

US Government Institution Acknowledges Medicinal Uses of Cannabis

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On March 17, 2011, the National Cancer Institute (NCI) added information to its website on the medicinal uses of cannabis (*Cannabis sativa*) in cancer treatment—marking the first time a US government agency has acknowledged the herb’s therapeutic benefits.^{1*}

Many organizations, media outlets, and individuals around the country are referring to this development as a groundbreaking event. “It adds to the growing scientific consensus around the medical efficacy of cannabis and firmly establishes the plant as a [complementary and alternative medicine] treatment alternative,” said Kris Hermes, media specialist for Americans for Safe Access (ASA), an organization promoting safe and legal access to cannabis for medicine and research (e-mail, April 11, 2011).

“And, it further contradicts the federal government’s position, and that of the Department of Health and Human Services (HHS)—which oversees [the National Institutes of Health] and NCI—in particular, that cannabis ‘has no currently accepted medical use in treatment in the United States.’”

The review summary, titled “Cannabis and Cannabinoids,” is located on NCI’s website under the main section “Cancer Topics,” and under subsequent subsections “Complementary and Alternative Medicine,” “Pharmacologic and Biologic Treatments,” and, lastly, “Complex Natural Products.” It includes a general overview of research supporting cannabis’s use in cancer treatment, as well as its mechanisms of action. Additionally, it includes sections on cannabis’s and cannabinoids’ history; laboratory, animal, and preclinical studies; human clinical studies; and overall level of evidence. The review features strong language, such as “Cannabis has been used for medicinal purposes for thousands of years prior to its current status as an illegal

substance,”² and, “The potential benefits of medicinal Cannabis for people living with cancer include antiemetic effects, appetite stimulation, pain relief, and improved

sleep.”³

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“Overall, I'm impressed favorably with the breadth, scope, and details of the summary,” said Dennis McKenna, PhD, a senior lecturer and research associate at the University of Minnesota's Center for Spirituality & Healing. Dr. McKenna is an ethnobotanist who has extensive research expertise on psychoactive medicinal plants.

“Considering this is the NCI, and that the [US Food and Drug Administration]'s official position is that cannabis has no medical use, this is a remarkably honest and objective assessment.”

Impact on Cannabis' Schedule I Status

Despite the relatively quiet manner in which NCI implemented its new cannabis page, the addition has spurred much discussion over its impact on the movement to have cannabis rescheduled. Cannabis is currently listed by the US Drug Enforcement Agency (DEA) as a Schedule I drug, a classification that prohibits cannabis use for anything other than research. Cannabis shares this status with drugs like heroin and LSD. According to the Controlled Substances Act, Schedule I drugs meet 3 criteria:

(1): having a high potential for abuse; (2) having no currently accepted medical use in treatment in the United States; and (3) having a lack of accepted safety for use of the drug or other substance under medical supervision.⁴ Some say that NCI's addition of information on cannabis's medicinal uses in cancer treatment to its website further challenges the validity of this Schedule I status, particularly in regards to the second criterion.⁵

The rescheduling movement aims to have cannabis downgraded to a Schedule III or lower classification. Schedule III drugs are considered to have a less significant potential for abuse than Schedule I and II drugs, as well as a currently accepted medical use in treatment in the United States.⁴ They are available through prescriptions, are permitted to have 5 refills in 6 months, and may be ordered orally.⁶ Dronabinol (brand name Marinol®), a synthetic drug containing tetrahydrocannabinols (THC), is currently a Schedule III drug. A federal petition to reschedule cannabis, which was filed in 2002 by the multi-organizational Coalition for Rescheduling Cannabis, has gone unanswered by the US government for almost 10

years.⁷

Dr. McKenna said he thinks the NCI review will probably, and “unfortunately,” have very little impact on the scheduling of cannabis. “These decisions are made by politicians, who as a rule are not scientists or clinicians and are quite happy to ignore scientific evidence when it's inconvenient,” he said, noting mounting scientific concerns about climate change as an example. “Only when this information becomes widespread enough in the public domain, and is understood by sufficient numbers of people, who then demand changes in the scheduling, will this information make a difference. What will or may also make a difference is when a politician, or a close relative of one, receives significant benefits from cannabis as an adjunct treatment in cancer therapy. Then, and only then, will you see a change.”

