

physicians that such prescriptive authority was non-delegable. Dr. Quinn was caught in this crossfire.

Given the choice of agreeing to a relatively brief suspension of her license or running the risk of a licensure revocation following a contested case hearing before the New Jersey Medical Board, Dr. Quinn opted to enter into a consent order. The suspension of her license in New Jersey was only the beginning of a host of problems. Nearly every jurisdiction in which Dr. Quinn was licensed required her to report her suspension; a failure to timely do so would be an added count of discipline and subject the doctor to additional fines.

In addition to reporting the disciplinary action against Dr. Quinn's license to the NPDB, the New Jersey Medical Board reported it to each state in which she was licensed, thereby triggering the filing of disciplinary complaints against her in all 20 states. Many state boards customarily seek "reciprocal discipline"; that is, to mirror the discipline issued by the New Jersey Medical Board. Fortunately, most of those state boards, after reviewing Dr. Quinn's response to the New Jersey Medical Board's consent order, declined to pursue reciprocal discipline and either dismissed the complaints outright or simply placed Dr. Quinn's license on probation until such time as the discipline in New Jersey was lifted. However, five medical boards chose to mirror the suspension of her license, to be followed by probation, fines, and prescribing courses. In New York, where her private practice was at risk, Dr. Quinn decided to have her case heard on the merits. The New York Medical Board dismissed all charges against her after hearing her case.

Dr. Quinn's challenges were not limited to state licensure, however. She had to respond to inquiries from government

payors, such as Medicaid, Medicare and TRICARE, as well as private health insurance companies. In addition, Dr. Quinn faced inquiries from the DEA, the hospitals where she held privileges; and credentialing boards, such as the American Board of Family Medicine, where she held a certification. Fortunately, no adverse action was taken against her by any of those bodies.

This conscientious and dedicated doctor spent a substantial amount of time over the course of three years responding to the disciplinary proceedings and the resulting inquiries, and traveling to states where in-person attendance was required for medical board meetings or hearings, taking time away from her office and part-time practice.

One can see how easily even a conscientious practitioner can run afoul of a state's practice act or regulations, considering the differences from one state to another. Physicians who are similarly licensed in multiple states would do well to take heed of Dr. Quinn's experience and maintain a heightened awareness of the myriad of rules and regulations that apply to their practice in those states. ■

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*Grant advises physicians to consult with a lawyer prior to meeting with an investigator from the State's health department. Doctors and other practitioners often readily meet with investigators without fully understanding the pertinent regulations and full ramifications of "admissions."*



## Medical Marijuana: Therapy or an Oxymoron?

By Michael J. Baron, MD, FASAM  
Medical Director



**With the current marijuana legalization tide sweeping the nation,** the question among medical professionals has to be, *"Is medical marijuana actually therapeutic, or is it an oxymoron, given there is nothing currently 'medical' about the way this plant is being handled by our pharmaceutical and medical systems?"*

This treatise is not meant in any way to alter the legal regime applicable to Schedule I substances. This is purely for educational purposes and not meant to be a push for or against how marijuana is treated by the federal government. So let me explain...

Unfortunately, there is more emotion and entrepreneurship surrounding medical marijuana than research or science. Currently in the United States, the use and possession of marijuana is illegal under federal law for any purpose because of the Controlled Substance Act (CSA) of 1970. Under the CSA, marijuana is classified as a dangerous, addictive Schedule I substance by the Drug Enforcement Agency (DEA), thereby prohibiting even medical use of the drug. Individual states have passed bills, referendums, propositions and amendments to make medical marijuana legal and available with a doctor's recommendation for certain ailments. State laws regarding marijuana now conflict significantly with federal law. With the results of the November 2018 election, medical marijuana is now available in 33 states and recreational marijuana is available in 10 states and Canada. Marijuana is generally first approved by the state as medical marijuana, followed by approval of marijuana for recreational use, usually within a few years.

States where medical marijuana is legal have circumvented the complex, lengthy and expensive process required of pharmaceutical firms by the Food and Drug Administration (FDA) to bring a medication to market. Although the FDA

process is arduous, it ensures that our prescription pipeline is effective and safe. There is no federal process in place to test, guarantee or regulate medical marijuana. Individual state testing requirements vary greatly from state to state when they are present.

