

# MARIJUANA AS A MEDICINE - POLICY, SIDE EFFECTS, SPECIFIC ILLNESSES

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## Introduction

The marijuana industry referred to here are those who illegally, negligently or fraudulently produce, market, or distribute marijuana. The marijuana industry’s advocacy surrounding marijuana as medicine is riddled with half-truths, anecdotes, and empty promises.<sup>1</sup> This paper will discuss policy when marijuana is used as a medicine. It will then discuss the negative side effects of marijuana use. We will also look at particular ailments that marijuana is used for and discuss its safety and effectiveness for those conditions.

You can also learn about the problems marijuana causes by doing some research about marijuana on a number of websites.<sup>2</sup>

When most people think of medical marijuana these days, they don't think of a pill with an isolated component of marijuana, but rather the smoked, vaporized or edible version of the whole marijuana plant also known as “botanical” marijuana.<sup>3</sup>

Rather than isolate active ingredients in the plant - as we do with the opium plant when we create morphine, for example - many legalization proponents advocate vehemently for smoked (or vaporized) marijuana to be used as a medicine. But the science on smoking any drug is clear: smoking - especially highly-potent whole marijuana - is not a proper delivery method, nor do other delivery methods ensure a reliable dose. And while parts of the marijuana plant have medical value, the Institute of Medicine said in its landmark 1999 report: "Scientific data indicate the potential therapeutic value of cannabinoid drugs

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<sup>1</sup> <https://learnaboutsam.org/wp-content/uploads/2017/02/SAM-testimony-Kansas-Feb-2017.pdf>

<sup>2</sup> <https://www.ncbi.nlm.nih.gov/pubmed/?term=marijuana>  
<https://www.sciencedaily.com/>  
<https://clinicaltrials.gov/>  
[http://www.who.int/medicines/access/controlled-substances/6\\_2\\_cannabis\\_update.pdf](http://www.who.int/medicines/access/controlled-substances/6_2_cannabis_update.pdf)

Much of the information used here comes from government publications in the public domain. They are cited.

<sup>3</sup> <https://learnaboutsam.org/wp-content/uploads/2017/02/SAM-testimony-Kansas-Feb-2017.pdf>

... smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances and should not be generally recommended. . . " <sup>4</sup>

Non-botanical synthetic THC has proven medical benefits in particular formulations. The FDA has approved synthetic THC-based medications, dronabinol (Marinol®) and nabilone (Cesamet®), prescribed in pill form for the treatment of nausea in patients undergoing cancer chemotherapy and to stimulate appetite in patients with wasting syndrome due to AIDS. In 2018 the FDA also approved a CBD-based liquid medication called Epidiolex® for the treatment of two forms of severe childhood epilepsy, Dravet syndrome and Lennox-Gastaut syndrome. It's being delivered to patients in a reliable dosage form and through a reproducible route of delivery to ensure that patients derive the anticipated benefits. <sup>5</sup>

Marinol is better for many patients because it is often cheaper and more convenient to use than smoked marijuana. Marinol as an FDA approved drug is covered by medical insurance plans and can be obtained at local drug stores. In addition, Marinol can be ingested more privately than smoked "medical" marijuana. Some people who use marijuana have built a tolerance for the drug and claim that Marinol does not work. This is because they have a tolerance to it. All a doctor has to do to overcome the tolerance is increase the dosage and it will work. Some people who inhale marijuana claim that it works faster to get the effect. However, the effect from inhaling also goes way faster. Marinol provides a longer period of effect which is better for the patient. They also claim that some people cannot swallow a pill but pills can be crushed and swallowed that way. Researchers generally consider medications like these, which use purified chemicals derived from or based on those in the marijuana plant, to be more promising therapeutically than use of the whole marijuana plant or its crude extracts. Development of drugs from botanicals such as the marijuana plant poses numerous challenges. Botanicals may contain hundreds of unknown, active chemicals, and it can be difficult to develop a product with accurate and consistent doses of these chemicals. Use of marijuana as medicine also poses other problems such as the adverse health effects of smoking and THC-induced cognitive impairment. The negative side effects of marijuana use are provided in detail herein. <sup>6</sup>

