</td>
<td>Too much red tape. I wouldn't even go through the trouble of the application</td>
<td>1/15/2017 8:44 AM</td>
</tr>
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<td>60</td>
<td>The general criteria could be to provide relief for some severe intractable chronic medical conditions that do not have any treatments to correct the problem causing debility.</td>
<td>1/15/2017 7:31 AM</td>
</tr>
<tr>
<td>61</td>
<td>I think you have done a good job with the rules. I am just very uncomfortable with the limited amount of evidence available prescribing marijuana to my patients.</td>
<td>1/15/2017 7:30 AM</td>
</tr>
<tr>
<td>62</td>
<td>There has not be enough good quality research done to justify or safely prescribe medical marijuana at this time. If the state wants people to have access to marijuana, it should not be done under the guise of treating medical conditions</td>
<td>1/15/2017 7:25 AM</td>
</tr>
<tr>
<td>63</td>
<td>None</td>
<td>1/15/2017 7:25 AM</td>
</tr>
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<td>64</td>
<td>at least at this time. It would depend on the scientific evidence coming out as research is funded in the US</td>
<td>1/15/2017 3:11 AM</td>
</tr>
<tr>
<td>65</td>
<td>I have no disagreements with the rules as drafted. The most important aspects, as I see it, are ensuring that prescribing physicians have been educated in the use of medical marijuana, particularly in management of complications/side effects of its use, and that prescribing physicians have a true and ongoing therapeutic relationship with those for whom they are prescribing.</td>
<td>1/14/2017 10:38 PM</td>
</tr>
<tr>
<td>66</td>
<td>I feel this should only be rx by specialists treating pts with the chronic condition... e.g. oncologist, neurologist, etc. NOT primary health care providers</td>
<td>1/14/2017 10:05 PM</td>
</tr>
<tr>
<td>67</td>
<td>seem reasonable</td>
<td>1/14/2017 10:01 PM</td>
</tr>
<tr>
<td>68</td>
<td>These rules are going to dissuade most physicians to prescribe medical marihuana. If that's the desired result, you should say so rather than dress it up with unrealistic requirements. I think the annual report requirement was particularly poorly thought out.</td>
<td>1/14/2017 9:45 PM</td>
</tr>
<tr>
<td>69</td>
<td>I think it is a bad idea to use marijuana to treat any condition.</td>
<td>1/14/2017 9:35 PM</td>
</tr>
<tr>
<td>70</td>
<td>If accepted I think ultimately medical marijuana should be treated like any other medication when data has been gathered. It is after all a medication is it not?</td>
<td>1/14/2017 9:27 PM</td>
</tr>
<tr>
<td>71</td>
<td>Current list of conditions is a good starting point.</td>
<td>1/14/2017 9:26 PM</td>
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<tr>
<td>72</td>
<td>I think only specialists should be able to prescribe this. I don't think pcp's should be expected to do this.</td>
<td>1/14/2017 7:25 PM</td>
</tr>
<tr>
<td>73</td>
<td>There are too many &quot;doctors&quot; here in Colorado that will give the patient the ability to have marijuana in almost any diagnosis. I think there are too many times when it is not justified.</td>
<td>1/14/2017 7:19 PM</td>
</tr>
<tr>
<td>74</td>
<td>There are too many conditions in the qualifying conditions that should not be there- Such liberal use of marijuana will cause an abuse epidemic</td>
<td>1/14/2017 6:20 PM</td>
</tr>
<tr>
<td>75</td>
<td>Rules should take into consideration pediatric populations - What steps will be in place to ensure safety? How will you prevent a vulnerable child with a qualifying diagnosis from possibly becoming used by a guardian or other individual for secondary gain to obtain medical marijuana?</td>
<td>1/14/2017 5:39 PM</td>
</tr>
<tr>
<td>76</td>
<td>Seems odd that a doctor might recommend a federally banned substance and risk DEA licensure.</td>
<td>1/14/2017 5:28 PM</td>
</tr>
<tr>
<td>77</td>
<td>Need to add arthritis and degenerative disc disease. These are not always curable conditions and can be very painful.</td>
<td>1/14/2017 5:21 PM</td>
</tr>
<tr>
<td>78</td>
<td>The rules aren't the issue. Medical marijuana is. It is a joke. It's a money maker for the state and the growers- that's what it is about. Marijuana causes depression and paranoia and is habit forming. We are cracking down on pain mess Burt are okay with prescribing weed? I don't agree</td>
<td>1/14/2017 4:47 PM</td>
</tr>
</tbody>
</table>
As a movement disorders specialist and neuroscientist I find it difficult to understand how disorders such as Parkinson disease and Tourette's disorder could become "approved" conditions. There is very little scientific evidence in support of the benefits of cannabinoids in these disorders, and no convincing clinical trials. Why are we bypassing science to fast-track unproven therapies? Of equal concern is the lack of dose and frequency control.

Would be much more beneficial to my patients to have an integrated mental health provider in my office than to passively numb my patients with yet another substance/drug! Patients too often take the easy way out instead of actively working on their health.

Scrap the whole thing

Scrap the whole marijuana issue. It is just a way for those looking to get high to do so legally. It serves no medical purpose.

Marijuana is not an FDA approved medication, nor is there good randomized control trials showing it is a benefit for any condition over existing proved medications. I would consider it however if it was an alternative to opiates although I don’t think patients would just accept one over the other

I would suggest that the physician education portion focus more on marijuana than on diagnosing the appropriate conditions, which I would hope anyone planning to recommend marijuana would know. There are so many different forms and purities of marijuana, issues about "dose" vs concentration, and implications with regard to contamination of the more than 70 bioactive compounds in the Cannabis plant - all of these would be important for anyone recommending this product to know. Also, my ability to prescribe it will depend on my hospital's legal position since I am employed by an organization that must comply with federal rules. We are considering this now but have not made any decisions.

I suspect the annual reporting requirement will effectively dissuade physicians from prescribing this. I for one am already overwhelmed with documentation requirements.

PARAMETERS ARE EXTREMELY NARROW

Patients on Medical Marijuana - If admitted to hospital will start requesting Marijuana or equivalent doses of opiate.

I don’t think they are restrictive enough

Qualifying conditions should be evidence based, and contraindications must be published.

Based upon current IOM and JAMA systematic review on conditions with true evidence based medicine, only neuropathic pain and spasticity of MS have high evidence for being treated by medical marijuana. Most of the conditions that Ohio states can be treated by medical marijuana have very little if any evidence for efficacy. We need to stop bowing to patient pressure, like we did with opioids, and use science and evidence in medical marijuana. It is our duty to hold treatments to a high level of evidence for efficacy and safety. Current guidelines do not do this.

I do not want to have the responsibility for people seeking to use this product through me. There will be too much abuse. The worst is when relatives take take and abuse substances and somehow the physician should somehow know this.

not interestede in providing medical pot

Without clear evidence in peer-reviewed literature, I am unlikely to ever recommend marijuana as a treatment.

not under the current opiate crisis

Physicians have enough paperwork. The requirement of an annual report is excessive. Marijuana has proven to be effective and prescription records show who is prescribing and how much. The need to produce an annual report could keep patients who could benefit from marijuana treatment from receiving it. Or force them to go to a doctor they don't know because their physician would prescribe it too rarely to bother with a report.

Fibromyalgia SHOULD NOT be included . I think even adding chronic pain conditions is a mistake. It is too easy for people to fake those diagnosis. We already have a huge opioid epidemic in OH, we don't need a huge population misusing THC too.

Please get available ASAP

HIV and AIDS should not be considered conditions that are treatable with marijuana. these patients are already immunosuppressed and smoking marijuana is associated with invasive fungal diseases like aspergillosis.

Why burden physicians with the annual report on effectiveness? Isn't that why we have research facilities?

Is the State Highway Patrol ready to deal with the triple threat of Alcohol, texting and marijuana on the highways? Are ERs prepared? We just went down this road with nacrotics. Are we going to let big business force us into a repeat performance.
101 None

102 do we have an option to not get this certificate?

103 Make it otc like tobacco and cigarettes. I don't want any part in prescribing marijuana.

104 I am still not comfortable prescribing medical marijuana--unless it is a palliative patient where we have exhausted all other options

105 An annual report is an excellent idea, but my main concern with this treatment is long term effects. Opioids are great for a few months to years, but the long term effects (endocrine, immunologic, psych) are what bother me. I have a similar concern with medical marijuana.

106 Outrageous to validate the use of marijuana while making it hard on me to prescribe even tramadol

107 There needs to be a mechanism for removing a patient's access to marijuana if they present with cannabis hyperemesis syndrome.

108 Crohn's or sickle cell hopefully end stage The 180 day waiting period for approval to get the drug may make submission of an application be done in anticipation of when it is needed because of the long wait time. Why not tie it to dea rather than yet another certificate

109 Make as restrictive as possible.

110 will observe

111 Would this be marijuana that is smoked, tch concentrat, in edible/pills form, or all of the above?

112 Draft rules as presented I think would be in violation of federal regulation and should not be adopted. The use of medical marijuana by prescription at this time should be restricted to clinical research studies only until risk/benefit of the use of this substance can be proven.

113 should be straightforward and uncomplicated. It should be a "no brainer" to offer to patients suffering from cancer, esp where other drugs are not improving the QOL

114 Conditions treatable should have actual evidence-based proof of effect. For example, I see Hep C on the list...please. Is there any proof of value here?

115 Medical marijuana is oxymoron.

116 Make patient aware these federal law still prohibits its use and drug screen will be considered positive, This med is certified by their physician not prescribed

117 Medical marijuana is a terrible idea.

118 Marijuana should not be prescribed without passing studies with rigors equivalent to that of the FDA.

119 Side effects of it outweighs any benefit

120 The draft rules look good but as a psychiatrist I manage too many patients with addiction issues and would be concerned about this becoming an additional addiction.

121 I have an Ohio license, but live and practice in Oregon. Our clinic system has a no medical marijuana card policy. Additionally, no opioids prescribed in our clinic if you are using medical marijuana. You should consider adding this your regulations, at least for non-cancer pain.

122 I do not intend to prescribe medical marijuana.

123 I will not prescribe. There are too many risks to patients and family

124 State law should follow and be consistent with federal law

125 Seems fairly thorough and fair

126 Too vague.

127 Against federal rules

128 I have been treating both PTSD and Tourette's Disorder for 18 years. I have not had any patients in that time for whom I have felt marijuana would be helpful. In my professional experience, I have found that patients with PTSD generally find it makes them more anxious when they attempt to self-medicate with it.

129 Complicated and obfuscating.

130 The annual report is beyond the scope of practice without establishing a web based registry for patient input.

131 Available research and evidence of the benefits is poor to say the least.
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>132</td>
<td>I suspect that everybody in Ohio will soon have a diagnosis of fibromyalgia.</td>
</tr>
<tr>
<td>133</td>
<td>I work for the VA, a government organization that does not support use of marijuana based on its classification as a Class 1 drug.</td>
</tr>
<tr>
<td>134</td>
<td>No comments at this time.</td>
</tr>
<tr>
<td>135</td>
<td>I see medical marijuana as a back door pathway to legalized use, and likely to be abused by some providers to administer to young people with marginal indications...see California, Colorado experiences</td>
</tr>
<tr>
<td>136</td>
<td>Marinol really helps me when I manage hospice patients and others with failure to thrive, poor appetite, etc., so I look forward to continued uses of medical marijuana in the future.</td>
</tr>
<tr>
<td>137</td>
<td>The draft rules restricting physician ownership in any medical marijuana businesses are unfair and short sighted. Physicians take an oath to act only in the best interests of their patients. Who else involved in this industry can say the same.</td>
</tr>
<tr>
<td>138</td>
<td>I agree with minimal medical use only approved by a medical board</td>
</tr>
<tr>
<td>139</td>
<td>Believe this is overreach on the part of the board.</td>
</tr>
<tr>
<td>140</td>
<td>more details as to what the year end report would entail.</td>
</tr>
<tr>
<td>141</td>
<td>There was no mention of many psychiatric diagnoses.</td>
</tr>
<tr>
<td>142</td>
<td>I think this practice should be taken on by those with specific training, only, as there is a high likelihood of inappropriate drug seeking; I don't plan to incorporate this training into my practice.</td>
</tr>
<tr>
<td>143</td>
<td>As a psychiatrist I have patients who suffer from migraines, other types of headaches and depression, anxiety, agitation and even mixed mood states. I would like these conditions to be considered as legitimate reasons for prescribing this.</td>
</tr>
<tr>
<td>144</td>
<td>Why is an annual efficacy report required? Seems burdensome, not particularly valuable, and we don't do that for other treatments.</td>
</tr>
<tr>
<td>145</td>
<td>They seem appropriate</td>
</tr>
<tr>
<td>146</td>
<td>It should be legalized. Not medicalized</td>
</tr>
<tr>
<td>147</td>
<td>not so sure about fibromyalgia as a qualifying condition</td>
</tr>
<tr>
<td>148</td>
<td>The evidence for medical marijuana is poor at best. No other substance which such poor evidence would ever be considered for a &quot;rule&quot;.</td>
</tr>
<tr>
<td>149</td>
<td>As a physician who has been in Addiction medicine for nearly 3 decades, I strongly believe that marijuana is a gateway drug. Every effort should be made to prevent more addiction problems down the road—20, 30 years from now; that we would not have legitimized another path to addiction. Please mark my word!</td>
</tr>
<tr>
<td>150</td>
<td>This is one of the biggest health care errors our state could make. Virtually every patient I treat with Vivitrol for opioid or alcohol addiction have used and cont to use marijuana. What are we thinking?</td>
</tr>
<tr>
<td>151</td>
<td>The reporting of the annual report is a deal breaker for me. I do not believe this is part of the law that was passed and is very inappropriate for the state medical board to make this part of the requirements, unless of course your goal is to keep this from easily being available to patients.</td>
</tr>
<tr>
<td>152</td>
<td>There should be language such as &quot;No penalty shall be imposed for physicians who choose to refrain from prescribing medical marijuana.&quot;</td>
</tr>
<tr>
<td>153</td>
<td>The diagnosis of chronic pain will include a wide range of patient</td>
</tr>
<tr>
<td>154</td>
<td>I believe medical marijuana is a farce and the conditions that have been selected so vague and subjective-based that we will be contributing to the drug abuse culture by prescribing it.</td>
</tr>
<tr>
<td>155</td>
<td>I cannot find the draft RULES- I have tried to find them and cannot. YOU do not have a link to the draft rules- Please send them out.</td>
</tr>
<tr>
<td>156</td>
<td>I do not believe the risks outweigh the benefits of use.</td>
</tr>
<tr>
<td>157</td>
<td>indicated conditions are narrow. Trials of other diseases should be allowed between a patient and physician.</td>
</tr>
<tr>
<td>158</td>
<td>Seems reasonable</td>
</tr>
<tr>
<td>159</td>
<td>Just concerned no matter what rules are put in place there will be abuse of marijuana.</td>
</tr>
</tbody>
</table>
I would never prescribe marijuana because our advanced medical system has better drugs than marijuana (even a few derived from marijuana). It should just be legalized for recreational use instead of making it legal under the guise of "medicine" for political reasons. Marijuana will help lots of people feel better for the conditions for which it is approved (and many other conditions), just like a couple glasses of wine, scotch, meditation, strong social support, or a variety of other life style modifications.

Wanna see a mess? Go to Boulder Co and see how many kids get flushed out of school cause they cant handle legal pot. Beware the slippery slope

They seem reasonable.

My main concern regarding medical marijuana is regulation regarding safe driving while using, similar to alcohol, as well as regulation to avoid overuse in adolescents.

I would be willing to prescribe CBD but not THC. If THC is needed for a qualifying condition such as a terminal disease, then I would consider. I think more than half of the medical THC rx's are a sham. I'm from Michigan and plenty of abuses there.

No standardization of specific drug and concentration

If I read them correctly as a DPM I would not be able to prescribe medical marijuana anyway. What is the point of filling out this survey?

It would be a lot more compelling to use this if there was evidence of benefit for each condition.

Why yearly report?

More specific guidelines regarding prescribing marijuana for the listed conditions

Draft rules are reasonable but what do you do when you work at a large hospital and a patient comes in with a home prescription? How do we continue it in the hospital?

I am concerned that federal and state laws will have to match.

Good to have rules and regulations. Even despite these, there appear obvious loop holes. One is a petition for a diagnosis not stated. And the less objective diagnosis such as the fibromyalgia may shoot up in incidence. You may see the typical 3 ring circus that drives up cost (patient who desires it, physician who makes money off seeing them and prescribing it, and the pharmacy who makes it's share). Not to. Emotion the new line up of drugs from the pharmaceuticals. This will be the new moneymaking machine "pill mill" for those who see an opportunity. There are a few bad apples and for them, treating patients comes second to monetary gain. Perhaps I'm being negative but I've very concerned about the future. Please consider the following: one area should be cost. One regulation might be to restrict the number of patients seen by any particular physician (to avoid the surge of patients after word of mouth and lines out the door of a "popular physician"). Perhaps they need to keep a file and report of all patients seen that are treated and their diagnosis. If it's a few ok. If it's prescribed more than HCTZ by a primary care practice, or they see more fibromyalgia than the usual prevalence rates, there may be over use/prescribing. Good luck.

I think the diagnoses to treat must be very specific to a given pathological condition and not just for a "chronic condition" which can broaden it use.

Good to have rules and regulations. Even despite these, there appear obvious loop holes. One is a petition for a diagnosis not stated. And the less objective diagnosis such as the fibromyalgia may shoot up in incidence. You may see the typical 3 ring circus that drives up cost (patient who desires it, physician who makes money off seeing them and prescribing it, and the pharmacy who makes it's share). Not to. Emotion the new line up of drugs from the pharmaceuticals. This will be the new moneymaking machine "pill mill" for those who see an opportunity. There are a few bad apples and for them, treating patients comes second to monetary gain. Perhaps I'm being negative but I've very concerned about the future. Please consider the following: one area should be cost. One regulation might be to restrict the number of patients seen by any particular physician (to avoid the surge of patients after word of mouth and lines out the door of a "popular physician"). Perhaps they need to keep a file and report of all patients seen that are treated and their diagnosis. If it's a few ok. If it's prescribed more than HCTZ by a primary care practice, or they see more fibromyalgia than the usual prevalence rates, there may be over use/prescribing. Good luck.

Why is + HIV status considered to be an eligible condition and why is positive Hep C an eligible condition? Is this just a political issue?

It's crazy. There are plenty of other legitimate treatments,ent options.

personally, I think MJ should be legal for personal cultivation even though I do not use it. I do not like MDs giving unproven therapies but I think MDs should be able to prescribe when they judge it to be reasonable.

They seem reasonable to me.