### What We Know

The following is known about medical marijuana or cannabis. Cannabis comes from a flowering plant, native to central Asia and the Indian sub-continent. The genus includes three species: *cannabis sativa*, *cannabis indica*, and *cannabis ruderalis*. Each species has different quantities of the cannabinoids, the active medicinal compounds that are unique to the cannabis plant. The cannabinoids do not contain nitrogen, so they are not classified as alkaloids, differing them from most other psychoactive plant compounds.

The leaves and buds of the *cannabis* plant are cultivated to sell as medical marijuana. The cannabinoids can also be extracted from the *cannabis* plant and infused into edible products such as brownies. The extracted cannabinoids can also be concentrated to very high levels and sold as "concentrates" with product names such as "shatter." Marijuana growers are now producing strains of *cannabis* with varying quantities of the cannabinoids, depending on the desired content.

The cannabinoids are divided into 10 subclasses. The cannabinoids in each subclass are closely related structures differing by only a single chemical moiety or so, which indicates they are likely

intermediate compounds along biochemical pathways. The compound that shares the name with the subclass is generally the most pharmacologically active.

Eight of the 10 cannabinoid subclasses begin with the prefix "Cann," making these groups of compounds easy to confuse with each other. The two classes that do not begin with "Cann" are the tetrahydrocannabinols. The following is a breakdown of the 10 Cannabinoid subclasses and their medicinal properties:

- **Delta 9-tetrahydrocannabinol** ( $\Delta 9$ -THC) is the Cannabinoid with the most psycho-pharmacologic activity.  $\Delta 9$ -THC was first isolated and synthesized in the lab in 1964.  $\Delta 9$ -THC has euphoric, analgesic, antiemetic, antioxidant, and anti-inflammatory properties. In higher concentrations it has psychotogenic (causing psychosis) properties. Delta 8-tetrahydrocannabinol is the other non-Cann named Cannabinoid subclass and is similar to  $\Delta 9$ -THC, only less potent.
- **Cannabidiol (CBD)** is the other main and medically important Cannabinoid. CBD has anxiolytic, antipsychotic, analgesic, anti-inflammatory, antioxidant, and antispasmodic properties. CBD oil has been used to treat many ailments including infantile spasms. Cannabidiol is sold by numerous online retailers who claim their products are derived from industrial hemp and therefore legal. Cannabidiolic acid (CBDA) is another compound in the CBD subclass and has antibiotic properties.

\* This article is based on a true account of discipline against a physician's license. The name of the practitioner and the actual medical boards involved have been changed. We are grateful to "Dr. Quinn" for graciously agreeing to share her story in the hope that other physicians can avoid the problems she faced.

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- **Cannabigerol (CBG)** and **Cannabichromene (CBC)** compounds have antibiotic, antifungal, anti-inflammatory, and analgesic properties.
- **Cannabinol (CBN)** has sedative, antibiotic, anticonvulsant, and anti-inflammatory properties. CBN is a degradation product of tetrahydrocannabinol acid (THCA).
- **Cannabielsoin (CBE)**, **Cannabinidiol (CBND)** and **Cannabitriol (CBT)** are the remaining subclasses of Cannabinoids and have properties that have not been fully isolated or determined.

**What We Don't Know**

As one can see, many of the known cannabinoids have medicinal properties beneficial to patients suffering with a host of inflammatory, infectious, neurologic and painful conditions. So, what's the downside?

The downside is that marijuana — even “medical marijuana” — is a plant that, not counting the cannabinoids, has more than 480 different compounds. We've known for 20 years that marijuana smoke has many of the same carcinogenic compounds contained in tobacco smoke, including polycyclic aromatic hydrocarbons. Physicians learned years ago that smoking tobacco is hazardous. Inhalation of marijuana smoke, just like tobacco smoke, is not a safe delivery system. We have little knowledge as to what these 480 compounds do. Are they safe for human consumption? The answers are not known because the research has not been done, in part because Marijuana remains a DEA Schedule I, which can curtail research, grant funding and study.

The two main strains, *cannabis sativa* and *cannabis indica*, are sold at medical marijuana dispensaries. The following are descriptive compilations found at medical marijuana dispensaries:

*Cannabis Sativa* is typically less potent but tends to have higher levels of the psychoactive compound Δ9-THC. Most people who use *cannabis sativa* find that it increases energy, focus, and creativity, and elevates mood. *Cannabis sativa* is more cerebral and gives a headier, mind-based high. *Cannabis indica* strains are more relaxing and sleep-inducing. They tend to relieve nausea, stress, and anxiety and give patients a sense of calm.

