

Commentaries

Medical Marijuana: Politics Trumps Science at the FDA

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For a Food and Drug Administration (FDA) increasingly mired in controversies over the politicization of scientific and regulatory decisions, the agency's April 20, 2006 statement regarding medical use of marijuana may represent an all-time low point.^[1] Politics, it appears, has now completely trumped science at this once proudly independent agency. The FDA has announced that "no sound scientific studies" support the medical use of marijuana, contradicting an increasingly large body of scientific literature. To those of us who do research in this area, this is a personal affront.

Even the federal Drug Enforcement Agency's (DEA) own Administrative Law Judge, the Honorable Francis Young, stated in 1988, "Marijuana is the safest therapeutically active substance known to man..." He went on to say, "The evidence clearly shows that marijuana is capable of relieving the distress of great numbers of very ill people, and doing so with safety under medical supervision. . .it would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance."^[2] Perhaps more remarkable were the conclusions of President Nixon's Shafer Commission, who were appointed to investigate marijuana's available scientific and medical evidence. To the shock and dismay of President Nixon, the Commission found enough evidence to recommend that marijuana be decriminalized.^[3]

The FDA's announcement is puzzling at many levels. It makes no mention of any recent FDA analysis or investigation, regulatory filing, or any other activity within the normal scope of the agency's work that led to this policy change. Thus, there is no indication as to why the agency chose to issue this opinion at this particular moment. Rather than being based on new data or analysis, the statement appears to have been issued in response to the repeated requests from US Rep. Mark Souder (R-IN), a vehement opponent of medical marijuana use. Souder wrote to acting FDA Commissioner Andrew C. von Eschenbach on January 18, 2006, saying, "I am exasperated at the FDA's failure to act against the fraudulent claims about 'medical' marijuana." He urged that the FDA "post accurate information about the claims of 'medical' marijuana on its website."^[4] After 2 months he renewed the request, taking an impatient tone: "I have yet to receive a response from the Food and Drug Administration regarding my January 18, 2006 letter to you about the FDA's failure to provide any meaningful information on its website about the dangers of marijuana. I am quite concerned that the FDA does not take seriously the threat posed by marijuana, our nation's most abused drug."^[5] The FDA's missive appears to be just what Souder wanted; it asserts that there is a lack of evidence regarding the medical value of marijuana and argues that state laws permitting medical use of marijuana without criminal penalty "are inconsistent with efforts to ensure that medications undergo the rigorous scientific scrutiny of the FDA approval process." The statement concludes by saying that the FDA, along with 2 nonmedical agencies, the DEA and the White House Office of National Drug Control Policy, "do not support the use of smoked marijuana for medical purposes."

We beg to differ with Mr. Souder, who, to our knowledge has no scientific background or medical training. The scientific studies that document the medical efficacy and safety of smoked marijuana are published in peer-reviewed medical journals and are available through the National Library of Medicine. In our experience, the medical peer-review process is very harsh and stringent. Thus, it is not likely that the hundreds of peer-reviewed scientific articles published documenting the benefits of marijuana contain "fraudulent claims."

Moreover, maybe the FDA and Mr. Souder are not aware that The National Institutes of Health (NIH) and the Institute of Medicine have previously issued statements of support for medical marijuana and have called for further investigation.^[6,7] The Institute of Medicine reviewed the issue a second time at the request of the White House Office of National Drug Control Policy, resulting in a 1999 report which declared, "Nausea appetite loss, pain and anxiety are all afflictions of wasting, and all can be mitigated by marijuana." While expressing concern over the risks of smoking, the Institute noted that for some patients -- particularly those with terminal conditions or who do not respond to standard therapies -- those risks would be "of little consequence." The report added pointedly, "We acknowledge that there is no clear alternative for people suffering from chronic conditions that might be relieved by smoking marijuana, such as pain or AIDS wasting."^[8]