I think drivers on marijuana are as dangerous as drivers on alcohol.
<table>
<thead>
<tr>
<th>ID</th>
<th>Text</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>185</td>
<td>Who cares? Liberalism is gradually converting us into a nation of drug users. We are no longer in a democracy where the values of majority is respected.</td>
<td>1/13/2017 2:04 PM</td>
</tr>
<tr>
<td>186</td>
<td>Annual report could be cumbersome, depending on level of specificity that is required.</td>
<td>1/13/2017 1:58 PM</td>
</tr>
<tr>
<td>187</td>
<td>N/A</td>
<td>1/13/2017 1:52 PM</td>
</tr>
<tr>
<td>188</td>
<td>Most docs will do the right thing; however, there are docs who won't. Now we have effectively legalized MaryJane. What possibly could go wrong? The prescription opioid problem we have now is a result of docs over treating their patients. And better yet we think it's &quot;safe.&quot; Wait until we have a generation of stoned moms and babies! Oh yes! This Medicinal med will make it to the streets.</td>
<td>1/13/2017 1:48 PM</td>
</tr>
<tr>
<td>189</td>
<td>Use evidence based research to determine rules instead of lies/tweets promoted by Trump, drug companies, and criminals.</td>
<td>1/13/2017 1:45 PM</td>
</tr>
<tr>
<td>190</td>
<td>Education requirements are not enough Video with risks and benefits should be made</td>
<td>1/13/2017 1:44 PM</td>
</tr>
<tr>
<td>191</td>
<td>I am not currently working and cannot answer some of the questions appropriately.</td>
<td>1/13/2017 1:41 PM</td>
</tr>
<tr>
<td>192</td>
<td>None</td>
<td>1/13/2017 1:33 PM</td>
</tr>
<tr>
<td>193</td>
<td>seems like an unnecessary administrative burden</td>
<td>1/13/2017 1:33 PM</td>
</tr>
<tr>
<td>194</td>
<td>Cannabis has no place in medicine</td>
<td>1/13/2017 1:29 PM</td>
</tr>
<tr>
<td>195</td>
<td>Properly credentialed physicians should not have onerous state restrictions to appropriately prescribe marijuana</td>
<td>1/13/2017 1:29 PM</td>
</tr>
<tr>
<td>196</td>
<td>looks good</td>
<td>1/13/2017 1:28 PM</td>
</tr>
<tr>
<td>197</td>
<td>I did 4 yrs in ann arbor mi. in the 70s and pot was a $% fine. We had to smell it in the hospital halls and as transportation smoked pot we lost specimens at the hospital. People drank alcohol with thwe poat at concerts and the med school tied for years to get the pot controlled. Never ha any patient say pot helped their pain.</td>
<td>1/13/2017 1:26 PM</td>
</tr>
<tr>
<td>198</td>
<td>Please treat this drug the same as any other controlled substance.</td>
<td>1/13/2017 1:20 PM</td>
</tr>
<tr>
<td>199</td>
<td>I am completely opposed to this type of extension of its use. Many of the listed &quot;conditions &quot; include those of a chronic inflammatory nature if defined at such as fibromyalgia and &quot;chronic pain syndromes toname just a couple of the obvious culprits. These patients are very capable of spinning symptom sets and getting whatever meds they perceive will help them in ways that are often hard to define. They abuse all sorts of drugs often within the boundaries of so called medical indications. Your list of eligible diagnoses basically allows almost anyone willing to spin a tail or describe lengthy symptom sets to get this agent. Neat way to have a lot of stoned people and for you to look politically correct. In addition many practitioners who really have patients with serious indications such as cancer cachexia, HIV complications, uncontrolled seizures to name a few of the better known medical indications, will refuse to prescribe because of the cumbersome nature of your rules and fear that errors could threaten their license to practice. This happened with some of the very cumbersome rules for pain management substances all of which is well known. This is not theoretical to me as my practice is Medical Oncology/Hematology. In your push to follow the crowd of those states who have bent under the pressure of the Marijuana advocates, you will make it more difficult for patients with legitimate medical diagnoses to have access. One last comment- more and more data is appearing to show a deleterious effect on brain development and function in the young and well into the upper teens [please recall the recently published Japanese data]. I think marijuana should be virtually impossible to obtain in these young people except by Pediatric physicians specially trained for the indications. An 18 year old purporting to have a chronic inflammatory condition or fibromyalgia or any set of chronic symptoms does not qualify until we know a lot more about the safety of this substance on the brain. Will I personally use Marinol as I have done for two decades for indicated Oncology patients? The answer is NO!! I cannot trust a system that is so complicated and potentially punitive and I cannot condone or be part of a system that has so much potential for extrapolation to recreational use. Great work Medical Board. Just following the crowd!!</td>
<td>1/13/2017 1:16 PM</td>
</tr>
<tr>
<td>200</td>
<td>This will create a wave of physicians entering Ohio solely to become Pot Docs.</td>
<td>1/13/2017 1:10 PM</td>
</tr>
<tr>
<td>201</td>
<td>I am concerned as to how the approved forms would be treated if they are misused. It is not recommended to smoke it, but people will likely turn the plant into a cigarette form to smoke it. What would the consequences of misuse be?</td>
<td>1/13/2017 1:08 PM</td>
</tr>
<tr>
<td>202</td>
<td>I think they are appropriate. Just too much work and risk for me to prescribe marijuana.</td>
<td>1/13/2017 1:07 PM</td>
</tr>
<tr>
<td>203</td>
<td>If any other drug had the side effects and risks of medical marijuana it would never be approved by the FDA due to safety concerns. Marijuana should not be used medically.</td>
<td>1/13/2017 1:04 PM</td>
</tr>
<tr>
<td>204</td>
<td>I am against this.</td>
<td>1/13/2017 1:01 PM</td>
</tr>
<tr>
<td>205</td>
<td>Marijuana may have a beneficial role in Hospice Patients.</td>
<td>1/13/2017 12:58 PM</td>
</tr>
<tr>
<td>206</td>
<td>Please allow docs to sell and prescribe medical marijuana.</td>
<td>1/13/2017 12:48 PM</td>
</tr>
<tr>
<td>ID</td>
<td>Comment</td>
<td>Date</td>
</tr>
<tr>
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<td>-------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>207</td>
<td>Marijuana is illegal as per federal laws. There is no medical need for it. The State is worried about drug addiction with opiates and then is STUPID enough to try to skirt federal law for what will amount to more drug problems for Ohio. Stop the ridiculousness.</td>
<td>1/13/2017 12:45 PM</td>
</tr>
<tr>
<td>208</td>
<td>The annual report seems excessive &amp; almost a blatant deterrent placed upon physicians. I believe adequate documentation in patients' charts indicating the effectiveness of treatment should suffice.</td>
<td>1/13/2017 12:44 PM</td>
</tr>
<tr>
<td>209</td>
<td>How can there possibly be any justification for use of marijuana in the treatment of fibromyalgia when it is well known that opioids and similar medications increase pain in these individuals? I believe promoting inhaled marijuana as a superior means compared to oral intake is a complete farce and should not be supported by any reputable medical organization.</td>
<td>1/13/2017 12:39 PM</td>
</tr>
<tr>
<td>210</td>
<td>The rules pertaining to annual documentation and extensive record keeping seem superfluous. It would be more reasonable to track use of this as we would with benzodiazepines and opiates; with drug screens and frequent OARRS reports. If we are going to state that marijuana has medical value to treat, PTSD, for example, why would I have to prove it's benefit in patients with excessive record keeping and annual reports whereas the same is not done for patients with PTSD who are prescribed benzodiazepines. I would submit that both of these have similar abuse potential, perhaps even more with benzodiazepines. I similarly feel the registry of patients is superfluous for the same reasons. If we are using marijuana for medical purposes, as a controlled substance, it would seem reasonable that the same rules for substances like benzodiazepines would apply. I also worry about where the patient information on such a registry is stored, who is viewing it and what for what purposes these patients are being tracked. If the registry is somehow necessary, the use of information must be made transparently available to the public, especially to the patients who will be on it.</td>
<td>1/13/2017 12:39 PM</td>
</tr>
<tr>
<td>211</td>
<td>None</td>
<td>1/13/2017 12:38 PM</td>
</tr>
<tr>
<td>212</td>
<td>Marijuana should have been decriminalized years ago.</td>
<td>1/13/2017 12:34 PM</td>
</tr>
<tr>
<td>213</td>
<td>None</td>
<td>1/13/2017 12:33 PM</td>
</tr>
<tr>
<td>214</td>
<td>very vague right now</td>
<td>1/13/2017 12:30 PM</td>
</tr>
<tr>
<td>215</td>
<td>I think the rule about certified (to prescribe/recommend) physicians not being able own a dispensary is unfair as these physicians may be more likely to be open towards medical marijuana use for patients. I understand the need or thought to prevent unwarranted over prescription of medical marijuana and possibly Stark Law issues with referring patients to their own dispensary; however, I feel that patients will chose a convenient dispensary, and physicians wouldn't force patients to use their dispensary. I strongly encourage the board to reconsider that rule.</td>
<td>1/13/2017 12:24 PM</td>
</tr>
<tr>
<td>216</td>
<td>I see very little reason to prescribe &quot;medical&quot; marijuana.</td>
<td>1/13/2017 12:23 PM</td>
</tr>
<tr>
<td>217</td>
<td>None</td>
<td>1/13/2017 12:17 PM</td>
</tr>
<tr>
<td>218</td>
<td>I won't participate if I am not allowed to have any other interests in the medical marijuana business. It is wrong to presume that there would be a conflict of interest.</td>
<td>1/13/2017 12:17 PM</td>
</tr>
<tr>
<td>219</td>
<td>I do not think that prescribing it should involve too much paper work and overload the physician unnecessarily. It should be no different from prescribing any narcotic, anti-epileptic or any other medication for a medical condition which would benefit from its use. It should be left to the judgment of the treating physician, like other medications without putting any further restrictions and red tape.</td>
<td>1/13/2017 12:17 PM</td>
</tr>
<tr>
<td>220</td>
<td>I think that there should be age limits on the medical marijuana use. I think it will be critical that only 1 treating physician manage a patient's pain and marijuana use</td>
<td>1/13/2017 12:15 PM</td>
</tr>
<tr>
<td>221</td>
<td>Rules are good for writing and publishing and putting on other but in real world if you have to practice medicine it creates only problems. You should have guidelines and not these rules.</td>
<td>1/13/2017 12:13 PM</td>
</tr>
<tr>
<td>222</td>
<td>Needed</td>
<td>1/13/2017 12:11 PM</td>
</tr>
<tr>
<td>223</td>
<td>Drug discovery should not be done by states. There is a federal system called FDA that does this. This is just a dodge to appease the drug culture.</td>
<td>1/13/2017 12:08 PM</td>
</tr>
<tr>
<td>224</td>
<td>I do not have any</td>
<td>1/13/2017 12:08 PM</td>
</tr>
<tr>
<td>225</td>
<td>Over regulation</td>
<td>1/13/2017 12:03 PM</td>
</tr>
<tr>
<td>ID</td>
<td>Comment</td>
<td>Date/Time</td>
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</tr>
<tr>
<td>226</td>
<td>I think that proper control and enforcement of any rules will not be adequate: who will protect the public from a person using MJ and operating a motor vehicle, aircraft, watercraft? What are the reporting requirements to other governing bodies other than Medical Board or Pharmacy board (like Motor Vehicles, License Bureau, Insuring agencies/companies, FAA, employers)? will &quot;medical&quot; insurance cover cost of MJ? - I personally do not endorse insurance premiums (or state/federal wage withholdings) going up to cover a federally illegal substance. Will the medical MJ be biologically or chemically &quot;tagged&quot; to allow law enforcement to assess concretely usage to allow for prosecution of usage by individuals in situations that can adversely affect public health and welfare? The potential for misuse and abuse are great - akin to other controlled substances - and scrutiny must be extremely high - I view this as nothing more than an avenue for individuals to obtain MJ for recreational use with a further expansion of public health and safety issues associated with it akin to those encountered with other DEA controlled substances, legal alcohol used irresponsibly, and illicit drugs also used irresponsibly and with addiction and personal health issues in addition to public health issues. Make it easier to enforce any rules made by limiting the number of dispensaries and prescribers to a firm fixed number per capita and have routine reporting and inspections by law enforcement. The whole thing is a bad idea.</td>
<td>1/13/2017 11:56 AM</td>
</tr>
<tr>
<td>227</td>
<td>I prefer to prescribe medical marijuana for fibromyalgia and chronic pain rather than narcotics.</td>
<td>1/13/2017 11:56 AM</td>
</tr>
<tr>
<td>228</td>
<td>Reports to the State from physician regarding the efficacy of treatment should probably be twice a year, not once a year.</td>
<td>1/13/2017 11:55 AM</td>
</tr>
<tr>
<td>229</td>
<td>Where is the data showing evidence of effectiveness of MJ for treating these conditions</td>
<td>1/13/2017 11:50 AM</td>
</tr>
<tr>
<td>230</td>
<td>You know this is a special interest issue which is going to only enrich certain individuals while destroying families in Ohio. Shame on you. Shame on the governor.</td>
<td>1/13/2017 11:49 AM</td>
</tr>
<tr>
<td>231</td>
<td>The whole thing is a money making scam.</td>
<td>1/13/2017 11:46 AM</td>
</tr>
<tr>
<td>232</td>
<td>Read benefit and less long term side effects and less abuse of narcotics.</td>
<td>1/13/2017 11:44 AM</td>
</tr>
<tr>
<td>233</td>
<td>They are thoughtful.</td>
<td>1/13/2017 11:39 AM</td>
</tr>
<tr>
<td>234</td>
<td>The list of conditions is random and for the most part is driven by emotion and opinion, not science. It is important not to confuse what is being labeled as a &quot;qualifying&quot; condition with what we typically think about as an &quot;indication&quot;, which requires multiple positive controlled trials.</td>
<td>1/13/2017 11:39 AM</td>
</tr>
<tr>
<td>235</td>
<td>I am a retired physician with active license.</td>
<td>1/13/2017 11:36 AM</td>
</tr>
<tr>
<td>236</td>
<td>These will make the problem worse just like 2002 with the narcotics check list.</td>
<td>1/13/2017 11:34 AM</td>
</tr>
<tr>
<td>237</td>
<td>1. I think that this needs to be monitored very closely. 2. If the indications change or the available scientific evidence changes recommendations, it should be widely disseminated and rapidly incorporated. 3. There needs to be a clear description of the risks of this therapy as well.</td>
<td>1/13/2017 11:30 AM</td>
</tr>
<tr>
<td>238</td>
<td>It is important now that the State is taking this action that we all be advised as to handle overdose, emergency treatment while patient is under influence, etc.</td>
<td>1/13/2017 11:29 AM</td>
</tr>
<tr>
<td>239</td>
<td>I have none</td>
<td>1/13/2017 11:28 AM</td>
</tr>
<tr>
<td>240</td>
<td>N/A</td>
<td>1/13/2017 11:27 AM</td>
</tr>
<tr>
<td>241</td>
<td>Rules are much too liberal. Ramifications of these changes in laws will increase problems associated with drug use/abuse in a society. At most, license should be granted only to subspecialists in oncology, possibly neurology as well.</td>
<td>1/13/2017 11:26 AM</td>
</tr>
<tr>
<td>242</td>
<td>there are enough other alternatives, that medical cannabis not needed.</td>
<td>1/13/2017 11:25 AM</td>
</tr>
<tr>
<td>243</td>
<td>Bad idea</td>
<td>1/13/2017 11:22 AM</td>
</tr>
<tr>
<td>244</td>
<td>I believe there are many of my patients who would benefit from having this treatment option available to them, who have failed all other traditional TX options.</td>
<td>1/13/2017 11:21 AM</td>
</tr>
<tr>
<td>245</td>
<td>Potential for abuse is great! Pts are not always completely honest. Drs function on the basis of pts telling them the truth. Yet the one thing substance abusers all seem to have in common is willingness to deceive to get what they want or need.</td>
<td>1/13/2017 11:19 AM</td>
</tr>
<tr>
<td>246</td>
<td>The requirement for the annual report is arbitrary and subjective. In addition, it would not be patient specific. I do not see its relevancy to this process.</td>
<td>1/13/2017 11:19 AM</td>
</tr>
<tr>
<td>247</td>
<td>would consider for all except HIV and hep C, I treat a great number of both and unless they have another comorbid condition THC would be not medical but recreational</td>
<td>1/13/2017 11:15 AM</td>
</tr>
<tr>
<td>248</td>
<td>I would need clear understanding of the dosage to be use for different situations, what is the side effect profile and I would need it in a pill form with a clear amount of mg.</td>
<td>1/13/2017 11:14 AM</td>
</tr>
</tbody>
</table>
I would want more objective evidence that good outweighs harm. There is one type of seizures I know it helps—but I would want a neurologist to manage.

I have attended a medical marijuana convention in Baltimore, MD, and have continued my research on the use of medical marijuana in various medical conditions, especially in my field of orthopedic/neurologic conditions. I feel it is important for any doctor to prescribe marijuana to patients to understand the right conditions and benefits that it may provide without causing overall harm to the patient.

I would recommend expanding chronic intractable pain to complex unexplained syndromes, interstitial cystitis, headaches...

People need to realize that marijuana is progressing towards legalization for recreational use in all states over the next 10 years. Please be careful with punishment and severe mix signals with something that may be legal soon.

Prescription of medical marijuana should be restricted to physicians whose practice includes the care of those patients with a diagnosis that may benefit from the drug, with adequate documentation in records.

They seem reasonable, but a 90-day supply seems excessive and too likely to lead to abuse and diversion.

I think your plan is well thought out and reasonable.

I am a psychiatrist and the American Psychiatric Association holds the position that marijuana has not been proven safe and effective for the treatment of any psychiatric illness.

They are negated by current clinical and scientific research showing no definable medical benefit to marijuana for the conditions listed.

In dealing with patients in acute pain that have a history of chronic pain, I would be interested in prescribing MMJ. I believe all non-opioid adjuvant pain relievers should be on the table.

I would consider anxiety as a prudent indication if managed properly.

List of treatable conditions is too limited. This will lead to significant issues. Some patients who would benefit will be excluded. Is the Board prepared to oversee the diagnoses of providers?

I did not read cultivator or dispensary rules as they are too long. I would like you to immediately legalize cannabidiol (CBD) oil, as it is derived from agricultural hemp and contains virtually no THC. It is wrong that it is not legal already. It can help with so many conditions, as there are cannabinoid receptors throughout the body and CBD oil helps with bringing homeostasis to the body in people with many destabilizing conditions.

Just not sure if I am comfortable prescribing it with the type of patient population it will likely bring in the door.

There should be something in place so that we are not publicized as providers for medical marijuana to the public/patients. For instance, I am an oncologist who is considering prescribing medical marijuana to selected patients in my patient panel for relief of nausea, pain, etc. associated with their cancers. I absolutely do NOT want to be on some list that makes it so patients SEEK ME OUT specifically for this purpose. And I absolutely do NOT want to be seeing patients that are inappropriate for an oncology office just because they want someone to provide medical marijuana. I'm torn. I think there are some patients in my practice who could benefit, but I do not want to do it at all if I am somehow going to go on a list that drives new (and sometimes questionable) patients to me.

I am not convinced about utility of marijuana in medical practice.

The annual report of benefits seems useless unless it is set up as a study with specific scales to measure change.

I would hope that medical marijuana would only be available for conditions with objective findings. I have great hesitation to place "subjective" diseases like fibromyalgia on this list.

The studies in epilepsy are mostly being done with an ingredient of marijuana—not the entire substance.

You have an opioid epidemic base off of chronic non-malignant pain. The data has not shown benefits to outweigh the risk. Including pain is a mistake. We are still trying to get PCP to stop giving everyone opioids for basic lumbar sprains.

Totally against marijuana use.
276 I think the list of qualifying conditions is too broad. I don't believe there is good enough evidence to provide medical marijuana for several of those conditions except on an experimental basis.

1/13/2017 10:31 AM

277 An annual report may prove cumbersome providers, an electronic standardize form that captures, medical diagnoses treated, number of patients, amounts prescribed, frequency of visits, and types of metrics that are helpful for assessing effectiveness of therapy would be helpful. Without a guideline, the treatment effectiveness will be very subjective across providers and practices and run the risk of contradictions.

1/13/2017 10:31 AM

278 Not sure of the use in my practice

1/13/2017 10:26 AM

279 I work for a county hospital and would need approval from legal counsel before applying for an eligibility certificate

1/13/2017 10:25 AM

280 I will wait until more articles.

1/13/2017 10:21 AM

281 I have to abide by the Cleveland clinic overall recommendation

1/13/2017 10:20 AM

282 None at this time.

1/13/2017 10:19 AM

283 .

1/13/2017 10:18 AM

284 Seem reasonable.

1/13/2017 10:18 AM

285 n/a

1/13/2017 10:18 AM

286 High margin medical safety

1/13/2017 10:18 AM

287 Little 'science' behind this. Just legalize the product and take the 'medical' part out.

1/13/2017 10:16 AM

288 hate smoking marijuana when we have marinol for years, now other, for nausea/cachexia in cancer patients , most of these people who want it want to get high , smoke alone cause cancer , if i ever prescribe it for severe symptoms not relieved by other means it will be pill or liquid form.

1/13/2017 10:16 AM

289 The literature is not strong enough to support its use and the potential for abuse is very high.

1/13/2017 10:16 AM


1/13/2017 10:14 AM

291 An annual report seems onerous.

1/13/2017 10:12 AM

292 I am not aware of convincing evidence based data to support the use of marijuana for many of the disorders that I generally treat despite the fact that some of those disorders are on the list. I worry about patients resenting the fact that I am reluctant to prescribe this for "medical " use.

1/13/2017 10:12 AM

293 why need annual report. not needed for other medications or procedures.

1/13/2017 10:10 AM

294 None. Rules seem fair and appropriate.

1/13/2017 10:10 AM

295 I am concerned that, although these unfortunate pts may be aided by treatment, I suspect most certainly be abused and used by family members, friends, etc.

1/13/2017 10:09 AM

296 1) stop calling this "medical" marijuana. Why would any physician recommend smoking anything, given the well established toxins within smoke. If someone has strep throat we do not give them moldy bread; we purify the active ingredient and give them penicillin. Until research has identified and purified the active ingredients of interest (as has been done for marinol), this is NOT medicine. 2) have patients sign a letter of informed consent that acknowledges that smoking anything can be harmful and lead to death (much like the black box on cigarettes!). Patients should be forced to acknowledge that they are taking a calculated risk.

1/13/2017 10:05 AM
Rules seem clearly constructed to both benefit a pro medical marijuana lobby and to promote a financial agenda for a limited number of individuals that will be able to garner significant profit from the production distribution and sale of this product. The rush to silently push this legislation through is interesting in this light and I’d be curious to see how the bills primary authors stand to profit as it does not seem they are excluded from participation in the growth distribution and sale of this product. The legislation is largely driven by clinical assumptions that have no basis in the peer reviewed medical literature (for the most part) and present marijuana as a panacea for all maladies. There is no provision to educate the public about the risks of marijuana use, particularly to young children with chronic illnesses for whom its use (administered by parents) is rampant and (largely) inappropriate. There is no provision in the bill to dispel myths like medical marijuana cures cancer (and others). The bill largely ignores the well documented concerns about consumables (humorously suggesting that somehow simply making the packaging less attractive to children will prevent them from eating the cookies, brownies, etc... that medical marijuana will almost certainly be marketed in. In short a very poorly written bit of legislation that largely ignores medical fact in favor of financial gain for a minority and a growing public demand to get high - even in the setting of a crisis in opioid and, specifically, heroin use. It is highly disturbing that the state medical board has remained so silent on this issue.

I have no money problems with the draft rules but I will not be prescribing medical marijuana in my practice

Too cumbersome

No comment. MJ is probably less harmful than smoking tobacco or alcohol, so I doubt harm will come of it.

You have to be kidding me. There is currently an opiate and heroin epidemic going on in Ohio. People are dying every day and you develop these guidelines for Marijuana and do not even consider the more dangerous substances physicians are prescribing every day without a second thought. Narcotic pain medications and their control is so much more important than Marijuana. I think the provider provisions you have developed should be in place for prescribing narcotics which are a much bigger threat to our patient populations. Great job but I think you are missing the forest for the marijuana bush.

long –complex

I'm a medical oncologist so I would make a patient referral for MM to a physician specializing in Pain Management.

I am pleased that there will be adequate restrictions in place. It should not be easy to prescribe. It is important to back check use to make sure that the treatment is stopped if there is no response.

With all the drug problems OHIO has this is a bad law.

I am a pediatrician and think that only palliative care and pain specialists should be managing medical Marijuana

Use should be limited to conditions for which there are scientific data, not simply anecdotes, to support its use, just as for any drug physicians prescribe

It needs to be more clear what is going to be involved in the annual report.

I don't think we should restrict Dpms as chronic pain is a potential use

There is not yet scientific evidence to support the use of medical marijuana so I would never prescribe it until such evidence exists. And even then, it would be unlikely that I would ever prescribe it.

Rules are fine - Question 6 didn't allow for our health system (OhioHealth) to have said that they are currently reviewing and figuring out the impact of these guidelines, so they really haven't made a determination yet...but for now, they are not allowing it until they have had time to evaluate things. I marked "No" for this reason, which may skew your data pool - considering the size of OhioHealth's influence.

A stupid solution forwarded by a lazy society.

lack scientific evidence in most indications

Do not feel that an accepted list of qualified conditions being defined is necessary given the way that marijuana is regulated in other states, and feel it will limit utility for more rare conditions that will show the most benefit.

don't think we should restrict Dpms as chronic pain is a potential use

There will need to be a review process to ensure physicians are caring for these patients in an ongoing fashion.

Marijuana should be legal. Period.

I am not in agreement on MM however do understand it is now legal.
321 I do not believe that all the conditions listed should qualify for medical Marijuana. Have very difficult time considering some of those conditions as an indication.

322 All use of marijuana should be predicated on the results of high quality randomized trials. The same level of evidence required to support an indication for all other drugs and therapeutics should also apply to marijuana.

323 Great place to start.

324 Since you (the State Medical Board) are making it as difficult as possible to prescribe narcotics for chronic pain, but now are explicitly authorizing the prescribing of marijuana for chronic pain, the overwhelming impression is that you would strongly prefer that prescribers use marijuana rather than narcotics to treat chronic pain. I would therefore hope that the draft rules do not make the prescribing of marijuana even more odious than the current process for prescribing narcotics.

325 not involved in prescribing these drugs.

326 considering the risk of schizophrenia with marijuana, I would be very hesitant to prescribe this medication for anything besides terminal illnesses.

327 Recommendations and guidelines for our prescribing practices should come from scientific, double blind studies, with FDA and federal oversite, not based on anecdotal evidence deemed legitimate by the legislature. Calling something “medical” does not make it medical.

328 The only reason to make AIDS a qualifying condition is for the specific diagnosis of AIDS wasting syndrome. AIDS or HIV diagnosis by itself should not be a qualifying condition. I am an HIV specialist with extensive experience in treatment and research of HIV.

329 Dpms need to be included in the ability to recommend and or prescribe medical marijuana to our patients as we have full prescribing abilities through the DEA, including opiates and other narcotics.

330 I am against legalizing this drug under any circumstance.

331 ok

332 none

333 Repeal and replace seems the order order the day.

334 Being a physician specializing in Emergency Medicine I feel the ability of our specialty to utilize such medication in an acute setting will be limited.

335 patients with these chronic conditions are also taking numerous medications that alters neurotransmitters and we are unaware of the interactions of these drugs with marijuana. For example if marijuana is used for chronic pain then concomitant use of opioids should be contraindicated to reduce risk of overdose.

336 My opinion is that I don't see any real benefit for the use of this substance, mainly because I feel we already have enough other choices to treat these conditions and not necessarily narcotics. Lyrica might be one example.

337 I believe that the use of marijuana should be limited to extremely select cases.

338 I feel 2 hrs of cme are not sufficient. I know there are many studies underway to try and determine if there is any benefit over what treatments we currently have but most physicians I would think can not be up to date on this literature in 2 hrs.

339 Seems reasonable to me.

340 Doesn't discuss opioids or benzo use recommendations with marijuana. It doesn't specify about frequency of urine drug screens or visits.

341 Potential for misuse in certain diagnoses such as PTSD and guidelines or criteria to be established to identify and protect MDs.

342 The annual reporting of effectiveness must be standardized.

343 The qualifying medical conditions should be displayed in the draft rules.

344 The only qualifying condition I treat is glaucoma and there is not good evidence to support marijuana as a treatment for this. Dosing would need to be too frequent; less side effects with standard therapies.

