



THE MYTH OF “MEDICAL MARIJUANA”



In the United States, medications must be FDA-approved. Marijuana is not.

well-defined and measurable ingredients that are the same each time a person takes a dose. That means one pill has to have the same amount of medicine as the next. This way, a doctor can determine what dose to prescribe and how often a patient should take it.

Also, marijuana has harmful effects, especially when it is smoked, that must be considered. Smoking marijuana can cause a chronic cough and increased risk of bronchitis and other lung infections. It can also interfere with learning and memory, affect driving (especially if combined with alcohol), make some people anxious and paranoid, and can lead to addiction.

Why Do Some People and States Consider Marijuana to Be Medicine?

Some of the *ingredients* in marijuana, such as THC (delta-9-tetrahydrocannabinol), have medicinal effects. And some people get relief from symptoms of their illnesses by smoking marijuana. **However, using marijuana as medicine does not make it medicine.** It has not gone through the FDA approval process to show that its benefits outweigh its risks.

More than a dozen states and the District of Columbia have legalized the use of marijuana for medicinal purposes, but under federal law, marijuana remains *illegal*. So—*is marijuana medicine*? The short answer is **NO**. However, some of the chemicals found in marijuana have been developed into medications, and more medications may be on the way.

To understand why marijuana is not medicine, it helps to know how medications are approved in the United States.

The FDA Testing Process

All medicines in the United States must be approved by the Food and Drug Administration (FDA). The FDA is the government agency that is responsible for making sure that medications are safe and effective **AND** that their likely benefits are greater than any possible harmful effects. This requires careful scientific testing. If a drug doesn't meet FDA standards, it will not be approved and cannot be prescribed or sold as medicine in the United States.

Why Isn't Marijuana an FDA-Approved Medication?

Marijuana comes from the plant *Cannabis sativa*. It contains more than 400 different chemicals—many with unknown effects—which differ from plant to plant. For something to be a medicine, it must have

Did You Know? There is no such thing as “medical-grade marijuana.” The marijuana sold as “medicine” in dispensaries is the same as marijuana sold on the street and carries the same health risks.

FDA-Approved Medications Made From THC

Although marijuana is not medicine, there are some medications that do contain THC. Marinol® is synthetic (i.e., human-made) THC made into a pill. It is FDA-approved to relieve nausea and vomiting in cancer patients undergoing chemotherapy. It is also used to reverse severe weight loss in patients with AIDS.

Another medication, Sativex®, is a mouth spray made from a combination of two ingredients from the marijuana plant (THC and cannabidiol). Sativex® has been approved in Canada and the United Kingdom to relieve cancer pain and symptoms of multiple sclerosis and is currently going through FDA testing in the United States.

New medications that act on the

cannabinoid system (where the THC in marijuana acts) are being developed to treat a variety of symptoms, but with fewer side effects than smoked marijuana. For more on THC and the cannabinoid system, read "The Science of Marijuana" at scholastic.com/headsup/marijuana-science.

▶ For additional facts about marijuana and other drugs, visit teens.drugabuse.gov or scholastic.com/headsup.

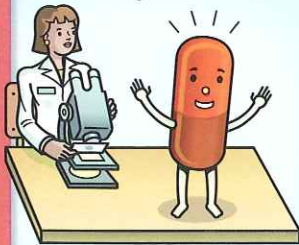
HOW MEDICINE IS MADE: THE PATH TO APPROVAL

Almost everyone has used a prescription medication to help treat or cure an illness. In fact, about 4 billion prescriptions were filled in the United States in 2010. Few people, however, know that it can take more than 15 years and as much as \$2 billion for a new drug to go from the research lab to a patient's medicine cabinet. So what's the path to testing to approval?

START

1. NONCLINICAL TESTING:

A drug that is made in a laboratory or extracted from a plant undergoes a series of tests to find out how it works, where it acts in the body, whether it is toxic (harmful), and how long it takes for the body to break it down.



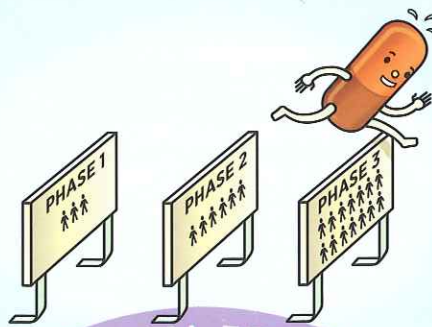
NONCLINICAL TESTING

2. FDA APPLICATION:

Based on the drug's safety and other information obtained from nonclinical testing, the FDA may grant permission for the drug to be tested in humans.



FDA APPLICATION



CLINICAL TESTING

3. CLINICAL TESTING:

This occurs in three phases.

- **PHASE 1:** The drug is tested in 20 to 100 healthy people to find out how it affects humans, if it's safe, and at what doses.
- **PHASE 2:** More testing is done, but in several hundred people with the specific disease or condition that the drug is meant to treat. This is to find out if the drug is safe and effective, and at what doses.
- **PHASE 3:** Testing is done in several hundred to several thousand people with the specific disease or condition the drug is intended to treat. This is to prove the drug has the intended effect, and to determine if it has side effects that would limit its use.

5. APPROVAL: If the FDA gives its approval, then the medication can be marketed and physicians can prescribe it to patients.



FINISH

4. FDA APPLICATION:

The drug company then submits its test results (from nonclinical tests and all three phases of clinical tests) to the FDA. Studies must show the drug is safe and that its benefits outweigh its risks before it can be approved.



FDA APPLICATION

APPROVAL