This was, in fact, the prior stance taken by the FDA itself, before this sudden turnaround.^[9] Perhaps the FDA has forgotten that doctors can prescribe dronabinol (*Marinol*), which is 100% pure synthetic delta(9)-tetrahydrocannabinol (THC). This is the most powerful psychoactive compound in marijuana, and it is placed in the same category as the prescription strengths of ibuprofen (schedule III), meaning a physician can phone in the prescription. Furthermore, the recent discovery of an endogenous cannabinoid system with specific receptors and ligands has increased our understanding of the actions of marijuana.^[10] The cannabinoid system appears to be intricately involved in normal human physiology, specifically in the control of movement, pain, memory and appetite, among others. Widespread cannabinoid receptors have been discovered in the brain and peripheral tissues. The cannabinoid system represents a previously unrecognized ubiquitous network in the nervous system. There is a dense receptor concentration in the cerebellum, basal ganglia, and hippocampus, accounting for the effects on motor tone, coordination, and mood state.^[11] There are very few cannabinoid receptors in the brainstem, which may explain marijuana's remarkably low toxicity. There has never been a lethal overdose of marijuana reported in

humans. In addition, we have shown that marijuana can be dosed, much like other prescribed drugs.^[12] Moreover, in some instances patients report it as more therapeutic and better tolerated than other medications.^[13,14]

Despite all of this scientific documentation, following the recent Supreme Court ruling [Gonzales v. Raich], Drug Czar John Walters commented, "The medical marijuana farce is done." He then added, "I don't doubt that some people feel better when they use marijuana, but that's not modern science. That's snake oil." But isn't the very definition of palliative care the abatement of suffering in order to make patients "feel better"? Isn't that what doctors and other health professionals are supposed to do for a living?^[15]

In what appears to be an effort to justify the issuance of a statement on medical marijuana with no evident scientific or regulatory reason to do so, the FDA misrepresents the nature and purpose of state medical marijuana laws, stating, "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," suggesting that such laws "seek to bypass the FDA drug approval process." If that were the case, the FDA might arguably have an interest in opining about such laws. But as a general rule, the 11 state medical marijuana laws do not make marijuana available or in any way address the issue of marketing or sales. Rather, they simply protect patients who meet certain conditions (usually including a physician recommendation and/or diagnosis with a qualifying condition) from arrest and punishment under state laws that otherwise forbid marijuana possession or cultivation. Indeed, the lack of a legal means for patients to obtain marijuana for medical use has been a source of controversy in some states that have adopted medical marijuana laws.^[16,17]

One wonders: Does the FDA not understand the difference between licensing a drug for marketing and simply choosing not to arrest individuals who possess that drug under certain conditions? Does the agency believe that arrest and imprisonment are appropriate ways of dealing with a patient's choice to self-treat with an herbal product not approved as a medicine by the FDA?

The recent change of heart by the FDA is disappointing on many levels. This is certainly not the first time the FDA has been accused of letting politics trump science.^[18-20] However, it is the duty of the FDA to be an impartial scientific body and not rent itself out to political agendas. Arguably, marijuana is neither a miracle compound nor the answer to everyone's ills. Yet it is not a compound that deserves the tremendous legal and societal commotion that has surrounded its use. Over the past 30 years, the United States has spent billions in an effort to stem the use of illicit drugs, including marijuana, with limited success. Some very ill people have had to fight long court battles to defend themselves for having used a compound that has helped them. There is no evidence that recreational marijuana use is any higher in states that allow for its medicinal use.^[21] Moreover, prohibition strategies have never proven terribly effective at limiting the use of a substance - whether it be alcohol or other compounds -- for any reason.

Rational, apolitical minds need to take over the debate on marijuana, separating myth from fact, right from wrong, and responsible, medicinal use from other, less compelling usages. However one feels about nonmedical use of marijuana, in our opinion, the medicinal marijuana user should not be considered a criminal in any state. The scientific process continues to document the therapeutic effects of marijuana through ongoing research and assessment of available data. With regard to the medicinal use of marijuana, our federal government and legal system should take a similar approach, using science and logic, rather than politics, as the basis of policymaking. This recent change of policy by the FDA, with politics apparently taking precedence over science, is disappointing and unwarranted.

Readers are encouraged to respond to George Lundberg, MD, Editor of *MedGenMed*, for the editor's eye only or for possible publication via email: glundberg@medscape.net

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