345 Let's prescribe pharmaceutically active agents without the potentially toxic excipients found in the natural plant. "Medical Marijuana " deserves no special treatment. We are scientists first-not politicians! Let our lawmakers decide whether to legalize marijuana instead of asking the medical community to bring it in the back door.

346 Unsure of cannabis being effective to treat PTSD. Concern it's a condition that may be over exaggerated to receive cannabis.
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>347</td>
<td>Merely having hep C or HIV infection seems a weak indication for any treatment not specifically targeting those infections. I would suggest that the indications be more specific, such as HIV wasting or peripheral sensory neuropathy, or HCV cryoglobulinemic vasculitis.</td>
<td>1/11/2017 10:32 PM</td>
</tr>
<tr>
<td>348</td>
<td>The annual reporting requirements are likely to prevent many physicians from prescribing medical marijuana.</td>
<td>1/11/2017 10:08 PM</td>
</tr>
<tr>
<td>349</td>
<td>Use should be tightly controlled and restricted to physicians trained in the use of thc. Registry and follow up research is essential so the drug is used appropriately and for good clinical outcomes.</td>
<td>1/11/2017 9:41 PM</td>
</tr>
<tr>
<td>350</td>
<td>If you allow it for 10 diagnosis, then you would be asked to make an exception, etc</td>
<td>1/11/2017 9:19 PM</td>
</tr>
<tr>
<td>351</td>
<td>Should be presented as a medical prepartation with FDA approval a and controlled contents and sound medical evidence including dosing; no desire to become a drug intermediary for non medicinal preparations</td>
<td>1/11/2017 8:40 PM</td>
</tr>
<tr>
<td>352</td>
<td>I don't know that I really can provide a comment. My readings indicate the only potential indication for cannabadiol might be seizure disorder. I have many concerns about &quot;medical marijuana&quot; per se as an addiction psychiatrist</td>
<td>1/11/2017 7:16 PM</td>
</tr>
<tr>
<td>353</td>
<td>Don't add so much paperwork burden and practice cost</td>
<td>1/11/2017 6:46 PM</td>
</tr>
<tr>
<td>354</td>
<td>The list of &quot;qualifying conditions&quot; is amazing - just about any &quot;chronic&quot; condition qualifies. I am not aware of any Evidence-Based studies that &quot;prove&quot; this stuff works in all of these conditions. No way am I going to be involved in this &quot;game!&quot;</td>
<td>1/11/2017 2:53 PM</td>
</tr>
<tr>
<td>355</td>
<td>The draft rule I think is pretty good.I think it cover everything.</td>
<td>1/11/2017 2:07 PM</td>
</tr>
<tr>
<td>356</td>
<td>Investment interest in a cannabis related company should in no way be a restriction to ability to obtain certification to recommend medicinal cannabis. The cannabis industry is starting to be a booming new industry, predicted to be a multi-billion dollar industry, and investment opportunity should be open to all. This would be no different than physicians owning stock in healthcare related companies in which they simply provide full disclosure. At most, restriction to ownership in a company or stock could be considered if the company is somehow related to the Ohio cannabis industry. However, if the company that one owns stock in is unrelated to OH or even the US, this should in no way be a restriction to certification. Please remove this clause or revise.</td>
<td>1/11/2017 1:52 PM</td>
</tr>
<tr>
<td>357</td>
<td>Submitting an annual report seems burdensome.</td>
<td>1/11/2017 12:18 PM</td>
</tr>
<tr>
<td>358</td>
<td>Recommendation of marijuana for treatment resistant depression after ECT</td>
<td>1/11/2017 10:39 AM</td>
</tr>
<tr>
<td>359</td>
<td>I appreciate it's similarity to opiate prescription rules. This will help keep the rules clear and simple in the mind of prescribing physicians. I would want some more clarity on the annual report required on its efficacy.</td>
<td>1/11/2017 9:38 AM</td>
</tr>
<tr>
<td>360</td>
<td>as a medical oncologist I find very few uses or need for this &quot;drug&quot;</td>
<td>1/11/2017 9:22 AM</td>
</tr>
<tr>
<td>361</td>
<td>Why are DPM deemed unqualified to treat chronic pain in the lower extremity with medical marijuana.</td>
<td>1/11/2017 9:17 AM</td>
</tr>
<tr>
<td>362</td>
<td>If it provides a health benefit and is not abused I would support it. As long as it is properly regulated.</td>
<td>1/11/2017 8:48 AM</td>
</tr>
<tr>
<td>363</td>
<td>I will not be making any recommendations, for any patient, regardless of medical diagnosis, for medical marijuana as long as it remains illegal per the FEDERAL Government/DEA.</td>
<td>1/11/2017 8:43 AM</td>
</tr>
<tr>
<td>364</td>
<td>I believe this is still schedule I - &quot;no currently accepted medical use.&quot;</td>
<td>1/11/2017 8:42 AM</td>
</tr>
<tr>
<td>365</td>
<td>There may be medical conditions that may medical marijuana may help.</td>
<td>1/11/2017 7:17 AM</td>
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<tr>
<td>366</td>
<td>Remove the THC from all medical marijuana</td>
<td>1/11/2017 6:30 AM</td>
</tr>
<tr>
<td>367</td>
<td>too vague. It can be abused</td>
<td>1/10/2017 10:05 PM</td>
</tr>
<tr>
<td>368</td>
<td>I think the rules are well crafted. I don't think we have any business recommending medical marijuana until there are federal studies documenting benefit rather than patient report. Very sloppy medicine.</td>
<td>1/10/2017 7:45 PM</td>
</tr>
<tr>
<td>369</td>
<td>Make the registration of physician prescribers mandatory and define the yearly medical report better.</td>
<td>1/10/2017 7:33 PM</td>
</tr>
<tr>
<td>370</td>
<td>While I feel that recreational marijuana should be legalized, I do not feel that physicians should be in the marijuana business. I think it is absurd that I would give a &quot;recommendation&quot; for a &quot;medication&quot; without any input into how much or how often a patient would use this substance.</td>
<td>1/10/2017 7:18 PM</td>
</tr>
<tr>
<td>371</td>
<td>I practice in Colorado, having trained in Ohio and maintaining my license there as well. Please include in your 2 hour CME information for doctors information about cannabis hyperemesis syndrome, as we see this in my ER nearly daily. This is information that patients should know as part of their informed consent process.</td>
<td>1/10/2017 6:15 PM</td>
</tr>
<tr>
<td>372</td>
<td>Their is NO substantial body of evidence that &quot;medical&quot; marijuana does anything !!!! We already are dealing with opiates etc and then our dear governor then quietly passes &quot;medical marijuana&quot; when he is giving us physicians slides etc regarding drug abuse. Typical of our old political system &quot; TALK OUT OF YOUR MOUTH ON BOTH SIDES This is pure idiocy</td>
<td>1/10/2017 6:05 PM</td>
</tr>
</tbody>
</table>
The rules appear appropriate to me.

I am a pediatrician and am very concerned that children may be harmed by this law.

I'm not interested in prescribing.

I will not prescribe marijuana, under any circumstances. It is a federally illegal drug. It is a drug of abuse. It is a gateway drug, to move dangerous drugs. It has no proven medical value, including for pediatric epilepsy.

big hassle, will think twice about it

I am a pediatrician and am very concerned that children may be harmed by this law. I'm not interested in prescribing. I will not prescribe marijuana, under any circumstances. It is a federally illegal drug. It is a drug of abuse. It is a gateway drug, to move dangerous drugs. It has no proven medical value, including for pediatric epilepsy. I will not prescribe marijuana, under any circumstances. It is a federally illegal drug. It is a drug of abuse. It is a gateway drug, to move dangerous drugs. It has no proven medical value, including for pediatric epilepsy. big hassle, will think twice about it

Only concern is the detail / requirements of the annual report that this would be at standardized report and not be a burden to the prescriber

need fda approved indication

more confusing than needs to be

Many medical studies have recommended the use of medical marijuana as a treatment to wide range of diseases.

Rules appear to be reasonable, will be interesting to see what will be fee and process of the certification.

rules seem to make sense.

Results from states that have legalized medical marijuana have shown it reduces the need for opiates to manage pain.

While I understand the reasoning for making a reporting requirement, for me personally this makes I less likely that I will consider prescribing. While I don't think it will prevent physicians who prescribe inappropriately from doing so (although it may make it easier to prosecute them).

The law should never be passed. This is Kirk Shuring's baby! Follow the money. It's against Federal Law. How do you deposit the money? (Laundering) , how do you pay Federal taxes? You can't So where's the benefit. They should abolish this bill! Deeply against it.

Should not be allowed

I do not know if my employer will permit me to register to recommend medical marijuana, but I have patients who I believe would benefit. I believe the responsible prescribing of medical marijuana could help me to markedly reduce my opioid prescribing, which is something I am VERY interested in. I have a lot of questions about Rxing medical marijuana, and I feel we need to plan to fund responsible controlled scientific studies on the risks and benefits of medical marijuana with taxes from the sale of medical marijuana. For example, I think it will be hard to know what quantity of Marijuana is appropriate to Rx.

A lot of qualifying paperwork. Hope time of submitting to approval wont take forever

Medical marijuana has questionable, if any, value; this is just a successful ploy to introduce recreational MJ to the moronic public. After all none of our current heroin addicts started with MJ, did they? BTW ask the auto industry what helped to kill it, and substance abuse was high on the list (no pun intended).

Providers will need to be provided reminders regarding the 1 year updates on medical marijuana efficacy. Or a more appropriate study can be started statewide with protocols in place to evaluate the effect medical marijuana may have on patients

will likely not try to treat anyone with this therapy

I firmly believe it has medicinal uses and should be legalized.

Good initial draft

too much to follow and document in a busy practice, better not to prescrib

Make rx easier

This is a schedule I substance federally. This classification must be reconciled with state law. 2 hours of CME? There must not be much that is known. The rules are cumbersome and impossible to follow for a busy doctor treating complex patients. It would seem marijuana can be prescribed for any intractable pain, which means everyone has an indication for treatment. Asking providers to report on the effectiveness makes it look like the Board is running an experiment instead of protecting the public.

why additional annual report when we have a chart

I am unwilling to commit to a 2 hr CME in order to prescribe it

I would do it only if no onerous regulations will be installed.
I like them, I think they are fair. Getting feedback on the efficacy of the marijuana from the patients may be difficult.  

I will recommend it under limited circumstances but not prescribe it. I will leave the prescribing of it to other physicians. Marijuana, if legal, should be available without a prescription. If recreational marijuana is legal in some states (and I am not saying it should be), it should be legal in all states.  

The conflict of interest statement is inadequate ("In addition, the physician may not have any ownership interest in or compensation agreement with a medical marijuana entity"). This statement should be at least as complete as the typical "financial disclosure" statement used in research that includes the physician's spouse, children, etc and any indirect manner of profiting from the research in which the physician is participating. You must check those rules. What is here so far is grossly inadequate.  

It would be impractical to expect physicians to actively DISENROLL patients from the registry as that would also require the release if sensitive and possibly HipAA protected info, for access by anyone who reviews the registry.  

I think that the recommendation for use of Medical marijuana should be made by the treating specialist for each of the conditions only after documentation of failure of control of the target Sx by all conventional means, and should be based on results of evidence of effectiveness in randomized controlled clinical trials, not on the basis of anecdotal reports either in the literature, or by the prospective user him or herself that they have been using it for that purpose and it helped.  

I continue to struggle with this due to the at times negative effects of cannabis usage  

I would like the medical conditions organized by age-group.  

Giving a report to the state about the effectiveness of the drug seems odd.  

Physicians should be able to prescribe according to their specialty training only and not have carte blanche to prescribe for all approved conditions once they pass the generic approval process. Specialty boards need to offer prescribing guidelines for their respective members.  

No comment  

I do telemedicine and will not recommend medical marijuana for any patients due to the policies of my organization.  

very bad idea  

Keep up the good work. I believe Medical Marijuana is appropriate as a medical tool.  

Rules are appropriate and protective of patient and prescribers. Thank you for requiring a licensed person (pharmacist or prescriber) to be a director at the dispensaries. However I side with the DEA that medical marijuana has no legitimate safe medical use in the unrefined form and would NEVER request a certificate to recommend nor recommend this medication.  

Draft rules are appropriate  

chronic pain rules, previous evaluation by other specialist, patient history of no respond to other treatment.  

I agree to in principle to the rules.  

none  

I think the annual report is not likely to yield meaningful information and will waste a lot of people's time. Would be better to fund research to get data driven answers on the effectiveness for various conditions.  

make it clear what form, ie, CBD oil, how and they can take it, whether they can take it if there is smoking of MJ, rules on drug screening, other things that should be followed, centralized pharmacy/ dispensary or OARRS requirement  

requested x 2 last year the prescribing of THC and narcotics- medical board never responded.  

Physicians that provide these services should be able to assess for substance use disorders in all of their medical marijuana patients. I think regular urine drug testing for medical marijuana patients is in order to assure they are actually using the drug and to assess for other drugs of abuse.  

I'm in favor of decriminalizing marijuana, but don't believe evidence supports true medical benefits that outweigh risk. Patients will doctor-shop until they find a like-minded doctor.  

After my experience with Opiods/Benzos and OARRS I will definitely NOT be prescribing medical marijuana.  

the list of qualifying conditions and the provision of ability to ask for permission to treat a non-listed condition is reassuring. I practice pediatrics, so am less likely to prescribe medical marijuana, however, there are some individual cases of extreme behavioral problems which may be helped by medical marijuana, but have not been well studied.  

we do not need any more "dope smoking morons"
428 My main concern with medical marijuana is one of dosing. Like any other medication, the physician should choose the form, and dose, of the THC. This requires intense regulation by the FDA like any other drug. I worry that the law does not provide enough regulation of the "manufacturers." Also, it is too cumbersome to add to my practice. I treat a lot of spasticity in children and get asked frequently about marijuana. But there is minimal research available about efficacy due to it being illegal. That combined with the hassle of reporting to the board every year, and maintaining the CTR will be enough of a barrier for me.

1/9/2017 11:33 AM

429 There needs to be criteria for determining whether MJ is effective for the annual reports we are supposed to submit. Otherwise, it is meaningless. Metrics should be concrete/measurable, standardized and easily documented for mining from electronic medical records. "My patients say they feel better" is not a useful metric...

1/9/2017 11:28 AM

430 Marijuana should be actively studied during this process.

1/9/2017 11:22 AM

431 I have none at this time.

1/9/2017 11:11 AM

432 Federal legality needs clarification. Do I jeopardize my federal dea if i sign up to this?

1/9/2017 10:41 AM

433 Glaucoma is not treated with marijuana. Actually, if studies had been read correctly, glaucoma can be worsened by marijuana usage due to decreased perfusion to optic nerve head resulting in further death/apoptosis of the nerve fiber layer. Intraocular pressure reduction of 1-2 mmHg is minimal compared to current medications on the market that can lower IOP up to 13 mmHg with a single agent. Thus, lowered IOP while on Marijuana while lowering perfusion of optic nerve head results in faster degradation and blindness. Marijuana also must be inhaled to have any IOP effects which results in lung damage and further deprivation of good oxygen source to optic nerve head in the future (gastidic acid eliminates IOP reduction). Gov Kasich should not have glaucoma on the list of approved conditions in my opinion as I am both a pharmacists and a medical doctor. He can call me at 937-479-9697 anytime to further discuss above reasoning.

1/9/2017 10:38 AM

434 its a good idea for legalization

1/9/2017 10:35 AM

435 I currently prescribe cannabis for qualifying conditions in Quebec, where entry into a database for research purposes is mandatory. Your guidelines appear very good to me.

1/9/2017 10:28 AM

436 Once a physician obtains permission to prescribe the amount of hoops for the patient to jump through needs to be minimal, no different than other controlled substances

1/9/2017 9:59 AM

437 Of course, the posted rules are mostly references to information which will be forthcoming in the future. Having said, that, the only substantial information on this website is the list of disease or conditions which could qualify a patient for use of medical marijuana. I foresee a serious problem with the rules as proposed so far. Specifically, except for the opinion of the treating physician, I see no requirement for a severity of illness which would indicate the recommendation for medical marijuana. Furthermore, the diagnosis of fibromyalgia, for instance, is a clinical one, lacking any objective findings in most cases. By the way, I consider myself an expert on fibromyalgia, having studied the literature and treated many patients in the past. Given the above considerations, there is a wide opportunity for individuals to abuse the proposed system to obtain medical marijuana. The product so obtained could be used in trafficking. In my opinion, as long as marijuana is illegal federally, any medical marijuana system should require stricter rules to ensure that only bona-fide patients are able to obtain access. I would suggest that the Medical Board set up a program to review the practice patterns of physicians who do choose to prescribe medical marijuana. As the board knows, there have been many past physicians who abused the authority to prescribe narcotics, and their practice patterns were bizarre. Such patterns included patients travelling long distances to the provider. I would suggest that the Board create a limitation on the number of patients to which a physician may prescribe medical marijuana, in addition to a random audit of the charts of treated patients, to include an independent medical assessment of at least one such patient.

1/9/2017 9:56 AM

438 Need to consider cancer and hyperemesis of pregnancy. Many of my pregnant patients find it helpful.

1/9/2017 9:51 AM

439 The information required on the recommendation, ie patient address, DOB, qualifying condition as well as the physician's medical license #, DEA #, and Med Marijuana Certificate # seems unnecessary.

1/9/2017 9:43 AM

440 I dont think allowing everyone the right to prescribe marijuana allows for enough control or monitoring. I would restrict it to just a few providers and require patients to at least be screened initially by those providers to verify the use of medical marijuana. A two hour course which qualifies you to prescribe is just too lax.

1/9/2017 9:42 AM

441 I think many people would be uncomfortable prescribing marijuana for ptsd, positive hiv status. additionally chronic pain is a huge spectrum so prescribing it correctly for pain will make many doctors uncomfortable.

1/9/2017 9:35 AM

442 annual report burdensome

1/9/2017 9:30 AM

443 every state that has medical marijuana has seen this abused in heinous fashion. Unless the cannabinoid vs THC content is strictly monitored, it is impossible for physicians to make evidence-based recommendations for i'ts use. If the federal government deems marijuana dangerous enough to ban it, why does the State of Ohio not deem it necessary to even monitor the composition of this drug under medical guidelines?

1/9/2017 9:28 AM
You should not lump medical marijuana as one category. Medical marijuana is whole plant cannabis to treat disease. Products such as CBD without THC should be treated differently. Plus, testing and validity of products is needed. Dosing is not known, so this is a dangerous issue.

Based on the evidence that I have reviewed, there is no reason to believe that the crude, smoked marijuana is able to achieve any therapeutic effect not achievable with oral marinol or oral Epidiolex; using smoked weed instead of the medications is the equivalent of using crude foxglove instead of lanoxin: borderline malpractice, and an invitation to disaster.

Medical marijuana is less harmful than other drugs I currently prescribe such as benzodiazapines (Xanax), opioids, and non-controlled substances that have black box warnings and serious non tolerable side effects. In light of this, I think the rules should be eased due to patient access. Patients do not have to go through inconvenient steps to get the above mention medications from a physician. Medical marijuana should not be harder to get than a benzodiazepine or opioid. The Medical Board should REMOVE the stigma associated with Medical Marijuana as it has done with AIDS and HIV stigma. There are already townships in Ohio which have passed rules dissallowing medical marijuana dispensaries. Patients will have a harder time getting the medicinal marijuana, while they can go to several pharmacies in the same township to get opioids and benzodiazepines including their grocery store pharmacies. Please work on removing the stigma associated with a patient trying to get relief from their disease.

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Rules are very detailed and attempt to address all the issues. However, my experience as a hospice physician prescribing opioids regularly, tells me that the criminal element will still find ways around the rules. We see this all the time, even with our hospice patients. Even with the new state opioid regulations requiring us to report any potential diversion to the local police, we find there is little follow-up or willingness to take these reports from us, even for larger amounts of missing opioid. Due to the overwhelming burden of the current opioid epidemic on the local authorities, I am very concerned that regardless of the rules, with no more enforcement the diversion of "medical" marijuana to non-medical use will escalate.

Is glaucoma a qualifying diagnosis?

Should be limited to oncology

No Comment. I do not treat conditions that would require or qualify for med marijuana. Therefore I do not need ability to prescribe this

Medical marijuana is not evidence-based medicine.

No comments

I don’t understand how dementia and other neurologic conditions that cause confusion will be improved with THC

They are just fine

I will never prescribe marijuana

No Emergency medicine exemption. Sounds good to me.

I feel marijuana is less harmful than alcohol and it seems unfair that it can not be used for pain in difficult to treat illnesses.

I do not want to Rx Medical Marijuana

Right now, the American College of Rheumatology feels there is insufficient evidence of risks and benefits to recommend marijuana to treat fibromyalgia. Given that this is typically a young patient population, advising them to use marijuana is dangerous given the known risks without having proven long term benefits that outweigh the risks.

A major public education program needs to occur prior to initiation of this program.

It is difficult enough to treat fibromyalgia and chronic pain under current guidelines; this entire part of medicine is fraught with risk.

I support

There should be no expansion of qualifying conditions until the program has been proven successful for a reasonable "probationary" period of perhaps 5 years.

rules sound redundant

The annual report is a bad idea. We do not do that for other drugs or narcotics, so I think the OARRS requirement should be sufficient.

I think the presence of "Fibromyalgia" on the list of approved dx is a big problem.

It should be legal and be controlled

Reasonable

Don’t like the annual report. Physicians may have impressions of effectiveness based on the last few cases but unless these cases are chart reviewed, the information will be highly biased anecdotally. It is not as though effectiveness of a psychotropic agent is typically obvious,

I really don’t believe there is enough medical evidence on the efficacy of marijuana for most of the conditions in the draft rule. I treat HIV patients and in the current era of antiretroviral drug treatment, I don’t think previous research from many years ago is valid. I think this list of conditions is just copied from other states and true thought needs to go into this list with actual current medical evidence. We also have little information on long term hazards of smoking this product. As a profession, we do not need to be caught back tracking similar to the surgeon generals warning on tobacco products many years ago.

FIX the responses above! You put "extremely LIKELY" twice! I would be EXTREMELY UNLIKELY to recommend it!

I object to having to submit an annual report to the medical board regarding the effectiveness of medical marijuana in treating patients. This seems unduly burdensome.

I would have chosen extremely unlikely - but you did not give that option - there seems to be a typo - with 2 choices for extremely likely
I do not plan to provide medical marijuana. I do not think this substance should be used without FDA approval and until the federal government studies it and performs clinical trials. Your question 3 above has numerous errors and misspellings.

Note above comment extremely likely is mentioned twice and extremely unlikely is not an option. I would lean much more toward extremely unlikely. Synthetic marinol preferred as purity of compound smoked or in edibles cannot be regulated and may be unsafe for patients.

Why would a Podiatrist be excluded?

I think your answer choices are inaccurate. The are 2 answer choices the same and no option to answer Extremely Unlikely. Is that an answer you do not want to have as an option?

I do not understand why I have to provide the Board with an Annual Report. If this is for informational purposes, it should be optional. Otherwise, it appears that you are micromanaging my practice of medicine. The use of a non THC marijuana product should not be as regulated as a THC product. FYI - the only use would be for epilepsy. An FDA approved product should be on the market this year. I assume that this documentation would not be needed for this product.

I feel uncomfortable recommending a medication that is illegal on the federal level. If medical marijuana were legal under federal law, I would probably recommend it.

Including PTSD is a terrible decision. Anyone can give a history of mistreatment by a parent or having been in a MVA or witnessed a fight etc. Since diagnosis is by history it can be fabricated by anyone PTSD should be excluded. Dx is by history and incredibly easy to fabricate.

I think there is a typo in the above question #3 and I would be extremely unlikely to prescribe medical marijuana.

90% of the time there is an alternative medication that can be used. I firmly believe the benefit of marijuana to the patient is the euphoria derived.