An additional concern with "medical marijuana" is that little is known about the long-term impact of its use by people with health- and/or age-related vulnerabilities - such as older adults or people with cancer, AIDS, cardiovascular disease, multiple sclerosis, or other neurodegenerative diseases. Further research will be needed to determine whether people whose health has been compromised by disease or its treatment (e.g., chemotherapy) are at greater risk for adverse

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<sup>4</sup> Marijuana and Medicine: Assessing the Science Base, Institute of Medicine 1999.  
[http://books.nap.edu/catalog.php?record\\_id=63762](http://books.nap.edu/catalog.php?record_id=63762)

<https://learnaboutsam.org/wp-content/uploads/2017/02/SAM-testimony-Kansas-Feb-2017.pdf>

<sup>5</sup> <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>

<sup>6</sup> <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>

health outcomes from marijuana use.<sup>7</sup> The potential adverse health outcomes are discussed in detail in this document.<sup>8</sup>

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<sup>7</sup> <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>

<sup>8</sup>

## THE POLICY ARGUMENT AGAINST MARIJUANA AS A MEDICINE

### The FDA process of medicine approval

The FDA medicine approval process represents the best way to help ensure that safe and effective new medicines are available to patients in need of appropriate medical therapy. It is important and appropriate to use the same scientific standards in the development and assessment of any drug.

If any components of marijuana are ever shown to be beneficial to treat any illness then those components can and should be delivered by nontoxic routes of administration in controlled doses just all other medicines are in the U.S.<sup>9</sup>

In 2006, the FDA made the following statement about the smoking of the marijuana plant as a medicine.

#### Inter-agency Advisory Regarding Claims That Smoked Marijuana as a Medicine

Claims have been advanced asserting smoked marijuana has a value in treating various medical conditions. Some have argued that herbal marijuana is a safe and effective medication and that it should be made available to people who suffer from a number of ailments upon a doctor's recommendation, even though it is not an approved drug.

Marijuana is listed in schedule I of the Controlled Substances Act (CSA), the most restrictive schedule. The Drug Enforcement Administration (DEA), which administers the CSA, continues to support that placement and FDA concurred because marijuana met the three criteria for placement in Schedule I under 21 U.S.C. 812(b)(1) (e.g., marijuana has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and has a lack of accepted safety for use under medical supervision). Furthermore, there is currently sound evidence that smoked marijuana is harmful. A past evaluation by several Department of Health and Human Services (HHS) agencies, including the Food and Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA) and National Institute for Drug Abuse (NIDA), concluded that no sound scientific studies supported medical use of marijuana for treatment in the United States, and no animal or human data supported the safety or efficacy of marijuana for general medical use. There are alternative FDA-approved medications in existence for treatment of many of the proposed uses of smoked marijuana.

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<sup>9</sup> "Medical Marijuana: Clinical Considerations and Concerns," Richard G. Soper, MD, AZ Medicine, Summer 2011  
For complete reprints of the original article, contact Dr. Soper at the Center for Behavioral Wellness, 2830  
Bransford Ave., Nashville, TN, 37204; phone: 615-292-5747, fax: 615-2925749; email: mdjd@justice.com.

FDA is the sole Federal agency that approves drug products as safe and effective for intended indications. The Federal Food, Drug, and Cosmetic (FD&C) Act requires that new drugs be shown to be safe and effective for their intended use before being marketed in this country. FDA's drug approval process requires well-controlled clinical trials that provide the necessary scientific data upon which FDA makes its approval and labeling decisions. If a drug product is to be marketed, disciplined, systematic, scientifically conducted trials are the best means to obtain data to ensure that drug is safe and effective when used as indicated. Efforts that seek to bypass the FDA drug approval process would not serve the interests of public health because they might expose patients to unsafe and ineffective drug products. FDA has not approved smoked marijuana for any condition or disease indication.

A growing number of states have passed voter referenda (or legislative actions) making smoked marijuana available for a variety of medical conditions upon a doctor's recommendation. These measures are inconsistent with efforts to ensure that medications undergo the rigorous scientific scrutiny of the FDA approval process and are proven safe and effective under the standards of the FD&C Act. Accordingly, FDA, as the federal agency responsible for reviewing the safety and efficacy of drugs, DEA as the federal agency charged with enforcing the CSA, and the Office of National Drug Control Policy, as the federal coordinator of drug control policy, do not support the use of smoked marijuana for medical purposes.

