The FDA's Marijuana Problem

By Charles L. Hooper : **BIO** | 18 Aug 2006

The U.S. Food and Drug Administration has a marijuana problem. On April 20 of this year, the FDA rejected marijuana for medical uses. The FDA said, "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."

This conclusion contradicts a lot of other scientific research and expert conclusions, including that of the National Academy of Sciences and the FDA itself. In 1985, the FDA was so convinced of marijuana's medical benefits that it approved Marinol and Cesamet, both synthetic versions of delta-9-tetrahydrocannabinol (THC), the main active ingredient in marijuana.

Here's what the FDA has to say about Marinol. "MARINOL® (Dronabinol) Capsules is indicated for the treatment of: (1) anorexia associated with weight loss in patients with AIDS; and (2) nausea and vomiting associated with cancer chemotherapy in patents who have failed to respond adequately to conventional antiemetic treatments."

The FDA obviously thinks that Marinol and Cesamet are safe and efficacious drugs or else it wouldn't have approved them. If the synthetic versions are so good, why hasn't the FDA embraced the natural version? After all, in the Marinol statements above, the FDA is basically agreeing with marijuana advocates.

Two reasons that might come to mind are dosing and delivery mechanism. Although it may seem that an inability to pin down the ideal dose is a problem, the FDA is fully aware that the gold standard of analgesia in hospitals is patient-controlled analgesia (PCA), in which the patient pushes a button as often as desired to get I.V. doses of morphine. In other words, there is no one-size-fits-all dose with PCA. Empirical evidence shows that PCA produces better pain control with less morphine consumed. Marijuana can be used in much the same way as PCA.

The delivery mechanism of marijuana is usually smoke, which can irritate soft tissues and perhaps precipitate cancer. While certainly a problem, I estimate that marijuana smokers consume about one-percent as much per day as do tobacco smokers. Marijuana smokers take a few puffs ("hits") while tobacco smokers may smoke 20 or 40 entire cigarettes per day. Also, many AIDS and chemotherapy patients will be on short-term therapy or won't live long enough to worry about marijuana-induced lung cancer. Many of them would love to live long enough to have such a problem.

Look at the FDA's statements critically. The FDA isn't saying that marijuana doesn't have health benefits; it's saying that no good studies exist to prove that conclusion. In 2004, the FDA stated, "FDA will continue to be receptive to sound, scientifically based research into the medicinal uses of botanical marijuana and other cannabinoids." The key term is "sound research." The FDA recognizes only medicines that have gone through its long, expensive, and exhaustive investigational new drug (IND) application process -- its idea of "sound research."

The FDA is blind to anything that hasn't been through its process. What's worse, marijuana is highly unlikely ever to clear such hurdles. Why? The FDA requires controlled and consistent production batches and it wants to inspect each manufacturing facility. This would be very difficult for a dried weed that is grown in thousands of different places under thousands of different conditions. The FDA also requires placebo-controlled clinical trials

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with thousands or tens of thousands of patients. What placebo could possibly be used? I doubt that any other safe and medically inactive plant would smell and taste like smoked marijuana. Last, these clinical trials, I estimate, would cost tens if not hundreds of millions of dollars. Who would pay for them? Not the FDA. Not drug companies. Not self-medicating AIDS and cancer patients.

Drugs like marijuana almost certainly do have some health benefits for certain patients. But to put marijuana through the IND process would involve paying for clinical trials, manufacturing facilities, data analysis, legal fees, administrative staff, and FDA face-time, which are all private costs that someone must bear. Marinol's and Cesamet's manufacturers were willing to bear these costs due to the prospect of profits that accrue to the patent holder. For a widespread weed that's been around for millennia, how would anyone garner and enforce such patent protection?

Some say this is a weakness of the private enterprise system. The proponents of government spending on medical research use cases like this as an argument for the role of government. They shouldn't be too optimistic about their solution because that's what we have right now and it has failed miserably. Why? Certain parts of the federal government haven't allowed this scientific process to happen. Remember that, above all else, the government is a political organization and the U.S. government is fighting a war against the production, sale, and usage of marijuana.

The federal government maintains marijuana's status as a Schedule I controlled substance, keeping company with infamous drugs like heroin and PCP. A Schedule I drug is defined as having a very high potential for abuse, no accepted medical use in the United States, and a lack of accepted safety data for use under medical supervision. Interestingly, Marinol is rated as only Schedule III (less dangerous), just like, for example, Tylenol with Codeine.

Just recently, the FDA has landed in more hot water over its marijuana ruling. In 2000, Congress passed what is known as the Data Quality Act to help ensure that regulations are based on solid science. The two-paragraph Data Quality Act wasn't written by a member of Congress, but by James J. Tozzi, and included in a longer appropriations bill. Now Tozzi, who is founder of the Center for Regulatory Effectiveness, is suing the government because the FDA's marijuana ruling has ignored data showing that marijuana is helpful to some patients.

Should we pity the FDA? In some ways, yes, we should. The FDA behaves as a bureaucratic scientist. The FDA will always to be too slow and conservative and require too much data.

I am happy that there are such careful and plodding people in the world. I am not happy that they have the power to prohibit drugs like marijuana. In some cases, like this one, the FDA is the wrong tool for the job. Americans shouldn't rely on the FDA to control widely used and naturally occurring botanicals such as marijuana. The FDA is simply unable to effectively assess the medical value of natural plants like marijuana in any reasonable timeframe. AIDS and cancer are deadly serious diseases and the FDA's approach is fatally flawed. AIDS and cancer patients deserve a better path to useful medicines and than through the FDA's benediction.

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