U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA and Marijuana

Looking for Treatment

The FDA understands that caregivers and patients are looking for treatment options for unmet medical needs. In some instances, patients or their caregivers are turning to marijuana in an attempt to treat conditions such as seizures and chemotherapy-induced nausea.

Untested Drugs can have Unknown Consequences

Over the last few decades, there has been significant interest in the potential utility of marijuana for a variety of medical conditions, including those that already have FDA-approved therapies.

More recently, several states have also passed laws that remove state restrictions on health care professionals using marijuana as a medical treatment for a variety of conditions. A number of other states are considering similar legislation regarding the use of marijuana in medical settings.

FDA's Role in the Drug Approval Process

The FDA has not approved marijuana as a safe and effective drug for any indication. The agency has, however, approved one drug containing a synthetic version of a substance that is present in the marijuana plant and one other drug containing a synthetic substance that acts similarly to compounds from marijuana but is not present in marijuana. Although the FDA has not approved any drug product containing or derived from botanical marijuana, the FDA is aware that there is considerable interest in its use to attempt to treat a number of medical conditions, including, for example, glaucoma, AIDS wasting syndrome, neuropathic pain, cancer, multiple sclerosis, chemotherapy-induced nausea, and certain seizure disorders.

Before conducting testing in humans of a drug that has not been approved by the FDA, an investigator submits an investigational new drug (IND) application, which is reviewed by the FDA. An IND includes protocols describing proposed studies, the qualifications of the investigators who will conduct the clinical studies, and assurances of informed consent and protection of the rights, safety, and welfare of the human subjects. The FDA reviews the IND to ensure that the

proposed studies, generally referred to as clinical trials, do not place human subjects at unreasonable risk of harm. The FDA also verifies that there are adequate assurances of informed consent and human subject protection.

The FDA's role in the regulation of drugs, including marijuana and marijuana-derived products, also includes review of applications to market drugs to determine whether proposed drug products are safe and effective for their intended indications. The FDA's drug approval process requires that clinical trials be designed and conducted in a way that provide the agency with the necessary scientific data upon which the FDA can make its approval decisions. Without this review, the FDA cannot determine whether a drug product is safe and effective. It also cannot ensure that a drug product meets appropriate quality standards. For certain drugs that have not been approved by the FDA, such as marijuana, the lack of FDA approval and oversight means that the purity and potency of the drug may vary considerably.

As with other drugs that are not approved by the FDA, the agency works closely with the medical and patient communities, and our federal partners when necessary, to allow access to experimental treatments through the expanded access provisions described in the FDA's statute and regulations. The FDA's expanded access provisions are designed to facilitate the availability of investigational products to patients with serious diseases or conditions when there is no comparable or satisfactory alternative therapy available, either because the patients have exhausted treatment with or are intolerant of approved therapies, or when the patients are not eligible for an ongoing clinical trial.

FDA Supports Sound Scientific Research

The FDA also has an important role to play in supporting scientific research into the medical uses of marijuana and its constituents in scientifically valid investigations as part of the agency's drug review and approval process. As a part of this role, the FDA supports those in the medical research community who intend to study marijuana.

The FDA also supports research into the medical use of marijuana and its constituents through cooperation with other federal agencies involved in marijuana research. Conducting clinical research using marijuana involves interactions with **other federal agencies (/NewsEvents/PublicHealthFocus/ucm421173.htm)**:

- The FDA reviews the IND application and the research protocol submitted by the applicant.
- The Drug Enforcement Administration (DEA) reviews the registration application filed by the researcher.
- The National Institute on Drug Abuse (NIDA) within the National Institutes of Health operates

pursuant to the Single Convention on Narcotic Drugs. NIDA has been designated the responsible agency to supply research-grade marijuana to researchers.

State Legislation on Marijuana

Several states have either passed laws that remove state restrictions on the medical use of marijuana and its derivatives or are considering doing so. The FDA supports researchers who conduct adequate and well-controlled clinical trials which may lead to the development of safe and effective marijuana products to treat medical conditions. We have talked to several states, including Florida, Georgia, Louisiana, New York and Pennsylvania, who are considering support for medical research of marijuana and its derivatives to ensure that their plans meet federal requirements and scientific standards.

Related Information

- **FDA and Marijuana: Questions and Answers (/NewsEvents/PublicHealthFocus/ucm421168.htm)**
- **Marijuana Research with Human Subjects (/NewsEvents/PublicHealthFocus/ucm421173.htm)**
- **Warning Letters and Test Results (/NewsEvents/PublicHealthFocus/ucm435591.htm)**

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