Need to look at CBD as a separate set of regulations or exclude same. It does not have psychotropic properties.

It should be for after failure of many other treatments first.

Would put never even if managed patients with these conditions as do not believe there is enough science

Your question above has some major spelling and content errors. The answer is extremely unlikely

there is no documented monitoring recommended or required for secondary ill effects effects. No way to limit driving etc. while under the influence. Nor are there laws that protect the physician in the circumstances in which a patient harms self or others while under the influence of the drug.

Re the use for anxiety and chronic pain--it does not make sense to limit narcotics and bzd but to promote marijuana--please reconsider this will only lead to abuse. Its use should be palliative only--e.g. cancer, end of life,

None currently

question 3 is missing extremely UNlikely was this an intentional slippage?

It will be important to screen and monitor patients in a responsible manner additionally there must be a way to evaluate and monitor the drug being Rx for quality and efficacy of administration.

Please remove Post Traumatic Stress Disorder from the list of conditions!

Sound reasonable

The choice that I marked means "Extremely UNlikely". I believe the choice had a typographical error.

Is the one response supposed to be extremely unlikely? Then I would pick that answer.

I believe that all patients should have a mandatory urine drug screen prior to receiving a recommendation for marijuana, and then should have periodic urine drug screens to assess compliance and make sure no other illegal substances are being used or any other non-prescribed controlled substances.

They seem adequate

I would not prescribe thc

until this "medication" is removed from DEA class 1 controlled agent list I will not prescribe or recommend it; also needs more studies to prove efficacy, should be approved for research
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
<th>Date/Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>518</td>
<td>Do not consider the requirement to submit an annual report about prescribing medical marijuana necessary. This is another barrier for physician participation.</td>
<td>1/8/2017 8:41 AM</td>
</tr>
<tr>
<td>519</td>
<td>I do not have any suggestions at this time.</td>
<td>1/8/2017 8:39 AM</td>
</tr>
<tr>
<td>520</td>
<td>Each dispensing practice should be required to test all patients prescribed mm at least twice a year.</td>
<td>1/8/2017 8:36 AM</td>
</tr>
<tr>
<td>521</td>
<td>An annual report for this treatment of patients seems burdensome. It's not required for HTN, diabetes etc.</td>
<td>1/8/2017 8:34 AM</td>
</tr>
<tr>
<td>522</td>
<td>Filing a report at the end of the year about efficacy is too much of a burden for doctors. Documentation is already a cause of burnout. The year end report is unnecessary and a deterrent to the appropriate use of medical marijuana.</td>
<td>1/8/2017 7:42 AM</td>
</tr>
<tr>
<td>523</td>
<td>no comment</td>
<td>1/8/2017 7:38 AM</td>
</tr>
<tr>
<td>524</td>
<td>I think they for the most part are good but I am a little worried that any doctor that does prescribe medical marijuana will have more scrutiny than the average doc from the medical board. Medical marijuana is a much safer product than narcotics which is what we are stuck prescribing now. I would make the conditions for which we can prescribe medical marijuana understandable and not nebulous. Also what about patients without insurance?</td>
<td>1/8/2017 7:05 AM</td>
</tr>
<tr>
<td>525</td>
<td>I am extremely unlikely to use it. But the above question did not have that option</td>
<td>1/8/2017 6:40 AM</td>
</tr>
<tr>
<td>526</td>
<td>they look fine</td>
<td>1/8/2017 5:59 AM</td>
</tr>
<tr>
<td>527</td>
<td>I think those with full blown AIDS, terminal cancer, intractable seizures not cured by surgery or meds only. The list it covers now is way too broad!</td>
<td>1/8/2017 3:28 AM</td>
</tr>
<tr>
<td>528</td>
<td>Should be expanded</td>
<td>1/8/2017 1:24 AM</td>
</tr>
<tr>
<td>529</td>
<td>Number 3 above should say &quot;Extremely UNlikely&quot; instead of Extremely Likely twice...</td>
<td>1/8/2017 1:24 AM</td>
</tr>
<tr>
<td>530</td>
<td>chronic back pain</td>
<td>1/8/2017 12:55 AM</td>
</tr>
<tr>
<td>531</td>
<td>Marijuana has never really been studied, and the board is bowing to public pressure.</td>
<td>1/8/2017 12:22 AM</td>
</tr>
<tr>
<td>532</td>
<td>As a board certificated pain management physician, I have a problem with having fibromyalgia as a listed condition to treat.</td>
<td>1/7/2017 11:47 PM</td>
</tr>
<tr>
<td>533</td>
<td>Surely we need more than two hours of CME before prescribing this.</td>
<td>1/7/2017 11:29 PM</td>
</tr>
<tr>
<td>534</td>
<td>The annual report part and the patient consent parts are too vague. Is it written consent or verbal consent? Does it need a witness? What does the annual report include?</td>
<td>1/7/2017 11:16 PM</td>
</tr>
<tr>
<td>535</td>
<td>unsure of dosing</td>
<td>1/7/2017 11:09 PM</td>
</tr>
<tr>
<td>536</td>
<td>I assume the 5th selection to question 5 is supposed to be extremely unlikely, in which case this would be my answer. The broad range of allowed diagnosis is sure to fill our offices and ERs with patients requesting this care. Good luck.</td>
<td>1/7/2017 11:06 PM</td>
</tr>
<tr>
<td>537</td>
<td>In Ques 3 extremely unlikely was a typo omission.</td>
<td>1/7/2017 10:49 PM</td>
</tr>
<tr>
<td>538</td>
<td>Don't allow pot to be legal in Ohio</td>
<td>1/7/2017 10:24 PM</td>
</tr>
<tr>
<td>539</td>
<td>Discard the &quot;Annual Report&quot;- This is onerous, and different than standard medical practice for all other conditions. This will lead many general practitioners to avoid prescribing this (which, on one hand may be desirable for some).</td>
<td>1/7/2017 10:15 PM</td>
</tr>
<tr>
<td>540</td>
<td>I'm assuming that was to be &quot;Extremely unlikely&quot; above as there are 2 &quot;Extremely Likely&quot;</td>
<td>1/7/2017 9:44 PM</td>
</tr>
<tr>
<td>541</td>
<td>I actually would be EXTREMELY UNLIKELY to prescribe medical marijuana but there were so many typos in the choices I picked somewhat unlikely to be sure I picked a negative one</td>
<td>1/7/2017 9:10 PM</td>
</tr>
<tr>
<td>542</td>
<td>the annual report is very vaguely described. Is this just to be my general overall impression in a paragraph or a list of patients with effect in each one or is it a form with check boxes</td>
<td>1/7/2017 8:52 PM</td>
</tr>
<tr>
<td>543</td>
<td>Make it easier</td>
<td>1/7/2017 8:52 PM</td>
</tr>
<tr>
<td>544</td>
<td>Please change your responses to Q3 above! My response is &quot;Extremely Unlikely&quot; at the bottom. It's mistakenly written as &quot;extremely likely&quot;!</td>
<td>1/7/2017 8:42 PM</td>
</tr>
<tr>
<td>545</td>
<td>the above answer has typographical error 5th choice should read extremely Unlikely which is choice I would make. Would recommend that data on effectiveness and safety from states that have legalized medical marijuana be required reading by physician prescribers and updated regularly. All women of reproductive age who are prescribed mmarijuana either be required to use birth control or have regular pregnancy tests (q 4 months).</td>
<td>1/7/2017 8:39 PM</td>
</tr>
<tr>
<td>546</td>
<td>Extremely Unlikely (you have a serious typo is question 3 that may invalidate your survey)</td>
<td>1/7/2017 8:37 PM</td>
</tr>
<tr>
<td>547</td>
<td>you have typos in the previous question. What kind of questionnaire is this? I would be extremely unlikely to recommend medical marijuana.</td>
<td>1/7/2017 8:28 PM</td>
</tr>
</tbody>
</table>
you have a misprint on question 3 - I think you mean extremely unlikely.

Seem appropriate ....

Note: your survey has an error—i believe you'll see you have two separate boxes in which one would indicate that a position is extremely likely to prescribe such substances but you meant for one to say extremely UNLIKELY-- For the record in extremely unlikely to prescribe

Need standard forms

none at this time

I have carefully looked into the data and there is no evidence to warrent the use of marijuana.

It's a chaos between federal regulations and state regulations.

will glaucoma, poorly controlled, be a qualifying condition?

I work in emergency medicine, will not have ongoing relationship with patients meeting criteria. Patients should be advised this Rx will not be refilled in EDs.

As a neurologist, I am very concerned about potential neurological complications of marijuana.

# 3. Extremely UN likely

Ongoing patient interaction requirements eliminate ER doctor's eligibility

No "extremely unlikely" option

I presume the above was supposed to be "extremely unlikely." I am completely opposed to medical marijuana for anything but the EXTREMELY RARE seizure disorders in children that are not controlled by anything else. I believe it is an entry drug leading to addiction to it and other drugs.

We need much more information before I would recommend it. For example, can the patient continue with narcotics and still use marijuana?

The question above has mis-spellings, and there is no choice for "extremely unlikely" = I cannot say NA, because I have numerous patients with the conditions mentioned, although I really don't want to rx the drug, and will avoid it like the plague.

The requirements to prescribe make it less likely for me to prescribe. I don't want to have to sort out who needs the med and who wants to "legalize" their habit.

Believe the draft rules as listed is both reasonable and allows appropriate oversight.

My qualifying condition is glaucoma

Hep C should not be a covered condition as most pts are asymptomatic and those asymptomatic patients may use this illness to get med pot which can be sold or traded for other drugs

EXTREMELY UNLIKELY TO RECOMMEND MEDICAL MARIJUANA

The above list does NOT include "extremely unlikely". Please review these surveys before publishing

Would rather change the law to make using not a crime that legalizing it due to unintended consequences. Docs did not do a good job controlling narcotic addiction so why would you expect that they would do a good job with THC

Get rid of the terminology, "based on chronic rules." Just say right state any basis right here.

The draft rules are adequate. I appreciate the ability to submit petitions to consider other qualifying conditions as well as the other state reciprocity rules. Online forms would best serve busy providers.

It is sad that this passed. It has no scientific merit.

The indications are too broad and not evidence based.

I am pleased with the draft rules.

Inflammatory conditions like severe rheumatoid arthritis.

I am not aware of any published peer-reviewed literature demonstrating that marijuana is equivalent or non inferior to the standard of care for managing any of the conditions listed.

seems reasonable

Too restricting
I agree that medical marijuana needs to be tightly regulated and think that the annual report that prescribers need to submit is appropriate.

Wanted to clarify that my answer above is extremely unlikely but there is a typo and the fourth choice states extremely likely which is already a choice above it. I think it's a terrible idea and have no plans to ever prescribe medical marijuana.

question 3 has an obvious typo in that the 5th choice should be extremely UNlikely which would be my response.

Need better input from neutral advisory bodies on state of current data for these "qualifying conditions."

They sound ominous and onerous. The process should be simplified.

The answer key above is wrong. I am sure that the 5th answer is extremely unlikely, and that is my choice.

I'm opposed to Medical marijuana. I think we should avoid more substance addictive compounds. Patents are already hooked up to high dose opiates and benzodiazepines. No need to bring more substances that in the long run just cause more addiction and they won't affect mortality or quality of life. Patients need to find other avenues to control their pain, like alternative medicine, meditation, acupunture, etc.

Be sure that health care providers have taken a REAL course with a written exam reviewed by the medical board.

How can Ohio over rule Federal Law... Still a Federal Schedule 1. This needs to be changed. Are the listed uses the F.D.A. Approved uses for marijuana or just the Ohio approved uses? I believe this needs to be addressed.

perhaps 3 hours cme

I am a forensic pathologist and all my patients are dead. I do not "manage" many patients at all!

Grandfather in Pain Clinics with TDD3-PMC licenses

Your question doesn't have "extremely unlikely" listed. It has "extremely likely" twice

great but will be rendered useless because the marijuana initiative won't rest until they pass a statewide marijuana for everybody law

Extremely unlikely - your survey does not make this an option - I expect this was a mistake

Too complex. I have enough to do already. I am not convince potential marijuana products are sufficiently evolved.

Change the rule that restricts physicians from being a part of a dispensary. Being associated with a dispensary will not change medical management. I would not recommend medical marijuana unless it is clinically indicated.

The qualifying conditions are vague. Many of these conditions are inappropriately diagnosed or mis-diagnosed. This seems to be an excuse for those who want funnel drugs of abuse to the general public. This is not science it is diversion.

glad there is no additional costs/testing. physicians being overly regulated for their degree of education and experience. board certification is intrusive and dot testing certification is overkill

This whole enterprise is misguided. THC makes most conditions worse. Cannabidiol is a promising agent, but research and standardized formulations are lacking.

Providing a yearly report to the board is cumbersome at the least. Reviewing physician prescriptions of the drug through OARRS should be adequate. This is done with narcotics already, why not add the drug to the profile, too.

A more thorough background check should be done on the physicians who will be prescribing medical marijuana. More tabs need to be kept on the physicians and dispensers of the marijuana.

I think recommending will be an exercise in wasted time and effort because my prediction is that the legally available form of THC are going to be substantially more expensive than black market marijuana. Thus patients who really want it will get it outside of the legal dispensaries.

I think there are likely some patients who get symptomatic benefit from medical marijuana. However, I am concerned that patients who currently smoke marijuana for recreational use will try to obtain medical marijuana as a means for continuing their illicit use under the guise of medical use.

I am appalled that this is being used without fda approval and appropriate evidence based scientific research to substantiate it's claims. I am a geriatrician many patients with dementia and have NO knowledge of its appropriateness.

Bad idea
Please do not treat physicians as criminals when they are making good faith effort to help patients (the current OARRS requirements and medical board threats are out of control) 1/7/2017 12:56 PM

I believe there are too many qualified conditions, remove some, this is pathetic!! 1/7/2017 12:53 PM

I would be extremely unlikely to recommend marijuana to my patients. (See question #3) 1/7/2017 12:38 PM

Cancer was not in the list I just read 1/7/2017 12:31 PM

Please consider excluding fibromyalgia as a qualifying condition. Otherwise, I am in favor of moving forward as this is clearly part of the future of medicine. 1/7/2017 12:24 PM

I think the 5th Answer to check in question #3 should be "extremely unlikely" (typo). I may have an infrequent patient where marijuana may be helpful, but if the amount of paperwork and reporting I have to do is too much, or IF I HAVE TO WORRY ABOUT NEWS MEDIA BEING NOTIFIED BY THE STATE PHARMACY BOARD (as they did with OARRS reporting) that I may be subject to criminal prosecution, I will not do it. Just having your name on a list of "non-compliant" physicians in not reporting the information correctly to the authorities puts the physician as a criminal in the public's eye. 1/7/2017 12:07 PM

The answer choices for question #3 have two Extremely Likely choices. I chose the one I assumed should be Extremely UNLIKELY. I believe the rules should be strict and strongly enforced, as undoubtedly, there will be patients trying to game the system to get their legally prescribed marijuana. 1/7/2017 12:07 PM

I think it is a travesty and ridiculous to allow physicians a loophole to break the federal law. I will never write a script for this as there are more than efficacious conventional meds and the list is one of the most hyped up and bogus list of diseases that can and "should" be treated with this it is disgusting to me to be a physician. Why are we contributing to this money driven government "non-medical" issue. 1/7/2017 12:05 PM

I have already provided comments in response to an earlier e-mail request. 1/7/2017 12:04 PM

I don't believe there is any benefit to medical marijuana, and it should not be allowed in Ohio. 1/7/2017 11:59 AM

There are too many qualifying conditions, such as fibromyalgia 1/7/2017 11:58 AM

do not do this! this is totally just an excuse for people to get high, There is absolutely no legit organized management of the pill mills in Ohio now and this will make things much worse. In the name of GOD do NOT do this to Ohio! 1/7/2017 11:58 AM

I prefer one day course or 8 hours (instead of 2 hrs.) for eligible to prescribe marijuana and 5 hrs CME every two years to continue certification. 2. I would like to take out Post Traumatic Stress Disorder (PTSD) as a condition and let psychiatrist to handle those patients. 3. I would like to add cancer patients having pain to the list. 4. I prefer 30 days instead of 90 days supply given to the patients. 5. I do not feel Ohio pharmacies to fill the prescription from out of state. In such cases, the approved Ohio physicians should re-evaluate the patient. 1/7/2017 11:54 AM

I still feel that although medical (not recreational) marijuana should be available for research, it is still too dangerous to be prescribed for any reason. More research is needed! Education of the public is also very important, as many don't know the difference between the types of marijuana, the well-documented dangers, lack of proven efficacy, etc. 1/7/2017 11:50 AM

Please correct the verbage in the question response of #3. The wording as stated makes the survey invalid. Please register my response for question #3 as Extremely Unlikely. Thank you. 1/7/2017 11:50 AM

Medical conditions that may qualify remains vague. National organizations could provide input for the different specialties. Its controversial in Psychiatry. 1/7/2017 11:48 AM

question 3 above: somewhat likely appears twice 1/7/2017 11:46 AM

Chronic (non-cancer) pain should not be a consideration. Enough problems with overprescribed narcotics already exist. Marijuana will not decrease narcotic usage; it will create more problems of its own. 1/7/2017 11:45 AM

Overly restrictive; this substance is safely being used in several states recreationally without this tremendous oversize. I would think scheduling as a Schedule IV-V type substance may be most appropriate 1/7/2017 11:42 AM

The selections has extremely likely listed twice 1/7/2017 11:40 AM

I guess I don't want patients coming to me stating they need medical marijuana for whatever reason and find a diagnosis to give it to me. They all will come up with fibromyalgia or like 1/7/2017 11:24 AM

Concern over people wanting it for selfish reasons and making up symptoms as I scrutinized already because of opiates 1/7/2017 11:20 AM

No use should be permitted UNTIL there is high grade/quality evidence that I'd BOTH safe and effective. Such evidence does NOT yet exist. 1/7/2017 11:19 AM

