

THE FDA AND MEDICAL MARIJUANA

The Food and Drug Administration (FDA) accepts or rejects a drug for medical use after receiving an application for a drug's approval as a prescription medicine, accompanied by supporting data provided by the company seeking to market that drug.

The FDA has never received such an application for marijuana. However, on April 20, 2006, the FDA issued an unusual press release restating the federal government's position that marijuana has not been shown to be a safe and effective medicine.

Did the FDA study marijuana prior to issuing the statement?

No. The FDA does not conduct its own trials of drugs, including marijuana. And the FDA statement did not refer to any new research or even any new review or analysis of existing data, even though much new research was available.

Did the FDA consider expert reviews of medical marijuana, such as the 1999 Institute of Medicine (IOM) report, which stated, "Nausea, appetite loss, pain and anxiety ... all can be mitigated by marijuana?"

Apparently not. There is no mention of the IOM report in the FDA statement, and IOM report co-author Dr. John Benson told *The New York Times* that the government "loves to ignore our report ... They would rather it never happened."

So if the FDA didn't study marijuana or even review old data, why did it issue a statement at that particular time?

The agency has never explained this, but the evidence points to political pressure. Congressman Mark Souder (R-IN), perhaps the most vehement opponent of medical marijuana in the U.S. Congress, wrote repeatedly to acting FDA Commissioner Andrew C. von Eschenbach seeking such a statement, writing in one letter, "I am exasperated at FDA's failure to act against the fraudulent claims of 'medical' marijuana."

Why haven't medical marijuana supporters tried to take marijuana through the FDA approval process?

A group of researchers at the University of Massachusetts at Amherst is actively seeking to do this, but the Drug Enforcement Administration is blocking their efforts. The researchers are trying to create a facility to grow specific marijuana strains under controlled, reproducible conditions to test marijuana's efficacy for various indications. Such research is essential for FDA approval, but the DEA has refused to approve such a facility. Until this changes, the door to the FDA is blocked.

Has any notable medical marijuana research occurred since the FDA statement?

Yes. Among others, a University of California study found that marijuana effectively relieves peripheral neuropathy, a type of debilitating nerve pain that afflicts many patients with HIV/AIDS,



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with few side effects. And an observational study found that patients being treated for the deadly hepatitis C virus (HCV) were much more likely to be cured of the lethal virus if they used marijuana, apparently because marijuana relieves the side effects of harsh, anti-HCV drugs, allowing more patients to complete treatment.

The FDA statement repeatedly refers to “smoked marijuana.” Does this mean that other ways of administering marijuana might be okay?

It should, but the statement’s intent in this regard is unclear. Smoking has distinct advantages, such as rapid onset of action and ease of dose adjustment, but it also has known health risks. The FDA statement did not acknowledge such established non-smoked ways of using medical marijuana as teas, tinctures, and cooking marijuana in food. Of critical importance, several studies have shown that vaporization allows the use of whole marijuana with the advantages of smoking but few, if any, of the pulmonary risks associated with smoking. MPP is unaware of any statement from any federal government agency even acknowledging that this technology exists.