## **CBD and THC**

Cannabidiol (CBD) is a derivative of marijuana and of the main active ingredients in the marijuana plant. The chemical in marijuana that causes the high (and many of its other effects) is delta-9 tetrahydrocannabinol, or THC. But there are over 100 other cannabinoid chemicals in the plant; CBD is one of those. Different cannabinoids can have very different biological effects; pure CBD, for example, does not normally make people high and is not intoxicating. Over the past several years, FDA has issued several warning letters to firms that market unapproved new drugs that allegedly contain cannabidiol (CBD). As part of these actions, FDA has tested the chemical content of cannabinoid compounds in some of the products, and many were found to not contain the levels of CBD they claimed to contain. It is important to note that these products are not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers should beware purchasing and using any such products.<sup>10</sup>

The FDA approved Epidiolex® (cannabidiol, CBD). CBD is one of more than 80 active chemicals in marijuana. The FDA was quick to note however, that this is not an approval of marijuana or all of its components. This is the approval of one specific CBD medication for a specific use. It was based on well-controlled clinical trials evaluating the use of this compound in

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<sup>10</sup> See the 2016 warning letter section at:  
<https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm>

the treatment of a specific condition. Moreover, this is a purified form of CBD. It's being delivered to patients in a reliable dosage form and through a reproducible route of delivery to ensure that patients derive the anticipated benefits. This is how sound medical science is advanced.<sup>11</sup>

### **CBD as a “Medicine” - the Wild Claims**

Some of the companies that are producing and selling CBD on a national scale have made wildly inflated medical claims about CBD. Acceptance of, and advocacy for, these claims by a percentage of the public shows the need for an assessment of the actual benefits and adverse side effects. Medications should be pure, of known and consistent efficacy and dose, and be produced by a manufacturer that is legally responsible for the quality of the medication. Because there are no or very loose standards in production of CBD most CBD products are suspect. The one exception is Epidiolex® an FDA approved medicine.<sup>12</sup>

In a paper published in Missouri Medicine, R. L. Hilderbrand PhD. noted that:

A 2017 study looking at market share of products by a Cannabis investment group finds CBD is being used to replace traditional pharmaceuticals. The top conditions being treated included anxiety (67%), insomnia (60%), joint pain and inflammation (52%) and depression (43%). Respondents preferred CBD derived from cannabis to CBD derived from industrial hemp and only 9% of respondents indicated using hemp-derived CBD exclusively. The preference for CBD from Cannabis is significant because, without purification, the CBD extracted from Cannabis will, most likely, contain a much higher percentage of THC than does CBD from hemp.<sup>13</sup>

### **The need for FDA approval**

It is our position that any marijuana product intended “for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or any function of the body” that has not been approved for marketing by the federal Food and Drug Administration it is neither safe nor effective and puts patients at risk. Section 201(g)(1) of the

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<sup>11</sup> Statement by FDA Commissioner Scott Gottlieb, M.D., on the importance of conducting proper research to prove safe and effective medical uses for the active chemicals in marijuana and its components.  
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611047.htm>

<sup>12</sup> Hemp & Cannabidiol: What is a Medicine? by R. L. Hilderbrand PhD  
[https://www.msma.org/uploads/6/2/5/3/62530417/hemp\\_and\\_cannabidiol\\_july\\_august\\_2018\\_momed.pdf](https://www.msma.org/uploads/6/2/5/3/62530417/hemp_and_cannabidiol_july_august_2018_momed.pdf)  
<https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm>

<sup>13</sup> Hemp & Cannabidiol: What is a Medicine? by R. L. Hilderbrand PhD  
[https://www.msma.org/uploads/6/2/5/3/62530417/hemp\\_and\\_cannabidiol\\_july\\_august\\_2018\\_momed.pdf](https://www.msma.org/uploads/6/2/5/3/62530417/hemp_and_cannabidiol_july_august_2018_momed.pdf)

Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)].

Before the development of modern pharmaceutical science, the field of medicine was fraught with potions. There were as many anecdotal stories about these potions as there are today about marijuana. Many people were convinced that these potions helped them; however, many of these potions were absolutely useless, or conversely, were harmful to unsuspecting ill people. Thus evolved our current FDA drug approval process. The FDA process has protected us for 100 years; it is dangerous to undermine it. A number of states have approved marijuana as a medicine. They have ignored the FDA process and made these decisions mostly based on anecdotal reports. The anecdotal reports regarding “medical” marijuana are not reliable scientific evidence because the claimed benefits were not independently verified and do not reflect double-blind controls. The anecdotal reports may also be inaccurate due to the emotional expectancy of the person using marijuana and the placebo effect. In some cases there may be deliberate exaggeration for ideological reasons.