NCI's Reaction

Addressing its role in the cannabis scheduling debate, NCI added information to the cannabis page, after its initial posting, stating that PDQ, which authored the review, “is editorially independent of the National NCI.”⁸ NCI wrote, “The summary on Cannabis and cannabinoids does not represent a policy statement of NCI or NIH. The summary statement represents an independent review of the literature; that review is not influenced by NCI or any other federal agency.”

PDQ, or Physician Data Query, serves as NCI's cancer database of information on cancer topics, international cancer clinical trials, a directory of cancer physicians, and cancer term and drug dictionaries.⁹ Several PDQ editorial boards regularly review new cancer-related research and information in consideration for adding to NCI's website. The Complementary and Alternative Medicine (CAM) editorial board of PDQ, which authored the NCI cannabis page, includes representatives of the cancer patient community and a variety of CAM and oncology experts.

“PDQ Editorial Boards summaries do not generate official NCI recommendations or establish official NCI stances on any issue,” said Jeffrey White, MD, the editor-in-chief of the PDQ CAM board. “Each PDQ Board is responsible for identifying the summary topics, writing, revising, and updating the summaries for which it is responsible. The NCI only establishes and financially and administratively supports the PDQ Editorial Boards. Therefore the posting of the PDQ Summary on Cannabis and Cannabinoids does not signal any official NCI opinion on this topic” (e-mail, April 29, 2011).

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However, possibly compromising NCI's statement on the unquestionable, clear separation between NCI and PDQ, Dr. White also serves as NCI's director of the Office of Cancer Complementary and Alternative Medicine.

"Saying that NCI didn't say this, [that] PDQ said it, is a bit disingenuous," said Dr.

McKenna. "[NCI] contracted the study and paid for it. It went through several levels of peer review by qualified experts; they put it on their website. That's a sign that they believe the information is accurate, at least enough to put [it] out to clinicians and others."

In trying to illustrate further why the new cannabis review does not signify a federal agency recognizing an accepted medical use of cannabis, Dr. White pointed out, "The summary states, 'At present, there is insufficient evidence to recommend inhaling [smoked] Cannabis as a treatment for cancer-related symptoms or cancer treatment-related side effects outside the context of well-designed clinical trials.'

Thus, the PDQ Editorial Board has not made a statement endorsing the use of cannabis in the management of cancer patients."

(For a discussion on the US government's alleged suppression of clinical cannabis research, please see this article published in HerbalGram issue 85.)

Due to media and governmental attention, NCI changed some sections of the review about 2 weeks after its initial posting. In a note explaining these changes, NCI wrote:

"Reviewers for the summary on the PDQ CAM Editorial Board... decided to change the wording, in order to clarify the meaning that the Board originally intended to convey and to correct several possible misinterpretations."⁸

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The changes, most of which can be considered relatively minor, consisted of clarifying that cannabis is not approved by the FDA for any medicinal use; that physicians appear to prescribe cannabis mostly for symptom management (in order to avoid the impression that it recommends the prescribing of cannabis by physicians); deleting mention of cannabis's potential anti-tumor properties from the general information section; and clarifying that "even abrupt cessation of cannabinoid intake is not associated with rapid declines in plasma concentrations that would precipitate severe or abrupt withdrawal symptoms or drug cravings."⁷

According to Dr. White, these changes were decided upon after the institute's Office of Communications noticed that various media outlets were "focusing on and misinterpreting" the following sentence: "In the practice of integrative oncology, the health care provider may recommend medicinal Cannabis not only for symptom management but also for its possible direct antitumor effect."

"The sentence was being interpreted as NCI's official support for the use of cannabis for the treatment of patients with cancer," said Dr. White. "This is partly because frequently PDQ summaries are misunderstood to be official NCI statements though they are not. However, it was also clear that the intent of the sentence was being misconstrued. It was in the general information section and was only intended to be a factual statement about what is happening in medical practice, at least where marijuana use can be legally recommended according to state or local law. It was never intended to be a statement about the appropriateness of such recommendations."

