

COMMENTARY

Eric A. Voth, MD, FACP

To the frustration and concern of many internationally recognized experts in drug policy, the American College of Physicians has advanced a position paper boldly supporting the use of marijuana for medicinal purposes. The footprints of the Marijuana Policy Project (MPP) are all over this position paper which was supposed to have been a neutral and objective look at the status of marijuana and cannabinoids. The MPP has subsequently used the ACP position as a centerpiece as they sponsor a similar position in the AMA house of delegates.

My specific concerns about the position paper are as follows:

There exists a selective element to the paper that excludes the opposition viewpoint. Positions 1-3 are generally reasonable. However, the conclusions 4 and 5 are not consistent with the literature and essentially allowing marijuana to be prescribed. This is contrary to the formal FDA position. The FDA position opposing medical excuse marijuana was excluded from the discussion as were other works which oppose medical excuse marijuana.

Furthermore, the paper blurs the distinction between research into the use of cannabinoids and the use or alleged benefits of marijuana.

The Institute of Medicine evaluation is heavily quoted. However, as a consultant and contributor to the IOM study, I am concerned that the most restrictive conclusions of the IOM study were conspicuously excluded such as the following:

Recommendation 5: Clinical trials of marijuana use for medical purposes should be conducted under the following limited circumstances: trials should involve only short-term marijuana use (less than six months); be conducted in patients with conditions for which there is reasonable expectation of efficacy; be approved by institutional review boards; and collect data about efficacy.

The section immediately following was excluded:

If there is any future for marijuana as a medicine, it lies in its isolated components, the cannabinoids, and their synthetic derivatives. Isolated cannabinoids will provide more reliable effects than crude plant mixtures. Therefore, the purpose of clinical trials of smoked marijuana would not be to develop marijuana as a licensed drug, but such trials could be a first step towards the development of rapid-onset, non-smoked cannabinoid delivery systems.

Also excluded:

Recommendation 6: Short-term use of smoked marijuana (less than six months) for patients with debilitating symptoms (such as intractable pain or vomiting) must meet the following conditions:

- ▶ *failure of all approved medications to provide relief has been documented;*
- ▶ *the symptoms can reasonably be expected to be relieved by rapid-onset cannabinoid drugs;*
- ▶ *such treatment is administered under medical supervision in a manner that allows for assessment of treatment effectiveness;*
- ▶ *and involves an oversight strategy comparable to an institutional review board process that could provide guidance within 24 hours of a submission by a physician to provide marijuana to a patient for a specified use.*

The problems involving state ballot initiatives and legislative initiatives were not explored at all. Also conspicuously absent were papers or references that oppose marijuana as medicine.

The ACP should oppose efforts to bypass the FDA and create medicine by popular vote, particularly in an effort to support consumer protection, and needs to either revise or abandon its current flawed position on marijuana. If the ACP refuses to revise its policy statement, then it needs to, at minimum, allow the development of a separate position paper called, "Opposing Research Into the Therapeutic Role of Marijuana."

Eric A. Voth, MD, FACP
Chairman, the Institute on Global Drug Policy

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Table 1. Understanding the "Compassion" Issues

Eric A. Voth, M.D., FACP

Chairman, The Institute on Global Drug Policy

We must differentiate between cannabis (i.e. marijuana) and cannabinoids. Just because a cannabinoid may have benefits does not mean that marijuana would.

It is not compassionate to settle for smoking pot in seriously ill or dying patients. This means that we would be settling for impure, non-standardized, smoked plant products rather than demanding reliable, effective, quality medications for debilitated or dying patients.

Below are some of the disorders that marijuana advocates contend that marijuana will help relieve:

- ▶ Nausea from cancer chemotherapy - Neither marijuana nor cannabinoids have been evaluated against the newer effective anti-nausea medicines such as Zofran or Kytril. Marijuana and pure THC are only approximately as effective as the ancient medication compazine. The newer medicines have far fewer side effects than cannabinoids.
- ▶ Glaucoma - There is no evidence that cannabinoids slow the progression of optic nerve deterioration, blindness, or any element of the disease. Marijuana would need to be used several times daily and has far more toxicity than available prescribed medications.
- ▶ Appetite in AIDS wasting or cancer - While cannabinoids and cannabis increase appetite, it appears that only body fat is increased. Healthy nutrition would need to increase lean body mass in order for the weight gain to be beneficial to the subject.
- ▶ Pain: While cannabinoids may have some benefit in modulating pain, they are no more effective than currently available medicines called neuroleptics or opiate-based pain medications. They also have a very small therapeutic window, so higher doses can actually increase pain.
- ▶ Spasticity in Multiple Sclerosis - While cannabinoids can reduce some muscle spasticity, they impair stable gait (ability to walk). They are generally more toxic than available MS medicines.
- ▶ Depression and anxiety - There is no compelling evidence that marijuana helps these disorders. In fact, marijuana is a cause of psychosis, enhances anxiety in some people, and higher doses actually cause depression. It also causes dependence.
- ▶ Headaches and menstrual cramps - Marijuana is dangerous in women of child-bearing age because of toxic effects on the fetus. There is also no clear evidence that marijuana actually benefits these disorders any more than sedatives, and perhaps only from the intoxicating properties.

Table 2. FDA Statement Position on marijuana for medicinal applications

FOR IMMEDIATE RELEASE Statement April 20, 2006 Media Inquiries: FDA Press Office, 301-827-6242 Consumer Inquiries: 888-INFO-FDA

Inter-Agency Advisory Regarding Claims That Smoked Marijuana Is 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.

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.

<http://www.fda.gov/bbs/topics/news/2006/new01362.html>