Too many rules. Should be no different from prescribing narcotics. Silly to have separate license 1/7/2017 11:18 AM
<table>
<thead>
<tr>
<th>Number</th>
<th>Text</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>631</td>
<td>I found the list of qualifying conditions to be surprisingly generous. Specifically, I do not know how glaucoma made the list as marijuana has never been shown to be an accepted treatment for glaucoma. Please, please remove it as we have many good treatment options for glaucoma and my patients are already asking for marijuana instead.</td>
<td>1/7/2017 11:08 AM</td>
</tr>
<tr>
<td>632</td>
<td>I don't think a special certificate is necessary, as none is needed for pain meds when used appropriately. I also do not see a need for the annual report, as none is needed for other meds.</td>
<td>1/7/2017 11:01 AM</td>
</tr>
<tr>
<td>633</td>
<td>So extensive as to limit the number of practitioners who will be willing to participate.</td>
<td>1/7/2017 11:01 AM</td>
</tr>
<tr>
<td>634</td>
<td>Provide evidence that medical marijuana is better than any alternate please.</td>
<td>1/7/2017 10:46 AM</td>
</tr>
<tr>
<td>635</td>
<td>No suggestions</td>
<td>1/7/2017 10:38 AM</td>
</tr>
<tr>
<td>636</td>
<td>This is a huge mistake. It should not be prescribed.</td>
<td>1/7/2017 10:37 AM</td>
</tr>
<tr>
<td>637</td>
<td>I work in Addiction Medicine and for the most part all my patients have used marijuana but I do not believe that lead them to use opiates. It appears that Ohio is taking a deliberate and careful approach to this issue.</td>
<td>1/7/2017 10:37 AM</td>
</tr>
<tr>
<td>638</td>
<td>Can we also review the current science regarding marijuana so we can prescribe it based on science and not politics, please?</td>
<td>1/7/2017 10:36 AM</td>
</tr>
<tr>
<td>639</td>
<td>I do not agree with medical marijuana usage for some of the diagnoses that you have provided. People with chronic pain are problematic and I feel medical marijuana will lead to further addiction issues within our state. My anticipation is that people who already abuse narcotics Will claim chronic pain in order to gain access to medical marijuana. I feel that medical marijuana use will most likely lead to further disability for patients. The question to ask is Who can use medical marijuana and what type of occupations can use medical marijuana...as an example, I am an orthopedic surgeon but would I be able to use medical marijuana if I claimed chronic pain due to degenerative disc disease in my back and proceeded to operate on a patient. Do I want a truck driver using medical marijuana? We are breeding addiction and people will abuse the program, and there will be providers who will go along with it.</td>
<td>1/7/2017 10:33 AM</td>
</tr>
<tr>
<td>640</td>
<td>look well thought out</td>
<td>1/7/2017 10:31 AM</td>
</tr>
<tr>
<td>641</td>
<td>I think they are a good place to start</td>
<td>1/7/2017 10:30 AM</td>
</tr>
<tr>
<td>642</td>
<td>seem reasonable</td>
<td>1/7/2017 10:28 AM</td>
</tr>
<tr>
<td>643</td>
<td>They look OK. The indications are a little BROAD! &quot;Chronic pain&quot;, &quot;HIV&quot;, almost anything related to the GI track... etc. I would be sure to make it clear that chronic &quot;medical&quot; MJ (prescribing for longer than 90-180 days) is like any other chronic controlled drug prescription, and thus apply all / any SMBO rules regarding the chronic prescribing of any other controlled drug to the prescribing of MJ. So, the chronic opioid and/or benzo and/or amphetamine rules should be applied. This should include the ongoing monitoring rules that you have put together for other controlled drugs. Also IF you can it would be good to stake out the &quot;typical safe dose&quot; rules (like the MEQ 80 etc from the get go. If &quot;we&quot; address this like all other chronic prescribing of other controlled drugs... learning from the issues that have come up with the other controlled drugs, it will certainly be 1) a helpful &quot;ounce of prevention&quot;, 2) will treat this from the start as controlled drug prescribing, 3) it will give the SMBO more specific things to review for when problematic cases arise, and 4) will help providers maintain their bearings when they are caught up in patient requests and trying to fit this into their own clinical reasoning algorithms. THANKS fro trying to tackle this amorphous area (where MANY other SMBs have really just punted and left it as a quasi-medical issue with little if any oversight). Please feel free to contact me for further thoughts and recommendations if you need to. Ted Parran</td>
<td>1/7/2017 10:25 AM</td>
</tr>
<tr>
<td>644</td>
<td>My answer would be extremely UNlikely in the previous question. I oppose medical marijuana and find this to have no place in our practice of medicine. This is akin to physicians prescribing herbal supplements with thousands of chemicals and one or two being helpful, many others being harmful. We just don't prescribe anything else similar to what is being proposed. I support drafting rules that make it so I physicians in ohio have have practical ability to prescribe marijuana. Our profession should not be used as a gatekeeper to clear alternative motives.</td>
<td>1/7/2017 10:21 AM</td>
</tr>
<tr>
<td>645</td>
<td>Just like tee over treated patients for pain with oxycodone and made a generation of people oipate dependent now we are prescribing marijuana all for the money in tax revenue. It's a shameful day in Ohio medicine</td>
<td>1/7/2017 10:21 AM</td>
</tr>
<tr>
<td>646</td>
<td>I do not think an annual report from a prescribing physician should be required. Otherwise rules seem reasonable</td>
<td>1/7/2017 10:21 AM</td>
</tr>
<tr>
<td>647</td>
<td>I expect that there will be a large demand from patients but they will not be happy with all the rules.</td>
<td>1/7/2017 10:17 AM</td>
</tr>
<tr>
<td>648</td>
<td>Concise</td>
<td>1/7/2017 10:11 AM</td>
</tr>
<tr>
<td>649</td>
<td>I would be extremely likely to prescribe medical marijuana to a patient with ALS, but unlikely to prescribe it to a patient with Alzheimer's disease. Etc.</td>
<td>1/7/2017 10:09 AM</td>
</tr>
<tr>
<td>650</td>
<td>I do not want to be part of this type of treatment</td>
<td>1/7/2017 10:05 AM</td>
</tr>
<tr>
<td>651</td>
<td>I am practicing in a state with medical marijuana, I have patients who are doing better with the use of marijuana, particularly chronic musculsketal pain</td>
<td>1/7/2017 9:55 AM</td>
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<tr>
<td>ID</td>
<td>Comment</td>
<td>Date/Time</td>
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<tr>
<td>652</td>
<td>none</td>
<td>1/7/2017 9:54 AM</td>
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<tr>
<td>653</td>
<td>chronic and intractable pain will be where the charlatans gather.</td>
<td>1/7/2017 9:54 AM</td>
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<tr>
<td>654</td>
<td>I work in the emergency department. If we are caring for a patient who is in the hospital and normally receives marijuana from a physician, will we be able to continue their dose in the ED or hospital similar to suboxone?</td>
<td>1/7/2017 9:47 AM</td>
</tr>
<tr>
<td>655</td>
<td>I have many patients with fibromyalgia and chronic pain who may benefit and I would consider use of medical marijuana under a controlled substance agreement after they have failed other conventional treatments. I am a little bit concerned about the annual report, however. What objective measures would be used to determine benefit to the patient? I would need to learn more about this new administrative chore prior to seeking the ability to recommend medical marijuana.</td>
<td>1/7/2017 9:40 AM</td>
</tr>
<tr>
<td>656</td>
<td>n/a</td>
<td>1/7/2017 9:40 AM</td>
</tr>
<tr>
<td>657</td>
<td>NONE</td>
<td>1/7/2017 9:35 AM</td>
</tr>
<tr>
<td>658</td>
<td>It would be helpful to have references. Also what the heck is a normal amount of marijuana and what doses and what administration method were used in studies.</td>
<td>1/7/2017 9:26 AM</td>
</tr>
<tr>
<td>659</td>
<td>Very reasonable</td>
<td>1/7/2017 9:25 AM</td>
</tr>
<tr>
<td>660</td>
<td>Use of marijuana for medical purposes is based on flimsy evidence</td>
<td>1/7/2017 9:23 AM</td>
</tr>
<tr>
<td>661</td>
<td>I treat pain and am authorized to prescribe narcotic pain meds, but my license will not permit me to rx medical marijuana. in addition, as a federal employee of the VA, medical marijuana will not be covered through the VA Also - your survey has 'extremely likely' twice. possibly a typo?</td>
<td>1/7/2017 9:17 AM</td>
</tr>
<tr>
<td>662</td>
<td>Up front notification of severe consequences for fraudulent and even inappropriate prescription.</td>
<td>1/7/2017 9:13 AM</td>
</tr>
<tr>
<td>663</td>
<td>What about patients with chronic low back pain or fibromyalgia, lupus, rheumatoid arthritis. Many of these patients are on narcotics or tramadol. Why are these conditions not included????</td>
<td>1/7/2017 9:07 AM</td>
</tr>
<tr>
<td>664</td>
<td>It is my personal opinion that the State of Ohio and US just need to legalize marijuana, tax it and get over it. ETOH is 1000 fold more toxic and has caused more death and destruction of lives than any so called &quot;drug&quot;. The State of Ohio and the pharmaceutical industry created the current national heroin epidemic by shoving the 5th vital sign and under treatment of pain BS down everyone's throat. What makes the State of Ohio and the medical board &quot;think&quot; they can manage this? I would personally be constantly fearful of the Geheime Staatspolizei statics of the current medical board as there is NO common sense or more importantly current medical acumen displayed at any level, with the exception of Dr. Soin who displays some voice of reason. The current medical board investigators exist simply to terrorize physicians and I would not recommend MM to anyone for constant fear of being terrorized by medical board investigators.</td>
<td>1/7/2017 9:01 AM</td>
</tr>
<tr>
<td>665</td>
<td>As long as the docs are legitimate as well as the patients then I am ok with it I am against marijuana clinics however where the purpose is to use medical marijuana as an excuse to sel marijuana</td>
<td>1/7/2017 8:56 AM</td>
</tr>
<tr>
<td>666</td>
<td>George Orwell would be proud</td>
<td>1/7/2017 8:56 AM</td>
</tr>
<tr>
<td>667</td>
<td>Neutral...I am not an advocate overall/such widespread generalized use for multiple reasons. I am also currently non-practicing clinically and am employed with administrative role.</td>
<td>1/7/2017 8:55 AM</td>
</tr>
<tr>
<td>668</td>
<td>Most of those medical &quot;qualifying conditions&quot; are bogus and unscientific. For example, medical treatment of glaucoma with marijuana has never been acceptable due to its inconsistent/minor benefit tethered to an unacceptable side effect profile (getting &quot;high&quot; impairs thinking and judgment). I'm board certified as an ophthalmologist and as a child, adolescent, and adult psychiatrist, so I know this from both a personal and professional experience. Marijuana use is a major problem, also, in the treatment of mental health conditions. It's often associated with poor medication compliance and inadequate improvement in overall mental health, although chronic users often report it helps them. The observed response from psychiatrists sees the user's mental health stagnate, and a decline in functioning occurs-not improvement. The only conditions I see as marijuana being helpful are in AIDS and terminal cancer patients for it's anti nausea and weight-promoting benefits.</td>
<td>1/7/2017 8:53 AM</td>
</tr>
<tr>
<td>669</td>
<td>Whoever wrote/edited question #3 was doing too much pot.</td>
<td>1/7/2017 8:53 AM</td>
</tr>
<tr>
<td>670</td>
<td>Actual answer is extremely unlikely but that was not a choice due to typo</td>
<td>1/7/2017 8:52 AM</td>
</tr>
<tr>
<td>671</td>
<td>consistent with other states, nice list!</td>
<td>1/7/2017 8:49 AM</td>
</tr>
<tr>
<td>672</td>
<td>The list of qualifying conditions is laughable. You are sitting patients up for drug abuse and doctors up for more problems. It is just unbelievable that we are now going to have to deal with this</td>
<td>1/7/2017 8:35 AM</td>
</tr>
<tr>
<td>673</td>
<td>They look good. May need ongoing cme rules given hopefully there will be a lot more research on this topic in the coming years.</td>
<td>1/7/2017 8:31 AM</td>
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<tr>
<td>ID</td>
<td>Comment</td>
<td>Date</td>
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<tr>
<td>674</td>
<td>There is no place for this in the practice of medicine.</td>
<td>1/7/2017 8:31 AM</td>
</tr>
<tr>
<td>675</td>
<td>I would still refer to either palliative care or pain management specialists for this treatment. Not appropriate for my OB patients.</td>
<td>1/7/2017 8:22 AM</td>
</tr>
<tr>
<td>676</td>
<td>The condition would have to be terminal, painful, and probably progressive.</td>
<td>1/7/2017 8:14 AM</td>
</tr>
<tr>
<td>677</td>
<td>The burden of documentation is too high. If this is to be offered like any other medication, there is no need for this level of administrative work. Simply prescribing according to FDA recommendations, like any other medication, should suffice. Why is it any different from opioid medications, which are illegal outside of medical practice just like marijuana?</td>
<td>1/7/2017 8:05 AM</td>
</tr>
<tr>
<td>678</td>
<td>I plan to never prescribe medical marajuana and think that it is ridiculous.</td>
<td>1/7/2017 8:02 AM</td>
</tr>
<tr>
<td>679</td>
<td>Insufficient peer reviewed, randomized prospective studies in support of medical marijuana therapy.</td>
<td>1/7/2017 7:59 AM</td>
</tr>
<tr>
<td>680</td>
<td>Look ok</td>
<td>1/7/2017 7:59 AM</td>
</tr>
<tr>
<td>681</td>
<td>Question does not have an &quot;Extremely Unlikely&quot; choice. If it did, I would have chosen it.</td>
<td>1/7/2017 7:58 AM</td>
</tr>
<tr>
<td>682</td>
<td>Get rid of med marijuana</td>
<td>1/7/2017 7:56 AM</td>
</tr>
<tr>
<td>683</td>
<td>Insure quality control in terms of canniniod composition, such as CBD/THC ratio and indications.</td>
<td>1/7/2017 7:56 AM</td>
</tr>
<tr>
<td>684</td>
<td>Qualifying conditions list is too broad and my answer to question 3 is extremely unlikely.</td>
<td>1/7/2017 7:56 AM</td>
</tr>
<tr>
<td>685</td>
<td>They seem reasonable, the sooner the better!</td>
<td>1/7/2017 7:54 AM</td>
</tr>
<tr>
<td>686</td>
<td>Unwilling to prescribe until recommended and supported by FDA with appropriate research and indications.</td>
<td>1/7/2017 7:52 AM</td>
</tr>
<tr>
<td>687</td>
<td>I think the qualifying conditions are too broad. I also think it is wrong to include psychiatric conditions when it is documented in medical research a possible correlation between marijuana use and schizophrenia. These conditions are not terminal and this is going to legitimize marijuana use. It's already hard enough to explain the potentially negative side effects of opioids to patients and now we will have to deal with marijuana. It is not a benign drug. No one believes cannabinoid hyperemesis syndrome is real when you try to tell them to stop using marijuana. Also this is going to complicate prescribing narcotics. People are going to think they should get opioids if they are using illegal marijuana because it is &quot;legal&quot;. This is a mess</td>
<td>1/7/2017 7:51 AM</td>
</tr>
<tr>
<td>688</td>
<td>Would not apply to me as I am an Emergency Medicine Physician that would not care for these patients on an ongoing basis.</td>
<td>1/7/2017 7:43 AM</td>
</tr>
<tr>
<td>689</td>
<td>Your options have extremely likely twice and do not offer extremely unlikely. I am extremely unlikely but that choice was not offered I expect in error</td>
<td>1/7/2017 7:40 AM</td>
</tr>
<tr>
<td>690</td>
<td>There should be language on continuous study and evaluation of benefits versus risks.</td>
<td>1/7/2017 7:37 AM</td>
</tr>
<tr>
<td>691</td>
<td>Your Question #3 Above is MISPRINTED, as it lists EXTREMELY LIKELY twice and FAILS TO LIST EXTREMELY UNLIKELY AT ALL. Had it been a choice, I would have selected EXTREMELY UNLIKELY as my answer for #3 Above.</td>
<td>1/7/2017 7:29 AM</td>
</tr>
<tr>
<td>692</td>
<td>I do not support this legislation.</td>
<td>1/7/2017 7:28 AM</td>
</tr>
<tr>
<td>693</td>
<td>seems very labor intensive to do annual report unless it is template form and standardized, easy to use</td>
<td>1/7/2017 7:20 AM</td>
</tr>
<tr>
<td>694</td>
<td>1) no supporting scientific evidence of positive effectiveness 2) multiple episodes of conditions listed as aggravated by use 3) board will be inundated with annual reports just to keep people legally using drug</td>
<td>1/7/2017 7:09 AM</td>
</tr>
<tr>
<td>695</td>
<td>The people wrote this survey need to go back to school. Neutral is misspelled and you have Extremely Likely listed twice. There is also no choice that says Never. Marijuana is not a medication. It is a recreational drug that causes severe physical and psychiatric injury and leads to more severe drug addictions. The rules should ban this entire absurd process. If doctors wish to prescribe cannabinoids, Dronabinol has already been FDA approved. We do not need the other recreational forms. Ohio is already the leader in opiates related deaths. Do we really need more controlled drugs that will be used by our children? Please use your legal skills to stop this poisoning our community. Then begin removing the other serious threats like opiates, stimulants, and alcohol.</td>
<td>1/7/2017 7:03 AM</td>
</tr>
<tr>
<td>696</td>
<td>To above question, highly unlikely</td>
<td>1/7/2017 7:00 AM</td>
</tr>
<tr>
<td>697</td>
<td>no comments</td>
<td>1/7/2017 6:58 AM</td>
</tr>
<tr>
<td>698</td>
<td>They seem appropriately cautious.</td>
<td>1/7/2017 6:56 AM</td>
</tr>
<tr>
<td>699</td>
<td>I assume you have a typo in #3 and that choice 4 means extremely UNlikely.</td>
<td>1/7/2017 6:49 AM</td>
</tr>
<tr>
<td>700</td>
<td>Tracking of cardiovascular status and / or change should be documented in a state registry</td>
<td>1/7/2017 6:44 AM</td>
</tr>
<tr>
<td>ID</td>
<td>Comment</td>
<td>Date</td>
</tr>
<tr>
<td>------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>701</td>
<td>The requirement of only 2 CME's to prescribe a new class of drug without studies without data seems preposterously low. This is a gateway to legal addiction. The only condition with sufficient data are rare seizures treated with non-THC variants of MJ.</td>
<td>1/7/2017 6:41 AM</td>
</tr>
<tr>
<td>702</td>
<td>Survey question 3 has a typo. There are two choices for Extremely Likely. I am Extremely Unlikely to be prescribing medical marijuana.</td>
<td>1/7/2017 6:34 AM</td>
</tr>
<tr>
<td>703</td>
<td>. Appropriate</td>
<td>1/7/2017 6:24 AM</td>
</tr>
<tr>
<td>704</td>
<td>Standardize a recommendation form for physicians to complete through OARRS or their EMR so that all guidelines are met and the physician's license is not compromised.</td>
<td>1/7/2017 6:23 AM</td>
</tr>
<tr>
<td>705</td>
<td>Extremely unlikely but your survey choices have an error and that is not a choice.</td>
<td>1/7/2017 6:20 AM</td>
</tr>
<tr>
<td>706</td>
<td>I am an oncologist and already prescribe a number of schedule 2 drugs. Checking the OARRS reports for this is already onerous and it seems like the added reporting expectations to prescribe medical marijuana will slow me down much more. There are reasonably effective alternatives to medical marijuana that I already prescribe and I think that obtaining a license for MM will be more of a burden than benefit. I will refer my patients to a colleague who is licensed to obtain if the standard measures are ineffective</td>
<td>1/7/2017 6:13 AM</td>
</tr>
<tr>
<td>707</td>
<td>me being required to submit annual report is an unnecessary burden. The only thing that may prevent me from obtaining.</td>
<td>1/7/2017 5:34 AM</td>
</tr>
<tr>
<td>708</td>
<td>OBGYN not malignancy or other wise</td>
<td>1/7/2017 5:32 AM</td>
</tr>
<tr>
<td>709</td>
<td>I mean to put &quot;extremely unlikely&quot; but typo</td>
<td>1/7/2017 5:18 AM</td>
</tr>
<tr>
<td>710</td>
<td>question #3 does not have a choice &quot;Extremely Unlikely&quot;.</td>
<td>1/7/2017 4:00 AM</td>
</tr>
<tr>
<td>711</td>
<td>I hope that anxiety disorder and chronic insomnia will be added to the list, as I have several patients that have admitted they get get better relief with marijuana than from sleeping pills or anxiolytics.</td>
<td>1/7/2017 2:42 AM</td>
</tr>
<tr>
<td>712</td>
<td>some of these diagnoses should not be managed with marijuana in my opinion</td>
<td>1/7/2017 2:30 AM</td>
</tr>
<tr>
<td>713</td>
<td>I will not prescribe marijuana</td>
<td>1/7/2017 2:05 AM</td>
</tr>
<tr>
<td>714</td>
<td>Needs to be very strict and for palliative treatment of terminal illnesses only. Do not like using it or allowing it for common ailments that are non terminal and do not think smoked should be available at all</td>
<td>1/7/2017 1:32 AM</td>
</tr>
<tr>
<td>715</td>
<td>it is my belief and professional opinion that marijuana has NO role in patient care. i will NEVER be a part of its use in any way.</td>
<td>1/7/2017 1:29 AM</td>
</tr>
<tr>
<td>716</td>
<td>Yearly reporting seems arbitrary for one particular treatment modality.</td>
<td>1/7/2017 12:54 AM</td>
</tr>
<tr>
<td>717</td>
<td>Time will tell and we need to give them time for tweaking as needed.</td>
<td>1/7/2017 12:40 AM</td>
</tr>
<tr>
<td>718</td>
<td>Note that distractors for question 3 include extremely likely twice. Stopping survey now.</td>
<td>1/7/2017 12:40 AM</td>
</tr>
<tr>
<td>719</td>
<td>draft rules are too demanding and not practical</td>
<td>1/7/2017 12:30 AM</td>
</tr>
<tr>
<td>720</td>
<td>Bipolar D/O should definitely be included in the list of medical uses as I have had thousands of Bipolar patients who have reported marijuana as being their D.O.C and when asked why they chose it they would all say it calmed them down and kept them out of trouble. I worked in a male prison and these inmates would have been much less likely to be incarcerated but for the fact that they committed their crimes when they were either caught with it or trying to obtain it for their mood disorder. The great majority of them had no idea they had a Bipolar D/O.</td>
<td>1/7/2017 12:08 AM</td>
</tr>
<tr>
<td>721</td>
<td>Consider removal of fibromyalgia and chronic pain</td>
<td>1/6/2017 11:58 PM</td>
</tr>
<tr>
<td>722</td>
<td>Too much red tape. Frankly I don't want to be bothered.</td>
<td>1/6/2017 11:58 PM</td>
</tr>
<tr>
<td>723</td>
<td>Please review your indications There are not good studies to back up all of those DX being treated with MM</td>
<td>1/6/2017 11:55 PM</td>
</tr>
<tr>
<td>724</td>
<td>I will not prescribe for anything</td>
<td>1/6/2017 11:48 PM</td>
</tr>
<tr>
<td>725</td>
<td>There is no reason to allow medical marijuana for glaucoma there are much better alternatives.</td>
<td>1/6/2017 11:40 PM</td>
</tr>
<tr>
<td>726</td>
<td>I have been against the use of marijuana for two reasons; 1) It's a gateway drug &amp; 2) For the people who compare it to ETOH there are no short or long-term testing available as there is for ETOH and other drugs.</td>
<td>1/6/2017 11:08 PM</td>
</tr>
<tr>
<td>727</td>
<td>The need for a CTR and an annual report are unnecessary burdens and will discourage physician participation, limiting patient access to a beneficial treatment. Any licensed physician should be permitted to recommend/prescribe marijuana at his/her discretion, subject to the same oversight as any other aspect of medical practice.</td>
<td>1/6/2017 11:03 PM</td>
</tr>
<tr>
<td>728</td>
<td>'medical' indications for marijuana are not decided at the ballot boxes and are currently extremely limited</td>
<td>1/6/2017 11:00 PM</td>
</tr>
<tr>
<td>729</td>
<td>The survey is wrong! Has two &quot;extremely Likely&quot; option! My answer is extremely unlikely</td>
<td>1/6/2017 10:58 PM</td>
</tr>
</tbody>
</table>
Clean up the language. Anyone may recommend pot to a patient, but it is another thing to prescribe it. Even tho pot is
prescribed, I am an Emergency Medicine physician so I will not be applying for the right to prescribe. 1/6/2017 10:12 PM

I am against the use and prescribing of medical marijuana 1/6/2017 10:26 PM

Perhaps well intentioned but so open to abuse. Just about everyone will qualify. 1/6/2017 10:26 PM

I think two hours of CME is excessive. There is clear evidence in epilepsy patients, and I'd be comfortable prescribing
it now. I think one hour CME is much more doable. 1/6/2017 10:26 PM

I am an Emergency Medicine physician so I will not be applying for the right to prescribe. 1/6/2017 10:12 PM

I am against the use and prescribing of medical marijuana 1/6/2017 10:26 PM

It is very subjective rather then objective 

The proposed rules are very restrictive, 1/6/2017 10:50 PM

When I entered practice my DEA license had in larger letters at the top of the certificate "Opium and Marijuana". I
never prescribed it because I wasn't educated about it. Where I did 4 years of my 7 years of postgraduate training in a
university medical school the house staff lived in an area that I only in retrospect years later realized was filled with
marijuana plants (I had looked upon them as weeds)! One of my colleagues smoked it to ameliorate his asthma and
told me it was a special cigarette for asthma (it worked) which I didn't have reason to question and he functioned very
well as a resident without me ever realizing it was marijuana he was smoking therapeutically (he only smoked a very
little and I never saw him high). This of course is not to say house staff should smoke marijuana!! It's just an
interesting anecdote about a well functioning resident who controlled his asthma with marijuana and a naive resident
(me) who didn't realize what he was smoking but who saw him as a well-functioning resident. Now I'm learning that
with or without THC it offers a whole pharmacy of ancient time tested medicines we are now studying and finding have
a range of amazing qualities, an endocannabinoid system within our very own physiology, and a range effectiveness
and safety that exceeds many accepted commonly used medicines today that also don't have the advantages of a
whole system of innate receptor sites and natural physiologic functions within us. Of course absolutely anything can be
abused however I would recommend balancing this by acknowledging and emphasizing the positive qualities of these
medicines including their range of effectiveness and safety. I do understand the fears that have been generated that
are quite exaggerated and out of balance and congratulate people and authorities for recognizing the plethora of
research that indicates how useful and safe marijuana in various forms can be in aiding what we as physicians are
charged and dedicated to serve. Thank you.

Marijuana has no place in modern medicine, we lower ourselves to the level of witch doctors to prescribe it 1/6/2017 10:48 PM

No comment 1/6/2017 10:45 PM

Our Addictionologists see marijuana as a gateway drug and I will never write marijuana for a patient. 1/6/2017 10:43 PM

Just FYI- I tried to pick what I thought was extremely unlikely even though not a choice in first question. 1/6/2017 10:39 PM

The issue is a some of these diagnosis like fibromyalgia and chronic pain hard to diagnose. I feel that someone would
need to show that cognitive behavioral therapy failed and other treatment modalities failed and a close follow up.
Similar to Suboxone. As you know the most simplistic rule is to make it legal. Like some other states because as you
know the patients will than sell there stuff to others and become legal dispensers of medical grade THC.

The requirement by the state Board of a yearly summary report in MM effectiveness, if considered useful, should apply
to all physician's treatment plans, not just MM. If that is an overreach, then don't single out MM. Why all of a sudden
the interest in effectiveness as presented in a year end summary? Either MM has usefulness from evidence based
medicine or it doesn't. Doctors going through the motions of producing a report that is of dubious design and value
seems political, not medical.

See above--extremely unlikely 1/6/2017 10:32 PM

There is poor to no scientific proof that MJA is effective for treating any of these. Total nonsense based on anecdotal
"evidence." How about adding hangnails to the list? 1/6/2017 10:28 PM

Conditions approved for use are a joke. Fibromyalgia is still diagnosis of exclusion rather her then disease with proven
diagnosis testing which is reliable. I am worried that it would be abused for purpose of prescribing marijuana because
it is very subjective rather then objective

Expand qualifying diagnosis list to include bowel fistula, chronic wounds, and failed orthopedic procedures. Consider
adding conditions where surgical procedures have unpredictable results like torn hip labrium or re-do total joints or
infected total joints with spacers. Medical marijuana could greatly reduce the dependence on opiates and lessen the
volume of opiates in the community 1/6/2017 10:27 PM

I think two hours of CME is excessive. There is clear evidence in epilepsy patients, and I'd be comfortable prescribing
it now. I think one hour CME is much more doable. 1/6/2017 10:26 PM

Perhaps well intentioned but so open to abuse. Just about everyone will qualify. 1/6/2017 10:26 PM

I am against the use and prescribing of medical marijuana 1/6/2017 10:26 PM

This is a law by the pharmacists for the pharmacists. Patients and doctors are second class citizens in the legislation.

