



In 1970, the United States Congress enacted into law the statutory definition of drugs for "currently accepted medical use".¹

In order for a drug to have a "currently accepted medical use" it must meet the following EIGHT criteria:

- 1. The Drug's chemistry must be known and reproducible.**²
What this means is the substance's chemistry must be scientifically established to permit it to be reproduced into dosages, which can be standardized.
- 2. There must be adequate safety studies.**³
No drug can be considered safe in the abstract. Safety has meaning only when judged against the intended use of the drug, its known effectiveness, its known and potential risks, the severity of the illness to be treated, and the availability of alternative therapies.
- 3. There must be adequate and well-controlled studies proving efficacy.**⁴
Studies involving related, but not identical drugs are irrelevant.⁵ Studies involving the same drug combined with other drugs are irrelevant. Incomplete studies, uncontrolled studies, statistically insignificant studies, poorly designed studies, poorly conducted studies, poorly documented studies, studies by investigators who are not qualified⁶, and studies which cannot be replicated (provide the same results across more than one study) are insufficient.⁷ Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in detail they cannot be scientifically evaluated, and all other forms of anecdotal proof are entirely irrelevant.⁸
- 4. Acceptance by qualified experts is required.**¹
Lay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in detail they cannot be scientifically evaluated, and all other forms of anecdotal proof are entirely irrelevant. The observations and opinions of medical practitioners who are not experts in evaluating drugs are also irrelevant.
- 5. The scientific evidence must be widely available.**⁹
Information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance must be reported, published, or otherwise widely available, in sufficient detail to permit experts, qualified by scientific training and experience to evaluate the safety and effectiveness of the drug.
- 6. General availability of a drug is irrelevant.**¹⁰
To simply measure the availability or use of a substance does not support points 1 through 5, and certainly does not mean the substance is medically beneficial.

7. Recognition in generally accepted text is irrelevant.¹

Information concerning the chemistry, pharmacology, toxicology and effectiveness of the substance must be reported, published, or otherwise widely available to evaluate the safety and effectiveness of the drug.

8. Specific recognized disorders are the referent.¹¹

It is impossible to judge the safety and effectiveness of a drug except in relation to a specific intended use. A drug cannot obtain approval except in relation to the treatment of a specific, recognized disorder.

Marijuana does not fit any of the above criteria.

¹ Controlled Substances Act of 1970

² Dorovic v. Richardson, 749 F.2d 242, 251 (7th Cir. 1973)

³ Hess & Clark Division of Rhodia, Inc. v. FDA, 495 F.2d 975, 993 (D.C. Cir. 1974)

⁴ 21 U.S.C. 355(d); 21 CFR 314.126

⁵ U.S. v. Articles of Food & Drug, 518 F.2d 743, 747 (5th Cir. 1975)

⁶ Cooper Labs v. FDA, 501 F.2d 772, 778 (D.C. Cir. 1974)

⁷ J.O'Reilly "Food and Drug Administration" 13-55 n. 12 (1985)

⁸ Weinberger v. Hynson, Etc., 412 U.S. 609, 630 (1973)

⁹ Cooper Labs Inc. v. FDA, 501 F.2d 772, 786 (D.C. Cir. 1974)

¹⁰ Tri-Bio Labs, Inc. v. United States, 836 F.2d 135, 142 n.8 (3rd Cir. 1987)

¹¹ Food, Drug and Cosmetic Act, 21 U.S.C. 355