As a rule, the *cannabis sativa*-dominant strains found in dispensaries have delta-9-tetrahydrocannabinol (Δ9-THC) content in the 18-to-30 percent range, whereas the *cannabis indica*-dominant strains have much lower Δ9-THC and higher cannabidiol (CBD) content relative to *C. sativa*.

FDA-approved medications have a strength listed on the container. For example, fluoxetine comes in 10mg, 20mg, and 40mg tablets. Medical Marijuana is made from harvested plant varieties of cannabis, some of which have high concentrations of Δ9-THC and some of which have higher amounts of CBD. Most, if not all, medications have an optimal therapeutic amount called the therapeutic index. Too much of a medication and toxicity occurs; too little and the desired clinical effect is missed. We don't know the ideal therapeutic index for the cannabinoids. That research is still in its infancy.

The individual states where medical marijuana is now legal have their own labeling requirements, all different from each other. **The following are examples of the Colorado warning label requirements for medical marijuana:**

*“There may be health risks associated with the consumption of this product.”*

*“There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding, or planning on becoming pregnant.”*

*“Contains Marijuana. For Medical Use Only. Keep out of the reach of children.”*

**This is also mandated to be listed on the label in Colorado:**

*“A complete list of all nonorganic pesticides, fungicides, and herbicides used during the cultivation of the Medical Marijuana.”*

*For each Harvest Batch of medical marijuana packaged within a container, the medical marijuana center shall ensure the potency of at least the medical marijuana's THC and CBD is included on a label that is affixed to the Container. The potency shall be expressed as a range of percentages that extends from the lowest percentage to the highest percentage of concentration, from every*

*test conducted on that strain of Medical Marijuana within the last six months.”*

**Labeling for medical marijuana infused products in Colorado includes:**

*“This product contains marijuana and its potency was tested with an allowable plus or minus 15% variance.”*

*“This product was produced without regulatory oversight for health, safety, or efficacy.”*

Allopathic physicians moved away from plant therapy decades ago. Physicians don't prescribe willow bark or foxglove extract or opium latex. Physicians prescribe FDA-regulated, inspected, and verified medications with known strengths listed on the container such as aspirin, digitalis and opioids.

Another reason we moved away from whole plant therapy is that plants can contain contaminants and compounds that are harmful when ingested. Our pharmaceutical industry learned to extract the beneficial compound and leave the rest. *Cannabis* is an accumulator and is often contaminated with heavy metals, pesticides, bacteria and fungus.

Phytoextraction can be defined as the use of living plants to absorb and accumulate metals from the soil into the parts of the plant that are above ground. Phytoextraction is used to clean up soil that has become contaminated. *Cannabis* is an exceptional phytoextractor. *Cannabis* hyper-accumulates heavy metals such as lead, cadmium, mercury, chromium, and cobalt present in the soil as a result of fertilizer use, pollution, emissions, runoff, and mining. *Cannabis* also accumulates herbicides and pesticides. Some states, but not all, require testing for bacteria, fungus and heavy metals. When medical marijuana is ingested, a host of toxic compounds are potentially being ingested as well. In the few states that require testing for heavy metals, up to 20 percent of products fail and are destroyed.

Colorado requires a list of pesticides, fungicides, and herbicides used during the cultivation, but that does not include the soil contaminants that have been extracted by the *Cannabis* plant.

Concentrating Δ9-THC or CBD can increase the amounts of heavy metals,

pesticides, or other substances that turn up in the end-product. These heavy metals and organic contaminants get extracted with the Cannabinoids when processing for “concentrates and edibles.” These products like “Shatter,” a popular concentrate which contains more than 90 percent Δ9-THC, are marketed as “healthier” because they don't involve smoking. Yet they may contain much higher concentrations of heavy metals or other soil extracted compounds. Also, there is no current standard to extract Cannabinoids. Manufacturers employ potentially harmful compounds like butane, rubbing alcohol, and industrial heptane to produce concentrates.

To date, Marijuana is a Schedule 1 drug, defined as having no currently accepted medical use and a high potential for abuse. This scheduling also makes human research more difficult. Because Cannabidiol, a compound with promising clinical efficacy, is found in the marijuana plant, it is also considered a Schedule 1 drug and therefore illegal.