I am an Emergency Medicine physician so I will not be applying for the right to prescribe. 1/6/2017 10:13 PM

Eliminate the entire draft Do not use medical Marijuana 1/6/2017 10:07 PM

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I am an Emergency Medicine physician so I will not be applying for the right to prescribe. 1/6/2017 10:13 PM

Eliminate the entire draft Do not use medical Marijuana 1/6/2017 10:07 PM
| 750 | Conditions for treatment should be evidence based in accordance with current peer reviewed medical literature and not public opinion. | 1/6/2017 10:02 PM |
| 751 | I do not agree with the use of THC or any addicting substance for that matter, our country already has a lot of addiction problems, patients want a pill for every ill, we are producing a generation of people with very low tolerance for any kind of discomfort. | 1/6/2017 10:01 PM |
| 752 | I wanted to check off extremely unlikely but there was duplicate choice- I think just typo on survey. I think there are a lot of regulations that will make it impractical for physicians who want/need to prescribe to do so. not sure what you meant by requiring an annual report on effectiveness- by patient? literature review? | 1/6/2017 10:00 PM |
| 753 | Lost in all of this kerfuffle is the fact that we have had prescriptive access to dronabinol (Marinol) for decades. The leaf legalizers shove this under the rug frequently and firmly. It would be great if medical societies could lobby the DEA and FDA to expand the approved indications for dronabinol for all of these indications. Then we would not have to have children with epilepsy exposed to hash brownies. It just seems wrong that this is what we have come to if we have had a completely clean and quality-controlled pharmaceutical product for all these that we are completely ignoring for these indications. We are ignoring it because of the inability of the FDA to expand the approved indications. Why must we have access to a smokable vegetable product when the pill is already in the pharmacy? | 1/6/2017 9:51 PM |
| 754 | I am extremely Unlikely to recommend or prescribe it but the people who made this survey probably use it since that is not listed as an option above | 1/6/2017 9:50 PM |
| 755 | Evidence-based data does not sufficiently support over well accepted options. | 1/6/2017 9:50 PM |
| 756 | Review question 3. choice 5. | 1/6/2017 9:42 PM |
| 757 | To clarify if an Rx is given for chronic intractable pain is limited to pain management physicians the same way opiates for chronic pain are limited. | 1/6/2017 9:42 PM |
| 758 | As a neurologist, certain diagnoses such as fibromyalgia, MS, Alzheimer's and Parkinson's disease would not be conditions for which I would prescribe medical marijuana. | 1/6/2017 9:40 PM |
| 759 | Question 3 is worded wrong; I think one option should be extremely UNlikely? That would have been my choice. I suggest stringent enforcement that more conventional treatment has been tried first. And also, that providers are required to monitor closely for abuse and negative effects of the prescribed THC. I also hope there will be support for providers choosing to NOT participate, to help with pressure from patients; such as printed information about the limited evidence and the risks. | 1/6/2017 9:29 PM |
| 760 | Have concerns about ease of annual report | 1/6/2017 9:20 PM |
| 761 | I think question 3 above has an error in it. there's no "extremely unlikely option". | 1/6/2017 9:16 PM |
| 762 | The answers to #3 are screwed up. I would have answered "Extremely Unlikely". | 1/6/2017 9:16 PM |
| 763 | Too many qualifying conditions | 1/6/2017 9:07 PM |
| 764 | Nothing could get me to jump through those hoops for the infinitesimal chance that Medical Marijuana would offer something better. | 1/6/2017 9:05 PM |
| 765 | #3 has a typo- the 5th choice should read extremely UNlikely | 1/6/2017 9:04 PM |
| 766 | I think this is great. Getting rid of having to treat patients with opioids for pain would be a great step forward. I'm all in favor of alternative pain treatments with less side effects and risk. | 1/6/2017 9:02 PM |
| 767 | Qualifying conditions are subjective, narrowly focused and not based on scientific evidence. There is way too much oversight, needless repetitive documentation and OARRS querying. There is nothing good about the way you're rolling this out and it would be better for the patient and the doctor just to recommend it to your patients and having them buy it off the street. The public will vote to legalize pot. This effort is a waste of time. | 1/6/2017 9:00 PM |
| 768 | I am against medical marijuana and do not plan on writing it for any reason. | 1/6/2017 8:59 PM |
| 769 | Waiting on course content. Rules look adequate. | 1/6/2017 8:57 PM |
| 770 | Additional regulatory exposure of the physician who chooses to use this therapeutic modality; more so than for other regulated drugs. | 1/6/2017 8:57 PM |
| 771 | Used only for medical purpose, it is a useful agent for the quality of life for the diseases permitted | 1/6/2017 8:53 PM |
| 772 | The current guidelines are over-reaching and unenforceable. These create a climate of uncertainty and, in my view, stupidity. Administrative rules, in general, benefit not the patient or the physician, BUT are a goldmine for the lawyers. Let's not pretend we're smart/leaders in this political game where science is missing. | 1/6/2017 8:51 PM |
| 773 | What a burden! | 1/6/2017 8:47 PM |
I assume that was supposed to say extremely unlikely. As an ophthalmologist I would only prescribe for glaucoma. I don’t think it’s very effective for that condition. I do think it has its use and other conditions however

As a psychiatrist I would have concern about the mental health consequences being underestimated, especially long-term use.

guidelines quantifying limits for individual diagnosis is important to limit diversion opportunities. My patients are mostly medicaid will their plans cover this treatment option?

I am glad state Medical Board is taking action to control this substance which has been known to be abused over years , by putting under the category of controlled substance . But is it enough as there r so many medical indication from minor to major e.g. sleep seizure , cancer and mental stabilization and recreation which r all supportive for quality of life which I learned by taking course on that subject. I am worried that financial commercial institute of different label ( including Warren Buffet , George Soro and company like Scot Miracle Grow company) are jumping on this Van Wagon by2 nd hand info from internet. That’s why I am afraid t get involved even though it’s a very new promising area for patient’s benefits even though it has crossed my mind to be involved. Hope I didn’t bored the Board.

As one strong opined & trained in addictive care, this only adds potential avenue for addiction

The draft explains everything

require an observed UDT before treatment and during treatment

You mistakenly placed two extremely likely.

Please be advised that question number 3 above has a typo in that there are two answers for "extremely likely" and none available for "extremely unlikely"

Cannabis has no medicinal value, and this is a political farce. Expanding marijuana into the medical field is stain on our profession. Legalize it completely to end the drama of political manipulation of the medical field.

Extremely unlikely to recommend was not in Q #3 -- my preferred answer

Need to permit pain doctors to be able to recommend medical marijuana to their patients without risking conflict with the DEA ( state vs federal). Chronic pain patients may benefit from both medical marijuana and prescribed pain medication. As is stands now, pain patients risk no longer being eligible to be pain patient if marijuana is ever used. Marijuana should be able to be used in conjunction with other pain options to decrease the amount of narcotics required to permit pain relief for patients.

The burden of proof needs to be shifted back to the physician patient relationship. The reporting rules appear to be onerous

The list of medical conditions is to limited. I’d focus on a more comprehensive list.

I will not prescribe it

Hep C? HIV? I thought these viral illnesses are painless, especially when with novel treatment options h ep c is up to 96-98% cured. The same with HIV as long as the patient is compliant with the therapy. I do not think these illnesses require additional therapy other than antivirals.

Please look at the options you provided for question 3. There is no option to choose for extremely unlikely.

Question #3 has a typo on the answers. Extremely unlikely is not an option. I would have chosen that option were it available.

1. Defective q3. 2. Little quality evidence for GI and Hepatologist diagnoses MM is largely a scam

it would be helpful to have the rules clear and concise .

Your survey needs a spell check. Also your "extremely unlikely" option for the question about prescribing is not present. Instead there are only 2 "extremely likely" options.

As an oncologist I have too many other meds to use now that we live on the slippery slope of "being responsible" for the narcotic epidemic

The annual report needs more clarification and I'm not sure that I understand it's value to physicians or patients. Some of the qualifying diagnoses are potentially vague and could lead to significant overuse of marijuana therapy.

I am not likely to do two hours of CME and have no interest in being micromanaged even further by providing annual reports and who knows what else. So as it stands now unless I start losing a boatload of patients over this issue I see no reason to participate. I am confused about the need to provide quote on going Karen quote to a patient to be able to prescribe. It would seem to me that a patient should be able to remain under my care but see a separate doctor for this just like I might often refer complicated chronic pain patients to pain specialist to manage their narcotics.
I'm assuming that choice was meant to mean extremely unlikely

What the heck kind of an annual report must be sent? That seems like a huge waste of time-- in addition to all the other documentation that we must do.

The choices in question number three include two "extremely likely"

None

The rules are appropriate.

Consider diabetic neuropathy

Poorly devised survey Q # 3 has incorrect choice (#4) "Medical" marijuana is a misnomer. This is NOT medicinal

Good

excellent start

Adding Indication for Treatment of Generalized Anxiety Disorder/Panic Attacks

No comments on the rules, only on the competence of the proofreader for #3. ?Nuetral? Extremely Likely listed twice? Is someone already experimenting with marijuana or just this careless? My answer for #3 ie EXTREMELY UNLIKELY!!!

Not many but the above question has two "extremely likely" answers but no "extremely unlikely" answer

Just a note: Options in question #3 need correcting. There are 2 options that read "Extremely Likely"

Your survey does not have correct responses. Extremely unlikely has typographical error. I would have chosen that, but had to chose NA.

Is there strong medical evidence that medical marijuana helps the conditions listed or is it expert opinion-- It seems like a lot of medical conditions and I am aware of only a few with strong evidence Annual report to the medical board regarding each physician yearly seems onerous and unlikely to be truly evaluated by the medical board (do they really have the resources for this) What other medical condition or procedure or drug use does a physician have to report to the board annually? Either there is good medical science to use the drug or not-- reporting to medical board like we are conducting state wide research program does not seem appropriate, Do it really have medical benefit or not Medical board needs to get pass the pseudo science around medical marijuana Need to avoid creating another epidemic as was done with opioids which now federal and state government is trying to change

An attempt to have doctors control what really is a societal issue, not a medical issue. Trying to control pot today sure looks like prohibition did in the '30s.

It is a slippery slope. Always starts out with good intentions and before you know it, things are out of hand.

How were qualifying conditions selected? Based on what evidence? I'm aware of evidence for intractable epilepsy and pain related to incurable cancer. I'm concerned about a nebulous diagnosis like fibromyalgia being on the list.

Number three above makes no sense-please re-write the responses. Also check your spelling!

They appear reasonable to address conditions for which other treatments have failed

QUESTION 3 HAS EXTREMELY LIKELY IN 2 PLACES. SHOULD THE BOTTOM ONE BE EXTREMELY UNLIKELY?? If so my answer would be extremely unlikely. Also with the drug epidemic in Ohio and the bad medical effects of marijuana I think it is a bad idea to prescribe it.

NA

I say extremely UNLIKELY. but in the options on survey you have two extremely likely's. come on.

N.A.

in no.3, my answer is extremely unlikely which is not listed as an option.

I am not interested in prescribing or recommending medical marijuana

Interested in taking CME course before I would ever recommend to a patient.

For question #3, there's an error In answer choices. I'm extremely unlikely to recommend.

Suggest limiting the number of patients a provider may prescribe to/follow

Not I favor of any plan for marijuana.

The annual report is unneeded and creates an unnecessary reporting burden
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>829</td>
<td>Too complicated. Reporting rules seem burdensome.</td>
<td>1/6/2017 6:49 PM</td>
</tr>
<tr>
<td>830</td>
<td>There should be clear peer reviewed studies documenting the benefit of marijuana in any medical condition that is an indication for use of marijuana.</td>
<td>1/6/2017 6:46 PM</td>
</tr>
<tr>
<td>831</td>
<td>Medical THC is not a good medical treatment...period</td>
<td>1/6/2017 6:43 PM</td>
</tr>
<tr>
<td>832</td>
<td>Question 3 should say extremely unlikely after Somewhat Unlikely but the &quot;un&quot; is missing...I answer extremely unlikely</td>
<td>1/6/2017 6:42 PM</td>
</tr>
<tr>
<td>833</td>
<td>Question 3 above has &quot;Extremely Likely&quot; as 2 answers. I assume one should have been &quot;Extremely Unlikely.&quot;</td>
<td>1/6/2017 6:42 PM</td>
</tr>
<tr>
<td>834</td>
<td>Rules are too onerous</td>
<td>1/6/2017 6:41 PM</td>
</tr>
<tr>
<td>835</td>
<td>It is wrong to request the working class tax payer to pay for medical marijuana. There is no justification to explain forcing tax payers to pay for anyone to get high. Legalizing marijuana will make it sufficiently affordable to everyone who wants to smoke it for whatever reason. Tax dollar funded marijuana use is immoral as the tax payer has absolutely no say or voice in the matter. I am not against the use of marijuana, but I don’t plan to buy it for everyone with back pain, dyspepsia or fibromyalgia either. It is enough that marijuana becomes legal. It has no life saving value worthy of escalating its status to &quot;necessary&quot; medication.</td>
<td>1/6/2017 6:41 PM</td>
</tr>
<tr>
<td>836</td>
<td>This is not a state issue. All of this should be done at federal level only.</td>
<td>1/6/2017 6:40 PM</td>
</tr>
<tr>
<td>837</td>
<td>I'm concerned that long term use of medical marijuana with potential side effects and drug interactions are not known. I'm concerned physicians do not have enough training, for example, concerns about Cannabinoid hyperemesis syndrome. <a href="https://www.ncbi.nlm.nih.gov/pubmed/22150623">https://www.ncbi.nlm.nih.gov/pubmed/22150623</a></td>
<td>1/6/2017 6:40 PM</td>
</tr>
<tr>
<td>838</td>
<td>Need to include anxiety unresponsive to traditional treatments.</td>
<td>1/6/2017 6:39 PM</td>
</tr>
<tr>
<td>839</td>
<td>Evidence for efficacy of medical marijuana in epilepsy and seizures is weak. It seems premature to list this condition as a justifiable reason to Rx MM.</td>
<td>1/6/2017 6:34 PM</td>
</tr>
<tr>
<td>840</td>
<td>I will never prescribe this since I only work in the ER and I cannot always verify what patient’s tell me. Your question #3 answers are not listed correctly.</td>
<td>1/6/2017 6:32 PM</td>
</tr>
<tr>
<td>841</td>
<td>We should be more restrictive, and use this for end stage cancer, end of life care like ALS. I do not think Hepatitis C should be eligible. We should also consider the side effects of hyperemesis syndrome if these are prescribed liberally</td>
<td>1/6/2017 6:31 PM</td>
</tr>
<tr>
<td>842</td>
<td>Appropriate</td>
<td>1/6/2017 6:30 PM</td>
</tr>
<tr>
<td>843</td>
<td>Just want to make sure that the process is not adversarial toward physicians with too many administrative reporting tasks.</td>
<td>1/6/2017 6:30 PM</td>
</tr>
<tr>
<td>844</td>
<td>Get your questions right with proper spelling clinic director yeah sure why not</td>
<td>1/6/2017 6:23 PM</td>
</tr>
<tr>
<td>845</td>
<td>Annual reporting requires keeping special records which is burdensome and not required of other drugs I prescribe.</td>
<td>1/6/2017 6:22 PM</td>
</tr>
<tr>
<td>846</td>
<td>There is an error in this survey. In question 3, the fifth answer option should read &quot;Extremely unlikely&quot; rather than extremely likely. Also, Neutral is misspelled.</td>
<td>1/6/2017 6:21 PM</td>
</tr>
<tr>
<td>847</td>
<td>I do not personally feel that doctors should be prescribing marijuana.</td>
<td>1/6/2017 6:21 PM</td>
</tr>
<tr>
<td>848</td>
<td>Seem reasonable</td>
<td>1/6/2017 6:20 PM</td>
</tr>
<tr>
<td>849</td>
<td>having to submit 12 month report is very cumbersome</td>
<td>1/6/2017 6:20 PM</td>
</tr>
<tr>
<td>850</td>
<td>My answer to the above question (3) would be &quot;NEVER&quot; but there is not even a choice for extremely unlikely. The draft rules seem fair as long as there is a regular process to audit and review medical records in these cases.</td>
<td>1/6/2017 6:17 PM</td>
</tr>
<tr>
<td>851</td>
<td>Is there a limit on the number of patients that a physician can recommend for MMJ? Are you going to intervene in practices that resemble &quot;pill mills&quot;? Already, predatory groups are enrolling patients with affirmative defense cards.</td>
<td>1/6/2017 6:15 PM</td>
</tr>
<tr>
<td>852</td>
<td>I feel the requirement to submit an annual report on each patient places undue burden on physicians and will discourage physician certification of a potentially very useful therapeutic option for patients.</td>
<td>1/6/2017 6:14 PM</td>
</tr>
<tr>
<td>853</td>
<td>None.</td>
<td>1/6/2017 6:14 PM</td>
</tr>
<tr>
<td>854</td>
<td>realistically the potential for abuse is legion., violations should be punished drastically. There should also be a restriction that under NO circumstances may a patient taking medical marijuana drive a motor vehicle or operate machinery within 3 hours of taking the medication. There is a space/time relationship distortion which would predispose someone to lose reasonable judgement. My colleagues will sell this product or massively abuse it if guaranteed.</td>
<td>1/6/2017 6:11 PM</td>
</tr>
</tbody>
</table>
855 I am not convinced an annual report will be added value in this process. It tends to sound like added administrative duty when the care is already being documented with follow up visits and medical documentation. What is the purpose of an annual report besides seeking data— it won't be consistent enough to make any judgements on so far as research— it wouldn't even be valid. So, why?

856 The data for medical marijuana is rather clear for seizure d/o, chronic pain, and cancer related nausea/vomiting...Outside this no other conditions have reached the data level required. This I see this a a rare specialist issue.

857 N/a

858 careful crafting to avoid problems with DEA

859 one has to be cautious because each case can be evaluated on its own merit because i practice psychiatry and there lot of bad side off.from marhuana and there is addiction problem too.

860 There is an error in answer 5 of question 4.

861 2 hours mof specific education does not sound like enough.

862 I am employed by the VA where THC has no accepted medical indication yet.

863 It's a good alternatives to treat pts w CTE, cognitive d/o (Parkinson's, alzheimer), PTSD

864 I anticipate no way in which I would prescribe under the proposed rules/regulations. Zero.

865 I would want to attend educational session(s) on where medical marijuana fits into treatment of the qualifying conditions - faculty would have to free of conflict of interest - would have to present data from high quality research journals. I would PREFER that we had good studies on safety before we incorporated medical marijuana into our treatment. I would likely use medical marijuana only when other treatments are not effective enough.

866 I am absolutely against use of marijuana as a pharmaceutical medically managed treatment. Potential for damage and harm far outweigh benefit. We are doubling down on the harm done by the medical profession in recommending broader use of opiates which was strongly encouraged and supported by the medical board years ago.

867 I am extremely unlikely to prescribe which is not a listed option in question #3.

868 Correct options on question number 3 above.

869 There is only a tiny amount of (anecdotal) evidence for the use of "medica" marijauana

870 Marijuana is federally illegal. It should be allowed to be prescribed unless the federal law is changed!

871 Needed to have - not going to prescribe period as an answer. Also there was not an extremely unlikely choice on my survey. Would have checked that box!

872 It would be helpful if the evidence base for treatment with medical marijuana were more readily available.

873 Medical marijuana should be made available.

874 rules are too burdensome for primary care MD to utilise Med MJ. this is likely to encourage Mds to set up "specialist" Med MJ clinics and charge $$$ and operate outside the patinets usual medical provider network. I think what we really want is responsible recommendations within patients usual provider network

875 The regulations and rules should be VERY liberal in the availability of Medical Marijuana

876 none

877 Qualifying conditions listed will include majority of pain patients and everyone will be asking for medical marijuana. On one end we are trying to find opioids crisis, on the other hand, we are willing to replace it with much stronger, class I medication. You gotta have better and stricter control than what's being suggested. We are creating a monster!

878 Question 3 above has an error in the second to last response., should be " extremely unlikely".

879 Your survey question is misworded. I am extremely UNlikely to recommend medical marijuana.

880 Fibromyalgia is a poorly defined illness, and often a "trash can" diagnosis. Also, there clearly needs to be peer-reviewed medical evidence to support any of the diagnoses listed. I am not aware of any peer reviewed scientific papers or research that supports medical marijuana for any of these conditions.

881 Revise question 3 to add an option of "Extremely Unlikely", as I do not plan to recommend marijuana for any patient unless new evidence develops showing significant benefit. That evidence is currently not available.