Marijuana with THC is intoxicating, so it's not surprising that sincere people report relief of their symptoms when they smoke it. They may be feeling better - but they are not actually getting better. They may even be getting worse due to the detrimental effects of marijuana.

### **No medicine is smoked**

Smoking is a very poor way to deliver a drug because we cannot calculate the dose of smoked marijuana since there is no way to determine how much is actually inhaled. In addition, the harmful chemicals and carcinogens that are byproducts of smoked marijuana create new health problems. The smoking of marijuana has significant risks. For a drug to be acceptable, its beneficial results must outweigh the adverse effects, especially when the advocates argue for the repeated use for symptomatic relief.<sup>14</sup>

### **What are the effects of second hand exposure to marijuana smoke?**

Researchers measured the amount of THC in the blood of people who do not smoke marijuana and had spent 3 hours in a well-ventilated space with people casually smoking marijuana; THC was present in the blood of the nonsmoking participants, but the amount was well below the level needed to fail a drug test. Another study that varied the levels of ventilation and the potency of the marijuana found that some nonsmoking participants exposed for an hour to high-THC marijuana (11.3 percent THC concentration) in an unventilated room showed positive urine assays in the hours directly following exposure; a follow-up study showed that nonsmoking

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<sup>14</sup> Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is a Medicine. U.S. Food and Drug Administration, April 20, 2006

“Smoked Marijuana as Medicine: Not Much Future,” *Clinical Pharmacology & Therapeutics* (2008), H Kalant, Department of Pharmacology, University of Toronto, Toronto, Ontario, Canada

people in a confined space with people smoking high-THC marijuana reported mild subjective effects of the drug - a "contact high" - and displayed mild impairments on performance in motor tasks. A 2016 study in rats found that secondhand exposure to marijuana smoke affected a measure of blood vessel function as much as secondhand tobacco smoke, and the effects lasted longer. One minute of exposure to secondhand marijuana smoke impaired flow-mediated dilation (the extent to which arteries enlarge in response to increased blood flow) of the femoral artery that lasted for at least 90 minutes; impairment from 1 minute of secondhand tobacco exposure was recovered within 30 minutes. The effects of marijuana smoke were independent of THC concentration; i.e., when THC was removed, the impairment was still present. This research has not yet been conducted with human subjects, but the toxins and tar levels known to be present in marijuana smoke raise concerns about exposure among vulnerable populations, such as children and people with asthma. <sup>15</sup> Marijuana smoke is a known carcinogen. <sup>16</sup>

### **Botanical Marijuana Is More Dangerous than FDA Regulated Drugs**

Here are some of the reasons that marijuana may be more dangerous than FDA regulated drugs

1. There is no pharmacy label with warnings.
2. There are no standardized dosages.
3. There are unknown contaminants, unknown contraindications, unknown drug interactions unknown effect and unknown side effects.
4. Marijuana has been shown to cause many physical and mental ailments
6. The adverse risk associated with marijuana treatment is greater than that associated with FDA approved treatments.
7. The risks of adverse events is unknown and not adequately tested.
8. Marijuana as medicine was designed, tested, manufactured, marketed, produced, distributed, and advertised negligently, defectively, fraudulently and improperly.

### **Use of Other Prescription Drugs**

A study showed that medical marijuana users were significantly more likely to report medical use of prescription drugs in the past 12 months. Individuals who used medical marijuana were also significantly more likely to report nonmedical use in the past 12 months of any prescription drug with elevated risks for pain relievers, stimulants and tranquilizers.<sup>17</sup>

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<sup>15</sup> <https://www.drugabuse.gov/publications/research-reports/marijuana/marijuana-safe-effective-medicine>

<sup>16</sup> Evidence on the Carcinogenicity of Marijuana Smoke, August 2009, Reproductive and Cancer Hazard Assessment Branch Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/finalmjsmokehid.pdf>

<sup>17</sup> Journal of Addiction Medicine, <http://www.newswise.com/articles/view/693004/?sc=dwtn>