To confuse matters, the FDA recently approved Epidiolex,® a Cannabidiol oral solution for Dravet Syndrome and Lennox-Gastaut Syndrome, rare forms of epilepsy that emerge during childhood and can be difficult to treat. In contrast to Schedule 1, this new medication is classified as a DEA Schedule 5 controlled substance, the lowest level, defined as having a proven medical use and low potential for abuse. This is the first FDA-approved drug that contains a

purified drug substance derived from marijuana. Dronabinol (Marinol®) is a synthetic form of Δ9-THC, not an extracted compound and is a DEA Schedule 3. Epidiolex is 100mg/ml and is dosed starting at 2.5mg/kg oral, twice per day.

“Medicalizing” marijuana sends a signal that this is a “safe” drug. People will assume if it is recommended or prescribed by doctors then it must be safe to use. Marijuana is currently the second leading cause for entry into a drug treatment center. By legitimizing marijuana as “medical” we are enticing people to use a product of which they might otherwise steer clear.

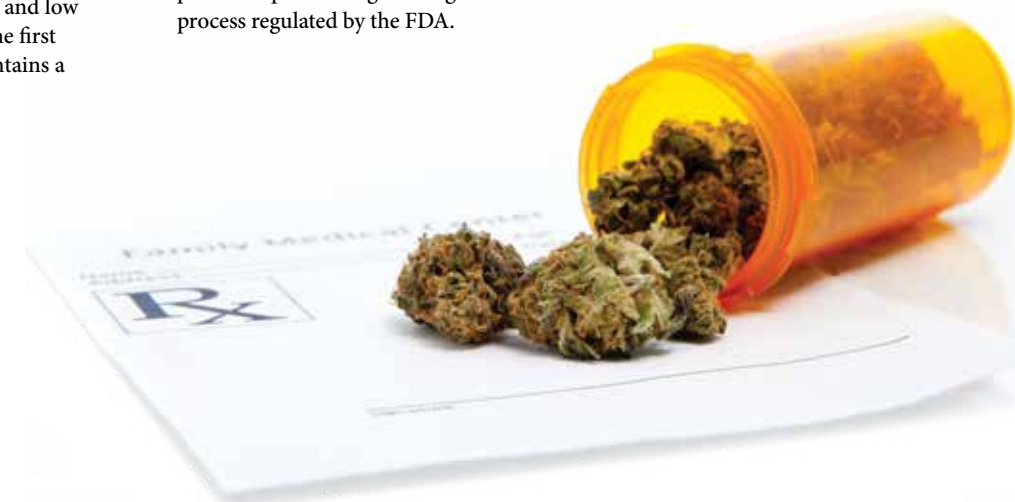
**Let's Do the Research**

It is becoming clear that cannabinoid compounds are effective in treating certain disease processes. However, administering the whole plant to get one cannabinoid compound is not an effective, safe, or even practical delivery method.

By studying the properties of the cannabinoids, we will have a much better idea as to which ones are helpful or harmful. We need to explore this option to get the best data to help guide and educate us. Cannabinoid compounds need to be researched, developed, and when found efficacious, put into our pharmacopeia through the rigorous process regulated by the FDA.

Like a contaminated factory that produces unsafe medicinal products, *cannabis* the plant, has numerous safety concerns. Let's make the cannabinoids safe for those patients who will benefit from their use. ■

*If you or someone you know is actively suicidal, please call Mobile Crisis, a 24/7 response team in Tennessee, at (855) 274-7471. For less emergent referral needs, the Tennessee Medical Foundation Physician's Health Program (TMF-PHP) is a physician resource that provides assessment and referral information. The TMF-PHP can also provide monitoring and advocacy when appropriate for physicians needing that level of care. The program exists for physicians struggling with illnesses that include depression and suicidal thoughts or actions. It is a confidential service provided for physicians to improve the quality of healthcare in Tennessee. Learn more at e-tmf.org or call 615-467-6411.*



*For assistance or to make a tax deductible contribution to the Physicians Health Program, contact the Tennessee Medical Foundation at 615-467-6411; write to the Tennessee Medical Foundation, 5141 Virginia Way, Ste 110, Brentwood, TN 37027; or visit e-tmf.org to send a confidential email or donate online.*