882 The above question contains a typo, making it impossible to answer extremely unlikely

883 let docs and only docs prescribe at will
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>884</td>
<td>chronic pain conditions. acute pain in the setting of major surgery</td>
<td>1/6/2017 5:28 PM</td>
</tr>
<tr>
<td>885</td>
<td>How exactly would we submit an annual report on its effectiveness? This needs to be expounded upon.</td>
<td>1/6/2017 5:22 PM</td>
</tr>
<tr>
<td>886</td>
<td>The 5th answer on question #3 should read Extremely unlikely and not (Extremely Likely as it is written).</td>
<td>1/6/2017 5:21 PM</td>
</tr>
<tr>
<td>887</td>
<td>I would limit, in some way, the number of physicians that write these treatment.</td>
<td>1/6/2017 5:21 PM</td>
</tr>
<tr>
<td>888</td>
<td>Just don't think this is necessary</td>
<td>1/6/2017 5:19 PM</td>
</tr>
<tr>
<td>889</td>
<td>Extremely likely option was mention twice It is a typo in question 3 I wanted to choose extremely unlikely in q3 but no such option</td>
<td>1/6/2017 5:18 PM</td>
</tr>
<tr>
<td>890</td>
<td>This is unnecessary and nonsensical. &quot;Medical marijuana&quot; has no role in allopathic or osteopathic medicine.</td>
<td>1/6/2017 5:17 PM</td>
</tr>
<tr>
<td>891</td>
<td>seems like a lot of documentation</td>
<td>1/6/2017 5:16 PM</td>
</tr>
<tr>
<td>892</td>
<td>You need to fix Question 3.</td>
<td>1/6/2017 5:14 PM</td>
</tr>
<tr>
<td>893</td>
<td>I chose extremely unlikely, which is a guess as there is a typo on the survey.</td>
<td>1/6/2017 5:14 PM</td>
</tr>
<tr>
<td>894</td>
<td>An &quot;annual report&quot; to the medical board has no value, has no reasonable precedent and is burdensome. Base your judgment of the effectiveness of marijuana in treating patients on scientific studies as is standard of care, not an opinion report. This regulation is an embarrassassment.</td>
<td>1/6/2017 5:14 PM</td>
</tr>
<tr>
<td>895</td>
<td>The above answer should say &quot;extremely UNlikely&quot;</td>
<td>1/6/2017 5:14 PM</td>
</tr>
<tr>
<td>896</td>
<td>None. I think medical marijuana is a scam and will have a severe effect on the lower socioeconomic class</td>
<td>1/6/2017 5:13 PM</td>
</tr>
<tr>
<td>897</td>
<td>Would not leave this to mid level providers</td>
<td>1/6/2017 5:13 PM</td>
</tr>
<tr>
<td>898</td>
<td>Would the CME be internet based? Will the CME be Ohio specific? Hopefully, the CME would have a standardized, and vetted, agreement/consent.</td>
<td>1/6/2017 5:12 PM</td>
</tr>
<tr>
<td>899</td>
<td>probably would not prescribe, primary care already overwhelmed with current state of practice, would add another very complex issues requiring &quot;policing&quot;, thwarting manipulative and addicted pt, overly time consuming for correct use of prescribing privileges, suspect like to need &quot;pot clinics&quot; for referral purposes</td>
<td>1/6/2017 5:12 PM</td>
</tr>
<tr>
<td>900</td>
<td>extremely unlikely</td>
<td>1/6/2017 5:11 PM</td>
</tr>
<tr>
<td>901</td>
<td>I need to review in greater detail</td>
<td>1/6/2017 5:10 PM</td>
</tr>
<tr>
<td>902</td>
<td>I think whoever typed this is using marijuana medical or not due to typos and poor logic with 2 extremely likely choices ...</td>
<td>1/6/2017 5:09 PM</td>
</tr>
<tr>
<td>903</td>
<td>Post-surgical pain should be included as a qualifying condition</td>
<td>1/6/2017 5:09 PM</td>
</tr>
<tr>
<td>904</td>
<td>None</td>
<td>1/6/2017 5:08 PM</td>
</tr>
<tr>
<td>905</td>
<td>So you have a spelling error in choice 3 and you have 2 extremely likely choices ...</td>
<td>1/6/2017 5:08 PM</td>
</tr>
<tr>
<td>906</td>
<td>The rules appear reasonable</td>
<td>1/6/2017 5:08 PM</td>
</tr>
<tr>
<td>907</td>
<td>I am not opposed to the rules as they are proposed nor to the concept of medicinal marijuana.. I am just not interested in prescribing or making it part of my practice</td>
<td>1/6/2017 5:08 PM</td>
</tr>
<tr>
<td>908</td>
<td>Much of the opioid-related harm resulted from continued use in patients who showed no substantial benefit from it. Continued use of MU should be contingent on demonstrated increase in FUNCTION (as opposed to self report of benefit only.) Function can include social, religious, family activities as well as physical/vocational function.</td>
<td>1/6/2017 5:07 PM</td>
</tr>
<tr>
<td>909</td>
<td>number 3 above has an error in it -- my answer should be &quot;extremely UNlikely&quot;</td>
<td>1/6/2017 5:06 PM</td>
</tr>
<tr>
<td>910</td>
<td>Not enough evidence to convince me that it is useful. Anecdotal findings does not equal to quality medical evidence. YOU DO NOT NEED A TRAINED MEDICAL PROFESSIONAL TO PRESCRIBE A QUACK MEDICINE.</td>
<td>1/6/2017 5:05 PM</td>
</tr>
<tr>
<td>911</td>
<td>I have no desire to participate The indications should be for approved conditions only and those need to be articulated. You WILL NEVER HAVE enough access, See how hard it is to get someone into pain clinic</td>
<td>1/6/2017 5:04 PM</td>
</tr>
<tr>
<td>912</td>
<td>I think they are reasonable. It's a shame that we need to have a separate comprehensive process for one therapeutic modality and a controversial one, at that.</td>
<td>1/6/2017 5:04 PM</td>
</tr>
<tr>
<td>913</td>
<td>Clear enough.</td>
<td>1/6/2017 5:03 PM</td>
</tr>
<tr>
<td>914</td>
<td>No comment.</td>
<td>1/6/2017 5:03 PM</td>
</tr>
</tbody>
</table>
915 Strongly disagree with wording that physician must document that "physician's opinion that the benefits of medical marijuana outweigh the risks." Strongly disagree with need to submit annual report documenting effectiveness of medical marijuana in treating patients - Efficacy of a clinical intervention is evaluated through the mechanism of a clinical trial. It is beyond a reasonable expectation to require every physician to track efficacy and report outcomes in patients who are not enrolled on a clinical trial. This sort of data is only descriptive and very biased based on physician's and patients' individual beliefs. I think the way these rules are drafted are a serious mistake and will be very prohibitory to patients actually being able to receive medical marijuana. As the patient's treating physician, I am very happy to ensure they that they meet the diagnostic criteria for a qualifying condition and to sign off on that. I believe Ohio should follow the standard of other states (such as California, in which I have practiced) that then have the patient use that physician certification of need to then register at a dispensary to be able to receive medical marijuana. Given the discrepancy between state and federal law, asking a physician to state that they actually recommend medical marijuana is a big barrier. There is a big difference between saying, yes, this patient meets medical criteria and it is not contraindicated versus actually prescribing it as a medication.

916 Read literature on success of use of Medicinal Marijuana and decline in use of narcotics and all the side effects. Patients became more productive and quality of life if monitored carefully.

917 The prescribing of medical marijuana must be limited to physicians. This duty should not be expanded to PAs, NPs and dentists.

918 Extremely likely is listed twice above???

919 We have enough obligations, submitting an annual report will be time consuming and costly.

920 Too many conditions that are equivocal

921 Might want to include patient age

922 YOUR SURVEY QUESTION IS WRONG PLEASE CHECK IT IT SAYS EXTREMELY LIKELY TWICE INSTEAD OF UNLIKELY SO HOW CAN WE ANSWER THIS RIGHT!!!!????!!!!

923 Extremely unlikely to recommend. Apparently the folks who prepared the survey were using mj at the time. Question #3 did not give us the option of choosing "extremely unlikely". Also misspelled "neutral". Don't believe we have enough valid research to support it yet.

924 You have an error in your choices above. I wanted to say extremely UNlikely but that choice is not there. Suggestions: must document standard care that failed and document response to treatment including reporting any adverse side effects.

925 Your survey has "extremely likely" on it twice. Great job.

926 Question #4 does NOT have a response: "Extremely UNLIKELY".

927 Published studies clearly show that the dosage of active cannabinoids in marijuana products are highly variable, with either subtherapeutic or toxic levels measured in a large sample test. Additionally, edibles are a major risk to the safety of children, either treated with marijuana or otherwise in the home.

928 appropriate in my view

929 requirements for prescription appear too cumbersome and not necessary

930 Your answers to question 3 are confusing

931 They look good to me. You seem to be mirroring oversight of our care when we use other controlled substances which seems appropriate.

932 unlikely - question 3 on this survey is written incorrectly

933 Question #3 needs to be fixed and have a"extremely unlikely" choice which would have been mine.

934 Above question has typographical errors. I do not wish anything to do with medical marijuana!

935 no protection for the physician at a federal level

936 Question # 3 above has two "Extremely Likely" responses. Is one of them supposed to say "Extremely Unlikely"?

937 I would have selected "Extremely Unlikely", however, it was not an option listed. "Extremely Likely" is listed twice. Also, the word "Neutral" was misspelled.

938 none at this time

939 Mention should be made of the documented deleterious effects of marijuana on pediatric patients, especially on the brain. If medical marijuana is prescribed for a seizure disorder, only marijuana with elevated levels of CBD should be allowed.
940 Your options do not include "Extremely Unlikely," so you might add that, instead of duplicating "Extremely Likely." 1/6/2017 4:38 PM

941 to be specific as far as penalties if any. Chronic pain patients are usually correlated with an ugly criminal record so it is difficult to track down if history per px is credible. 1/6/2017 4:38 PM

942 There is no option of Extremely Unlikely for question number 3, it is not listed above do to a likely typo. Neutral is also spelled incorrectly. 1/6/2017 4:37 PM

943 I doubt that the required annual report from each physician will be helpful to them or the osmb 1/6/2017 4:37 PM

944 The list of qualifying diseases appears random and somewhat repetitive. Crohn's and ulcerative colitis are inflammatory bowel diseases. 1/6/2017 4:37 PM

945 I am not convinced that the evidence suggests that the benefits (modest at best) outweigh the risks of this drug. Increasing evidence is being offered that marijuana has many untoward side-effects. More data will surely be forthcoming on effects of long-term or chronic use. These combined with the societal impact makes me opposed to medical marijuana unless it is part of a formal research trial. The voluntary feedback offered in the regulations is insufficient as it is overly biased. Formal research protocols and consents are needed for this level of unproven and potentially harmful (for patient and society) drug. Once this program is started the financial gain will be so great that any caution will be quickly jettisoned. As we face an opioid epidemic that was largely due to good intentions in treating pain. We now are going to further another problematic substance - I would hope the medical board would resist any prescribing outside of formal research protocols – put this to the test like any other drug. Also - if this is a medical treatment and an active drug then pharmacists should be the only dispensary. 1/6/2017 4:36 PM

946 although my employer does not permit the use of medical marijuana through their clinics, I paid for my DEA certificate myself just for such a development at the state level 1/6/2017 4:33 PM

947 1. I HOPE that answer five to question #3 of this survey means "Extremely UNLikely" 2. While a few of the conditions listed have some reasonable evidence to support treatment with medical marijuana, evidence for others (PTSD and Fibromyalgia are the ones that just jump out) have very poor evidence. With this list all that I patient has to do to get marijuana is say that they “hurt all over” for not apparent reason, or that they had an adverse childhood event that has given them PTSD. Those two complaints represent about 90% of my patients, and the worst thing I could do for the majority of them would be to prescribe marijuana. (the ones who already "self treat" are fairly exclusively the ones who are worst off). 3. If we have to do this, at very least, let’s stick with the diagnoses that have the BEST evidence. Let’s not make it easy for “pill mill” (or in this case, “marijuana mill”) doctors to ask the patient if they “hurt all over”, fulfill all the other documentation requirements, and start handing out marijuana like candy. 4. It makes a LOT of sense to me to ADD TO THE REQUIREMENTS that Dronabinol (Merinol) has been tried and did not work. After all, it is far more regulated, and therefore MUCH safer for the patient. And in most cases works well–I am aware that for some conditions smoked marijuana seems to produce better results in some studies, but the evidence is not that great. Why subject our population to poorly done studies that poorly regulated product when a safer alternative is available? especially if the clinical difference in treatment effect is small? I also understand that we don’t want to seem as if we, as a state, are promoting one specific medication (ie: Dronabinol (Merinol)). However, this seems to be one case where it is important for patient safety that we really push this! 1/6/2017 4:32 PM

948 I see the need for a regimented system for medical marijuana. I personally would not seek to prescribe. However, in the opioid epidemic we face, marijuana as an alternative to opioid I believe is safer. Some studies have suggested the medical marijuana use to be effective. I would like to see more of those studies. Population health is very important in today’s society and health care trends. What is the appropriate risk benefit to recommending marijuana. 5-10 years ago, I would not be saying this. 1/6/2017 4:32 PM

949 you likely meant extremely unlikely as the 5th choice for question 3 I would choose that I think the evidence for the benefits of medical marijuana is thin We have enough of a challenge prescribing long term opioids responsibly and weaning our chronic patients to lower doses effectively. I would not welcome a group of patients taking two potential intoxicants for similar conditions. 1/6/2017 4:31 PM

950 why do you have two answers the same on question #3 both read extremely likely. maybe spend more time on Board stuff and not right to life.... 1/6/2017 4:31 PM

951 The fact that I have to notify the board and patient in advance if I want to stop prescribing to someone makes me think I don’t ever want to start. 1/6/2017 4:30 PM

952 Actual marijuana is still a class I drug and, with all due respect to the Ohio legislature, marijuana prescription is illegal under federal law 1/6/2017 4:30 PM

953 I do not want to prescribe it 1/6/2017 4:29 PM

954 They are too stringent 1/6/2017 4:29 PM

955 Look at number 3 - 2 extremely likely answers. I will never prescribe marijuana. 1/6/2017 4:29 PM

956 Typo in q 3 misleading, there is no explicit "extremely unlikely" 1/6/2017 4:28 PM
<table>
<thead>
<tr>
<th>ID</th>
<th>Comment</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>957</td>
<td>There is an error in #3- extremely likely is in the list 2 times. I don't think being HIV+ alone without AIDS, simply having hep C or Crohns or many other serologic diagnosis without specific symptoms should be &quot;cleared&quot; for this therapy. It should be very specific that to use this as a drug should be used to treat a specific symptom since there is NO EVIDENCE that medical marijuana treats not specific disease at it's biologic source.</td>
<td>1/6/2017 4:28 PM</td>
</tr>
<tr>
<td>958</td>
<td>Has not been shown superior to current treatment modalities. Prescribing is malpractice.</td>
<td>1/6/2017 4:26 PM</td>
</tr>
<tr>
<td>959</td>
<td>There are two answer choices for &quot;extremely likely&quot;. I picked the one I assumed was supposed to be unlikely. There does not seem to be any medical rationale for the choice of some of these conditions. It would be nice for the board to provide that information</td>
<td>1/6/2017 4:26 PM</td>
</tr>
<tr>
<td>960</td>
<td>No comments.</td>
<td>1/6/2017 4:26 PM</td>
</tr>
<tr>
<td>961</td>
<td>I disagree with the use of medical marijuana and will not be prescribing it, regardless of board rules.</td>
<td>1/6/2017 4:25 PM</td>
</tr>
<tr>
<td>962</td>
<td>Physician-patient relationship must be established and maintained with appropriate records. Client needs to be seen at least once between yearly renewal to declare patient health status and use of marijuana</td>
<td>1/6/2017 4:25 PM</td>
</tr>
<tr>
<td>963</td>
<td>Believe severe copd and endstage pulmonary conditions be added</td>
<td>1/6/2017 4:24 PM</td>
</tr>
<tr>
<td>964</td>
<td>above question answer should include extremely unlikely</td>
<td>1/6/2017 4:23 PM</td>
</tr>
<tr>
<td>965</td>
<td>Marijuana for fibromyalgia? Are you kidding me?</td>
<td>1/6/2017 4:23 PM</td>
</tr>
<tr>
<td>966</td>
<td>For a drug to be considered effective, it must produce its desired clinical effect in the absence of significant side effects, in the case of marijuana, sedation and psychotropic effects. All evidence indicates it's impossible for clinical effects to occur without these side effects.</td>
<td>1/6/2017 4:22 PM</td>
</tr>
<tr>
<td>967</td>
<td>Think above question's answers are printed wrong and I would be extremely unlikely.</td>
<td>1/6/2017 4:22 PM</td>
</tr>
<tr>
<td>968</td>
<td>I would like to see some training around the prescribing of Marijuana prior to being able to prescribe it.</td>
<td>1/6/2017 4:21 PM</td>
</tr>
<tr>
<td>969</td>
<td>2 hours of CME is not nearly enough. I would recommend a significant commitment, more like 50. Also question #3 lists &quot;extremely likely&quot; as an option twice. Type or freudian slip?</td>
<td>1/6/2017 4:21 PM</td>
</tr>
<tr>
<td>970</td>
<td>Your survey question number 3 has typos that render it confusing.</td>
<td>1/6/2017 4:18 PM</td>
</tr>
<tr>
<td>971</td>
<td>my answer is extremely unlikely!!! there is an error with the answer selection on question 3 (there are 2 choices for the same answer-extremely likely).</td>
<td>1/6/2017 4:18 PM</td>
</tr>
<tr>
<td>972</td>
<td>The system should be as restrictive as possible to limit pressure being placed on physicians by patients to recommend marijuana or by physician employers to require certification to recommend marijuana</td>
<td>1/6/2017 4:17 PM</td>
</tr>
<tr>
<td>973</td>
<td>There are response errors in question #3</td>
<td>1/6/2017 4:17 PM</td>
</tr>
<tr>
<td>974</td>
<td>I practice in both Lake and Summit counties, I marked Lake in the survey. I am an Emergency Medicine physician, I don't plan on recommending MM to my ED patients. I DON'T want to be flooded in the ER with patients requesting eval for MM. It would be nice, at least as this is rolled out, if ER visits / patient encounters were excluded from the ability to prescribe MM.</td>
<td>1/6/2017 4:17 PM</td>
</tr>
<tr>
<td>975</td>
<td>None</td>
<td>1/6/2017 4:16 PM</td>
</tr>
<tr>
<td>976</td>
<td>The role of medical marijuana in the practices of medicine will need to evolve. For example, I deal with cancer and cancer pain, but never have had marijuana as a &quot;tool&quot;. I would be reluctant to prescribe, at least early on, primarily because of the scrutiny.</td>
<td>1/6/2017 4:16 PM</td>
</tr>
<tr>
<td>977</td>
<td>I'm against it. If it is a medicine, isolate the chemical and test it per FDA, etc.</td>
<td>1/6/2017 4:16 PM</td>
</tr>
<tr>
<td>978</td>
<td>Why does extremely likely appear twice on the survey while there is no extremely unlikely option? There is no logic for many of these conditions e.g. alzheimers, the pathology of which is reproduced by marijuana consumption (recent PET based research).</td>
<td>1/6/2017 4:16 PM</td>
</tr>
<tr>
<td>979</td>
<td>I think it is on the cutting edge there are endocannabinoid receptors/system in the body so a pain related condition, depression, anxiety Along with any inflammatory condition should be considered</td>
<td>1/6/2017 4:15 PM</td>
</tr>
<tr>
<td>980</td>
<td>What will the &quot;annual report&quot; need to look like?</td>
<td>1/6/2017 4:15 PM</td>
</tr>
<tr>
<td>981</td>
<td>I work at the VA which does not approve prescribing marijuana. Data on the benefits for any psychiatric disorder including PTSD are very weak.</td>
<td>1/6/2017 4:15 PM</td>
</tr>
<tr>
<td>982</td>
<td>The rules seem reasonable however I have a concern about legitimately identifying appropriate candidates</td>
<td>1/6/2017 4:14 PM</td>
</tr>
<tr>
<td>983</td>
<td>Extremely unlikely however I have a concern about legitimately identifying appropriate candidates</td>
<td>1/6/2017 4:13 PM</td>
</tr>
<tr>
<td>984</td>
<td>Generalized anxiety disorder should be included</td>
<td>1/6/2017 4:12 PM</td>
</tr>
<tr>
<td>ID</td>
<td>Comment</td>
<td>Date/Time</td>
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<td>-----</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>985</td>
<td>I would add to the list for patients with: Hidradenitis (Diffuse, i.e. axillary and groin) End stage lymphedema/Elephantiasis Severe protein calorie malnutrition Failure to thrive</td>
<td>1/6/2017 4:12 PM</td>
</tr>
<tr>
<td>986</td>
<td>Draft rules too obtrusive.</td>
<td>1/6/2017 4:11 PM</td>
</tr>
<tr>
<td>987</td>
<td>Answer shouls read extremelu unlikely No data...not clinically appropriate</td>
<td>1/6/2017 4:11 PM</td>
</tr>
<tr>
<td>988</td>
<td>I would expand the list of qualifying conditions to include psychiatric disorders. Michigan has seen good effects with depression/anxiety, for example.</td>
<td>1/6/2017 4:11 PM</td>
</tr>
<tr>
<td>989</td>
<td>More clear cut data regarding efficacy in certain conditions. Suggested dosing parameters. Listing of possible AEs.</td>
<td>1/6/2017 4:10 PM</td>
</tr>
<tr>
<td>990</td>
<td>Legalize it!</td>
<td>1/6/2017 4:10 PM</td>
</tr>
<tr>
<td>991</td>
<td>I endorse strict control and reporting mechanisms.</td>
<td>1/6/2017 4:10 PM</td>
</tr>
<tr>
<td>992</td>
<td>The formal submission of benefit will be too time consuming in light of all the the other paperwork we have to currently complete on a frequent basis</td>
<td>1/6/2017 4:10 PM</td>
</tr>
<tr>
<td>993</td>
<td>I would have chosen extremely unlikely if that was an option on your survey</td>
<td>1/6/2017 4:09 PM</td>
</tr>
<tr>
<td>994</td>
<td>Include too few conditions that may be helped by medical THC.</td>
<td>1/6/2017 4:09 PM</td>
</tr>
<tr>
<td>995</td>
<td>No medical evidence that it helps</td>
<td>1/6/2017 4:09 PM</td>
</tr>
<tr>
<td>996</td>
<td>Clear plan of care needs to be established in writing between the patient and the provider. Agreement needs to include limitation allowing the patient to obtain the product from a single provider. Labs need to be established to test products for the content of various cannabinoids and for testing of blood/serum levels. Registry of patients needs to be establisised with mandatory reporting of responses, side effects, and severe complications of treatment.</td>
<td>1/6/2017 4:08 PM</td>
</tr>
<tr>
<td>997</td>
<td>I will be prescribing medical marijuana for epilepsy. I would like to use it like any other anticonvulsant. If it works, I will continue it, if not, I will discontinue it. That's what neurologists do. I do not see how submitting an annual report to a third party about its effectiveness in my pts helps anyone. This is unnecessary paperwork. Whatever rules are finalized -- I suggest a checklist for MDs that is easy and quick to complete to maximize compliance, ease the paperwork burden on MDs.</td>
<td>1/6/2017 4:07 PM</td>
</tr>
<tr>
<td>998</td>
<td>I would like to see the number of patients treated with medical marijuana limited to no more than 30 the first year and no more than 100 in subsequent years.</td>
<td>1/6/2017 4:07 PM</td>
</tr>
<tr>
<td>999</td>
<td>The above box I checked should read &quot;extremely unlikely&quot; you should correct it from your end</td>
<td>1/6/2017 4:06 PM</td>
</tr>
<tr>
<td>1000</td>
<td>EM physician not likely to initiate any marijuana therapy</td>
<td>1/6/2017 4:05 PM</td>
</tr>
<tr>
<td>1001</td>
<td>The annual report request needs to be more specific on what is require. Is this a book report on medical marijuana or a report about his/her own practice</td>
<td>1/6/2017 4:04 PM</td>
</tr>
<tr>
<td>1002</td>
<td>my hospital does not support the use of medical marijuana so limits my practice</td>
<td>1/6/2017 4:04 PM</td>
</tr>
<tr>
<td>1003</td>
<td>Submitting annual reports seems cumbersome and a definite impediment to wanting to prescribe. There are so many variables that go into the response. I can understand the 2 hours of CME training and granting a &quot;certificate&quot; but that one is a non-starter.</td>
<td>1/6/2017 4:03 PM</td>
</tr>
<tr>
<td>1004</td>
<td>Require that same standards of care be applied to medical marijuana prescriptions as prescriptions of narcotics for pain/anxiety e.g. OAAARS review every 3-6 months, frequent random urine drug screen, expectations of continuing other therapeutic modalities, avoiding co-prescriptions of multiple types of narcotics with marijuana etc.</td>
<td>1/6/2017 4:02 PM</td>
</tr>
<tr>
<td>1005</td>
<td>It would take a rare excuse to use and the med will continue long after indicated</td>
<td>1/6/2017 4:02 PM</td>
</tr>
<tr>
<td>1006</td>
<td>This should not be allowed</td>
<td>1/6/2017 4:01 PM</td>
</tr>
<tr>
<td>1007</td>
<td>Not sure why CTR is not inclusive of DPMs -when I have an unrestricted active license to practice medicine and surgery...seems very exclusionary.</td>
<td>1/6/2017 4:01 PM</td>
</tr>
<tr>
<td>1008</td>
<td>Please respect the intent of the electorate.</td>
<td>1/6/2017 4:00 PM</td>
</tr>
<tr>
<td>1009</td>
<td>Seem reasonable, I just don't feel comfortable prescribing medical MJ</td>
<td>1/6/2017 4:00 PM</td>
</tr>
<tr>
<td>1010</td>
<td>Allowing physicians to recommended medical marijuana (for cancer patients in my case) will be a big step forward in treating symptoms and focusing on quality of life as patients go through treatment. The annual report will significantly decrease feasibility of prescribing. We do not have to submit an annual report for prescribing narcotics or other medications (chemotherapy) with a much higher risk of side effects.</td>
<td>1/6/2017 3:59 PM</td>
</tr>
</tbody>
</table>
I am in general support of medical marijuana, however as an ophthalmologist with subspecialty of glaucoma, I can state there is no role for it management in treating this disease. Both the American Glaucoma Society and the American Academy of Ophthalmology have taken this position because there is no evidence to support its use. I would like to see glaucoma taken off the list of qualifying conditions.

Error in question #3 - the fifth choice should read "extremely unlikely"

Answer to # 3 is problematic. My response would have been extremely unlikely but that is not an option.

I think you have typo error in the previous question. You have two answers of "Extremely Likely" and none with "Extremely Unlikely".

Please be more specific about the duration and cause of pain under the chronic pain allowance

Fibromyalgia should not be a qualifying condition

question number 3 has extremely likely twice. I am assuming the second one near Not applicable is suppose to say extremely UNLIKELY. I will NEVER recommend medical MJ period. This is going to turn into yet another substance that we have to constantly battle. I cannot believe I live in a state that is going to open the doors to this. 100% AGAINST medical MJ.