NCI also received a message from the National Institute on Drug Abuse (NIDA) expressing some concerns with the same sentence. "The note from NIDA along with the other media statements were shown to me and I discussed them with Dr. Donald Abrams, who is the lead reviewer for the summary," said Dr. White. "I recommended changing the sentence to the current wording because I thought it was likely to be the most accurate and supportable statement that could be made about why cannabis was being recommended by healthcare practitioners. We agreed on this wording and the changes were made."

Possible Shortcomings of the Review

Though deleted from the general information section, data on cannabis's anti-tumor effects still exist in the review's section titled "Laboratory/Animal/Preclinical Studies."¹⁰ This information covers several published studies on anti-tumor effects, but it omits what some might consider

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evidence that is just as—if not more—compelling. A 2006 study published in *The Journal Of Pharmacology And Experimental Therapeutics*, for example, showed that cannabidiol (CBD) was the “most potent inhibitor of cancer cell growth” in mice injected with human breast carcinoma cells” (compared with cannabigerol, cannabichromene, cannabidiol acid and THC acid).¹¹

Additionally, in a 2006 study, Spanish researchers conducted a pilot phase I clinical trial on 9 patients with recurrent glioblastoma multiforme. After being administered THC, two patients experienced “inhibited tumor cell proliferation” and “decreased tumor cell Ki67 immunostaining.”¹² Furthermore, a January 2011 study in *Molecular Cancer Therapeutics*—published 3 months before the NCI cannabis review was posted—found that THC, CBD, and temozolomide exerted “strong antitumoral action”

in cultures of human glioma cells.¹³ Also of interest yet excluded by the NCI review, an in vitro study conducted in 2010 by researchers in California reported that CBD “inhibits human breast cancer cell proliferation and invasion,” and “significantly reduces primary tumor mass as well as the size and number of lung metastatic foci in two models of metastasis.”¹⁴

Inability to Maintain Position Against Science

According to Hermes of ASA, the medical cannabis access organization, the NCI cannabis review does not necessarily indicate a broader shift by larger US governmental entities, such as HHS. Instead, he said, it might signal a more general inability of the federal government to maintain its long-held position against public opinion and science.

“Certain agencies are reviewing their policies and changing them slightly enough to give the impression of meaningful change,” he said, noting the US Department of Veterans Affairs’ July 2010 decision to allow patients to use cannabis as prescribed by outside physicians without risking denial of VA services and benefits.¹⁵ “These policy changes are by no means comprehensive or adequate to solving this public health issue at the federal level, but it indicates that pressure on the government is working.”

Dr. McKenna also pointed out the problematic position of the US government. “The fact that there are FDA approved medicines for treating symptoms associated with cancer [like] nausea

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(e.g., Dronabinol) means that they must believe [cannabis], at least in that form, has some evidence for therapeutic use; yet the official position is that cannabis and cannabinoids have no medical uses. It's not a consistent position; it does not make scientific sense.”

Though the recent website addition by NCI offers a glimmer of hope for medicinal marijuana patients, researchers, and advocates, the administration of President Obama is not acting as many had hoped. ASA recently gave Obama a “failing grade for his record on marijuana,” citing, among other examples, federal “SWAT-style”

raids on medical marijuana dispensaries despite announcing that the administration would decrease focus of federal enforcement in states that have legalized medical

marijuana.¹⁶ Steph Sherer, executive director of ASA, said in a press release, “It is not acceptable to hold millions of sick Americans hostage to a political double standard. It's time for the Obama Administration to recognize the science, act with integrity, and reschedule marijuana.”⁷

*Both the Institute of Medicine (IOM) and a panel of experts convened by the US National Institutes of Health (NIH) have previously recognized that cannabis can be medicinally beneficial to some patients.¹⁷ But the IOM is “an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.”¹⁸ Additionally, NIH expert panels are independent bodies and usually consist of both governmental and non-governmental scientists who are called upon to make recommendations to policy makers. Neither of these entities are official bodies of the federal government.

—Lindsay Stafford

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