I have no objection to lawful access to MJ. But, I do not want be the one who makes the decision. I have no access to controlled studies as to how To treatment guidelines. Also as with the narcotics debacle, doctors were blasted for Not controlling all the suffering and then 20 years later, we are blasted as incompetent at best and criminal at worst because those people still are in pain and on narcotics. I can envisage some day that doctors were passing out pot for unfounded reasons and that again we were either incompetent at best or criminal at worst depending the zeitgeist. While I will be long gone by that time, I can see the problems. Again, if doc's are to rx this, they need education and studies otherwise, let the people legally treat themselves. Medical use will lead us to be scape goats again Also, if rx will be as much of a nuisance as present controlled substances, I will not go to that hassle. I already do no accept patients who need controlled substances or I will see them with the understanding that I will treat all their problems but will be rx with not rx of controlled substances. I would have the same approach with pot since, like Narcotics, is something I am apparently not educated enough to be in charge But X But

Does a proscriber need a DEA number to proscribe medical marijuana?

I just don't believe in this. I haven't seen any good evidence and am not planning on incorporating it into my practice.

The above is list is missing extremely unlikely, which would be my choice.

I will always remain one of the physicians who will never, ever write a prescription for marijuana! I believe that it violates the physician oath that we all took to become doctors! Marijuana is illegal and should remain that way! I never want to be on a bus or plane driven by someone who has the "right" to be high. I believe that pharmaceutical companies have worked long and hard on medications that can help the conditions listed. Marijuana is more of a "comfort" solution. So count me and hopefully many more doctors OUT on this entire proposal!

Decriminalization of marijuana is the goal. Treat it like alcohol in the legal system and medical system.

It's dope and would do onl harm to patients. I wrote somewhat unlikely as extremely unlikely wasn't an Option. Foolish and myopic political environ of today will affect generations to come negatively.

REALY !!!!! THIS IS STUPID LOOK AT THE ABOVE QUESTION I GET TO CHOSE EXTREMELY LIKELY OR AT THE BOTTOM GEE EXTREMELY LIKELY GEE ARE YOU HIGH??? STOP UNNECESSARY DRUGS NO MARIJUANA

please consider adding muscle spasms, nausea also need rules how to address the quarterly follow-up that is mentioned in the HB 523 legislation.

A really bad idea to go down this road

1) Each prescriber to have a limited number of patients, like Suboxone, to be prescribed. Some states have places that distribute marijuana with a doc in the same building making it TOO easy to get scripts. 2) no medical contraindications like schizophrenia. 3) negative urine drug screens for illicit substances other than marijuana that were not prescribed by a doctor

Section 3 has no extremely unlikely choice

I assume the second last entry in question 3 is supposed to be Extremely Unlikely". That is why I marked that

OK. Seems like you have given this a lot of thought and my initial resistance is softening.

Question 3 above has left out the choice of Extremely Unlikely
I would be uncomfortable with prescribing medical marijuana for fibromyalgia. It seems like this is mostly anecdotal evidence right now.

It will cause a lot of mental disorder.

Too broad. Needs more qualifiers. May need to prove that other pain control has not worked. This is still open to a lot of abuse. Physicians will be under great pressure to prescribe and will be criticized by employers when patients are unhappy. This places physicians in a no-win situation.

PTSD should not be one of the diagnoses listed.

I am a DPM so I will not be able to prescribe medical marijuana. However, I am a proponent for legalization of marijuana, medical and recreational. I do not personally use marijuana, I have in the past, but I think it is much safer than alcohol.

The Ohio medical board should come out strongly against the use of medical marijuana, until it is no longer considered a controlled substance by the federal government.

HIV should not be a qualifying condition. There should be a complication of HIV such as peripheral neuropathy, chronic pain, malnutrition, inability to tolerate medications, etc. HIV is now treatable and the life expectancy is the same as for people who do not have HIV infection.

Psychiatric conditions and substance use history that preclude

Unhappy to see that drug screen for ILLICIT drugs is not REQUIRED, only a possible suggestion. Kind of like Ohio taxpayer money for welfare patients who use money to buy street drugs.

I work in pediatrics and couldn't imagine ever prescribing medical marijuana to a young child. There should be an age requirement.

Please make it more clear how a physician can be "enrolled" or certified to recommend MM and what the Rx process will be.

I don't understand the need for the annual report from each physician. Shouldn't a central body be tasked with reviewing effectiveness, instead?

These are very good rules

don't write an RX for anybody

HIV should not be a qualifying condition.

An annual report is difficult. to maintain a separate list of patients that are prescribed marijuana. This is basically a research study without appropriate rules and IRB approvals.

#3 - I choose extremely unlikely. There is a very serious problem with illegal substances in my area and I will not be prescribing marijuana.

Being HIV+ should not be sufficient as a condition. There should be a complication of HIV such as peripheral neuropathy, chronic pain, malnutrition, inability to tolerate medications, etc. HIV is now treatable and the life expectancy is the same as for people who do not have HIV infection.

Question 3, choice 4 - extremely likely should be extremely UNLIKELY.

Physician conditions and substance use history that preclude
1061 On question 3, you have two choices of "Extremely Likely." You might want to correct that. I will not prescribe or recommend medical marijuana.

1062 There is a typo on question 3, "extremely likely" is listed twice.

1063 What information does the annual report need to contain? Is it patient by patient specific? Is it a summary with percentages of patients helped or harmed by the medication?

1064 I am a psychiatrist. I am unclear why PTSD is a qualifying condition. What exactly is the evidence base for that? Similarly, what is the evidence base for giving people with TBI marijuana? I don't agree with lawmakers simply choosing some diagnoses and legitimating the "prescribing" of marijuana for individuals without evidence base for effectiveness. It puts providers in a bind and it is not sound policy.

1065 Why have you listed 'extremely likely" twice in the preceding question, omitting the option of "extremely unlikely"? As well, "nuetral" is not correctly spelled. If you wish SINCERE INPUT FROM PHYSICIANS, YOU MAY WIST TO TAKE THIS MORE SINCERELY.

1066 I won't be open to prescribe it for these conditions. This is opening the door for more trouble on every aspect and category.

1067 What?? you didn't leave a box for EXTREMELY UNLIKELY which I would have chosen--Freudian slip??

1068 Consider requiring a trial of the appropriate chemical component of cannabis before the smoked variety is used. We will be causing a resurgence of lung cancer and haphazard dosing.

1069 My answer above is extremely unlikely

1070 The answers to question 3 need to be changed. Neutral is spelled incorrectly and Extremely Unlikely is not listed as an option. Didn't anyone proofread this? My answer is Extremely Unlikely

1071 I would like to suggest that restrictions are placed like the buprenorphine waiver, 30 patients the first 6 or even 12 months with subsequent limits. There is limited objective data regarding effective dose, serum concentrations, a rigorous evaluation process should be in place to monitor safety and effectiveness of this "new" therapy.

1072 There is no medical indication for medical marijuana

1073 We already have Marinol, not sure why we need "medical" marijuana.

1074 3 has two Extremely Likely options, and no Extremely unlikely, and neutral is spelled wrong. Are you in a hurry? I'm extremely UNLIKELY to recommend until US FDA says it's not Cat I abused drug. I love home rule, but won't violate federal laws.

1075 Your survey had duplicate answers and misspellings

1076 I am concerned about a flood of patients coming in and demanding treatment with medical marijuana.

1077 N/a

1078 Cannot be cumbersome for Drs. Rx of current scheduled drugs has added a layer of bureaucratic paperwork to our office

1079 I don't like that fibromyalgia is considered one of the best indications for medical marijuana. Now every patient will carry Fibromyalgia diagnosis.

1080 Question #3 does not have an extremely unlikely choice

1081 They seem reasonable and scientifically based.

1082 There are important typos in this survey- see question 3

1083 The "qualifying conditions" should be VERY NARROW and based on scientific evidence, not testimonial and myth.

1084 A great deal of new data has been accumulated regarding cannabinoid chemistry, pharmacology, and physiology. Physicians should demonstrate familiarity with this material as well as proficiency in considering the potential benefits and risks of medical cannabinoids.

1085 Rules seem a bit restrictive in terms of conditions that qualify for medical marijuana

1086 I practice on my Ohio license in a VA hospital outside of Ohio. So the rules, while making a great deal of sense, will not apply to me.

1087 Please keep most of the indications for cancer patients and terminally ill patients.

1088 I would like to see evidence-based articles on the subject.
<table>
<thead>
<tr>
<th>ID</th>
<th>Response</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1089</td>
<td>There is no evidence to suggest medical marijuana is effective for cancer therapy, so if this list was added to specifically an adjuvant to cancer treatment or hospice care, then yes. But it will send the wrong message to many cancer patients if we simply state the medical diagnosis of cancer is sufficient to receive medical marijuana as, again, there is absolutely no evidence that marijuana in any way cures cancer. I have seen people die after refusing chemotherapy and only being &quot;treated&quot; with medical marijuana, and we need to be clear if we are to move forward with this.</td>
<td>1/6/2017 3:37 PM</td>
</tr>
<tr>
<td>1090</td>
<td>I do not recommend medical marijuana for any condition, under current Ohio medical/pharmacy board rules/regulations I feel the risk is too high.</td>
<td>1/6/2017 3:37 PM</td>
</tr>
<tr>
<td>1091</td>
<td>Habit forming marijuana</td>
<td>1/6/2017 3:37 PM</td>
</tr>
<tr>
<td>1092</td>
<td>Very restrictive, but appropriately so.</td>
<td>1/6/2017 3:36 PM</td>
</tr>
<tr>
<td>1093</td>
<td>Too many rules and too much paperwork</td>
<td>1/6/2017 3:36 PM</td>
</tr>
<tr>
<td>1094</td>
<td>answer 3 above us extremely UNLIKELY. (no option given!)</td>
<td>1/6/2017 3:36 PM</td>
</tr>
<tr>
<td>1095</td>
<td>should be legal for recreational use anyway.</td>
<td>1/6/2017 3:36 PM</td>
</tr>
<tr>
<td>1096</td>
<td>The &quot;Annual Report&quot; seems ridiculous. You are essentially asking us to do research for you on the effectiveness of marijuana for these conditions. No busy practice has time for this. You are essentially making it very unlikely that any physicians are going to actually comply and recommend this treatment.</td>
<td>1/6/2017 3:35 PM</td>
</tr>
<tr>
<td>1097</td>
<td>As a Dr who is right on the Mich line... I see a lot of patients who are using this for an &quot;approved diagnosis&quot; which has been made up or malingered. This is not reasonable.</td>
<td>1/6/2017 3:34 PM</td>
</tr>
<tr>
<td>1098</td>
<td>Poor evidence to support this</td>
<td>1/6/2017 3:34 PM</td>
</tr>
<tr>
<td>1099</td>
<td>Misspellings!!! Would not prescribe</td>
<td>1/6/2017 3:34 PM</td>
</tr>
<tr>
<td>1100</td>
<td>No comment</td>
<td>1/6/2017 3:34 PM</td>
</tr>
<tr>
<td>1101</td>
<td>Would be using only for treatment of intractable infantile or childhood epilepsy.</td>
<td>1/6/2017 3:33 PM</td>
</tr>
<tr>
<td>1102</td>
<td>no comment</td>
<td>1/6/2017 3:33 PM</td>
</tr>
<tr>
<td>1103</td>
<td>response above should read extremely unlikely;</td>
<td>1/6/2017 3:33 PM</td>
</tr>
<tr>
<td>1104</td>
<td>Chronic pain from conditions other than fibromyalgia</td>
<td>1/6/2017 3:32 PM</td>
</tr>
<tr>
<td>1105</td>
<td>The annual report seems like unneeded paperwork.</td>
<td>1/6/2017 3:32 PM</td>
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</table>
Ohio Medical Marijuana Control Program
Medical Board Draft Rule Review with Patient Advocates
Jan. 4, 2017, 30 East Broad Street, Columbus, OH 43215

In attendance

<table>
<thead>
<tr>
<th>Ted Bibart, patient advocate, OMMCPAC</th>
<th>State Medical Board of Ohio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ian Heyman, Indigo Asset Management</td>
<td>AJ Groeber, executive director</td>
</tr>
<tr>
<td>Tom Jackson, Ohioans for Compassionate Care</td>
<td>Kimberly Anderson, chief legal counsel</td>
</tr>
<tr>
<td>Tim Johnson, Ohio Cannabis Safety First</td>
<td>Tessie Pollock, director of communication</td>
</tr>
<tr>
<td>Wendy Johnson, Ohio Cannabis Safety First Ian</td>
<td>Missy Craddock, Ohio Medical Marijuana Control Program</td>
</tr>
<tr>
<td>Robert Kowalski, Veterans Ending the Stigma</td>
<td></td>
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<tr>
<td>Rob Ryan, Ohio Patients Network</td>
<td>Erin Reed, Ohio Board of Pharmacy</td>
</tr>
<tr>
<td>Nicole Scholten, United Ohio</td>
<td></td>
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<tr>
<td>Ian Schwartz, Veterans Ending the Stigma</td>
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<tr>
<td>Samantha Stacy, nurse, caretaker</td>
<td></td>
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<tr>
<td>Penny Tipps, Public Policy Strategies</td>
<td></td>
</tr>
<tr>
<td>Rachel Winder, Benesch Law</td>
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</table>

Meeting was called to order by Mr. Groeber at at 2:07 p.m.

Mr. Groeber stated that the Ohio Medical Marijuana Control Program (OMMCP) rules created by the State Medical Board of Ohio (SMBO) reflect the same minimal standard of care required across all of the board’s rules. Certificates to recommend are restricted to MDs and DOs in the language of HB523. When benchmarking other states with medical marijuana programs, the board considered New York and Connecticut because they also have a certificate to recommend and Minnesota because the state produces and annual report. During the drafting of the rules, SMBO worked with a panel of physicians which included representation from the health cluster of state agencies, Ohio Osteopathic Association and Ohio State Medical Association. An initial survey of physicians was distributed by SMBO in September. Results were represented in the handout.

Mr. Bibart asked Mr. Groeber to elaborate about the impediments of working for a large health system. Mr. Groeber indicated that some physicians were receiving directives from their employers to not recommend medical marijuana. These statements could be found in the physician survey. Ms. Anderson furthered comment by stating many health care providers are true employees, or on contract, and that the SMBO is unsure as to what the large employers will be suggesting.

Mr. Ryan suggested the SMBO should survey the health organizations, possible via the Ohio Hospital Association.
Ms. Scholten stated that she would like to gauge what would encourage physicians to recommend and she was directed to the initial physician survey results which indicated ‘peer-reviewed research’ was the most favorable answer.

Ms. Anderson directed attendees to the presented rule package. She stated that the goal was to fold the required rules into current processes as much as possible, making it easy for qualified physicians to obtain a certificate to recommend.

Mr. Bibart asked for clarification on language indicating the SMBO may develop rules.

Ms. Anderson stated it means that the SMBO has the ability to do so, but there is no intention to develop them any at this time or any time before implementation.

Ms. Scholten: Can the SMBO revise the rules at any time before they are adopted and restart the draft approval and input process? Ms. Anderson: Yes.

In addressing Mr. Kowalski’s question about recommending to the veteran population, Ms. Anderson stated that physicians who practice through the US Department of Veterans Affairs (VA) do not need an Ohio-specific license and that the SMBO does not have jurisdiction over the VA because of that; it is a federal entity. She added that the OMMCP rules are for Ohio-licensed physicians and will not apply to physicians practicing in the VA.

Mr. Ryan alerted the attendees to some federal movement and progress which may eventually address this challenge.

Mr. Kowalski expressed concern that veterans may end up seeking a separate doctor solely for the recommendation in addition to have their primary care provider through the VA and that might contribute to a model of clinics for marijuana recommendations similar to opioid pill mills. This could also contribute to substantial medical bills if the individual must receive medical care from physicians outside the VA network.

Ms. Anderson stated that according to the draft rules, if an individual has already been diagnosed by any physician (such as a PCP), then the other physician recommending medical marijuana can simply review the documentation from the physician who did the diagnosis and confirm the diagnosis.

Mr. Bibart provided comment on the use of the term “pill mill.” He stated that the SMBO needs to recognize the stigma that medical marijuana proponents and patients face. He urged that the board recognize they are serving a population with a need, not a ‘pill mill’

Ms. Craddock stressed the importance of the SMBO’s rules as they set up the expectation for the standard of care before the OMMCP is implemented. She continued by saying not providing care was the problem with the pill mills, not the prescriptions. The rule does not place restrictions on
recommending medical marijuana, it just outlines a standard of care. She acknowledged that there could be physicians with a high number of recommendations, but this would be acceptable under these rules as long as a standard of care was met for each patient.

Ms. Scholten expressed her concerns that the program being put forward by the State of Ohio would not be functional. She wants good care for her daughter and for years that has happened because she has personally researched treatment. She also doesn’t support the notion that she may need separate doctors—she will not leave the pediatric specialist who has provided so much care for her daughter, but what if that person is not allowed by their health system to recommend? Will her family have to find a way to afford another doctor? She is also concerned about having to revisit the recommending doctor every 90 days. This would be a burdensome cost to her and her family, even though it could be a cost savings to Medicaid. Ms. Scholten feels that she will have more knowledge than the recommending physician. All of these items, she believes will lead to a non-functioning program and that people will find other means to obtain medical marijuana if OMMCP is too difficult to navigate.

**CMEs**

Mr. Johnson asked for further information about the CME requirements outlined in the draft rules. Mr. Groeber stated that 100 hours is already required every year by physicians and that the medical marijuana rule mirrors the requirements with a CME for licensure and for renewal.

To answer Ms. Winder’s inquiry about the process of getting approval for CME, Ms. Anderson stated that the Medical Board does not provide the approval, rather CMEs are usually granted by the Ohio State Medical Association or the Ohio Osteopathic Association. The role of the Medical Board is to do audits to confirm licensees have indeed completed the CMEs they claim for licensure or renewal.

Mr. Johnson asked if individual educators can create the educational training for physicians wishing to recommend. Ms. Anderson confirmed that individuals would need to go through the associations for approval of CME credit.

Mrs. Johnson stated that she believed that once the program is implemented, the 2-hour requirement might end up being the minimum physicians complete as they may wish to obtain additional knowledge about recommending medical marijuana.

**Standard of Care**

Mr. Kowalski asked if there was anything that was going to be done at the state level to change the definition of substance use disorder (SUD) as this is now very subjective and he is concerned that while one physician feels they are recommending medical marijuana while following the laws and rules, another physician may do a screen, find the marijuana and then diagnose the patient with SUD.

Ms. Anderson stated that she believes it would require more than just simple use of a substance to give a diagnosis of substance use disorder and the intent of this language in the draft rule was to make sure that physicians are aware of possible SUD, but this does not prohibit the recommendation of MMJ.
Ms. Johnson also stated her concern with use and possession of medical marijuana turning into substance use disorder and if charged, would medical marijuana patients be ordered to enroll in treatment.

Mr. Ryan talked about his concerns for patients who do need opioids for chronic pain management, many whom have a pain management contract which says they may not use marijuana. He suggested that the Medical Board reexamine the guidelines for pain management contracts and eliminate language about forbidding marijuana use.

Mr. Bibart suggested that as the board crafts the medical marijuana rules, the should be taking a holistic approach, considering how the medical marijuana rules impact other elements of physician education. He recommended a language tweak on ‘document potential drug interactions.’ Specific concern this could be a huge perception issue on the part of physicians.

Ms. Scholten continued with a recommendation to also change language in Rule 4731-32-03 Standard of Care section 7 where it states, “standard medical treatment has been attempted or considered and one of the following is met.” Mr. Schwartz agreed that medial marijuana should be an initial consideration, not a last resort. Mr. Ryan shared concern but also recognized the draft language stated a physician should “consider” other treatments, not that they “must” and that may make the language okay.

Ms. Scholten voiced her concerns that doctors will feel pressured to try other treatments first. Ms. Anderson state that this language was a suggestion from the physician panel to prevent patients from seeking medical marijuana first when other proven treatments exist. Ms. Scholten pointed out that exactly what she is advocating for— so other people do not have to put their children through 13 years of harmful treatments; so other patients could have this as an option not as a last resort. She stated that it seems like a risk/benefit assessment. Ms. Scholten shared that be believes there is a lack of knowledge of the impact of barbiturates and benzodiazepines on children and that access to medical marijuana could reduce unknown risks.

Ms. Stacy also stressed the importance of having that language; she also suggested that there needs to be clarification to as to the protection for the patient (and parent) when the child has to go into the hospital and the system won’t support the recommendation. She would like some type of protection for the patient once the recommendation is made.

Mr. Groeber acknowledged the concerns to maintain continuity of care, but reminded attendees that the board only has legislative authority set forward in statute. Mr. Bibart suggested that patient advocates might be able to better address this by talking to lawmakers about compassionate care legislation. Mr. Ryan asked if the medical board would be willing to testify. Mr. Groeber stated that the board would need to review the details of any proposed legislation, but everyone on the board is supportive of continuing and compassionate care.
As an answer to the concern over Rule 4731-32-03 Standard of Care section 7, Mr. Bibart requested ending the statement after “attempted or considered.” He believes (a) and (b) will cause tension; however, (c) does then address compassionate care and complimentary care. His suggested edit would mean that the rule would read:

(B) The physician shall create and maintain a medical record that documents the provision of medical services. The documentation shall include all of the following:

1. Patient’s name and date or dates of office visits or treatments;
2. A description of the patient’s current medical condition;
3. Documented assessment of the patient’s medical history, including prescription history and any history of substance use disorder;
4. Documented review of any available relevant diagnostic test results;
5. Documented review of prior treatment and the patient’s response to the treatment;
6. Documented review of the patient’s current medication to identify possible drug interactions, including benzodiazepines and opioids.
7. Documented review that that standard medical treatment has been attempted or considered, and one of the following is met:
   a. The patient had inadequate treatment response to standard medical treatment;
   b. The patient was unable to tolerate the standard medical treatment;
   c. Standard medical approaches are not appropriate in this patient for other documented reasons

All patient advocates in attendance concurred with this change.

Adding a Qualifying Condition
On the rule for adding a qualifying condition, Mr. Ryan expressed concern about the window during which people could petition to add a qualifying condition. He worries that the medical board will be overwhelmed with information at one time rather than spreading it out and reviewing/considering petitions on a rolling basis. Ms. Anderson stated that the window was created over concern that the medical board would not be able to have subject matter expert input on a rolling basis, but if a certain time period was outlined, then we would be able to contract with experts on those conditions. In response to Ms. Scholten’s question, Ms. Anderson said yes, the window for petition would be communicated broadly and the medical board would do all they could to ensure Ohioans would know about the opportunity.

Mr. Bibart further commented on the requirement to provide documentation along with the petition. He asked the medical board to adjust the language to reflect the statute when drafting rules 4731-32-05 when recommending medical marijuana, physician must only consider other treatments, but for the petition to add a new condition you would have to provide evidence that they are insufficient. That language needs to be considered significantly.

Mr. Johnson introduced an additional conversation stemming from concern for courts finding medical marijuana patients to have SUD. Ms. Anderson said this was an issue that she would take to the physician panel, asking if they would consider a conviction a diagnosis or just possession or positive
screen. Mr. Schwartz also encouraged the medical board to meet with the DEA to discuss issues of legality.

Mr. Bibart provided the following as a closing comment: the most important thing is that the OSMB is aware of the angst and pain of a parent who has a suffering child. It is something that causes financial distress, but more painful is the fear that your child could be taken away from you because of the criminal liability.

Mr. Groeber thanked everyone for attending and for their comments. The meeting concluded at 4:03 p.m.