

In the Matter of

MARIJUANA MEDICAL RESCHEDULING PETITION

September 6, 1988. Docket No. 86-22. Francis L. Young, Administrative Law Judge

“Based upon the facts established in this record and set out above, one must reasonably conclude that there is accepted safety for use of marijuana under medical supervision.”

“To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious....”

“The cannabis plant considered as a whole has a currently accepted medical use in treatment in the United States, there is no lack of accepted safety for use under medical supervision and it may lawfully be transferred from Schedule I to Schedule II. The judge recommends that the Administrator transfer cannabis .”

Section III: Issues To Be Heard and Decided in This Case

Principle issue: Whether the marijuana plant, considered as a whole, may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act.

Subsidiary issues: 1.) Whether the marijuana plant has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

2.) Whether there is a lack of accepted safety for use of the marijuana plant under medical supervision.

VIII: Cannabis / Marijuana’s Accepted Safety for Use Under Medical Supervision

3. The most obvious concern when dealing with drug safety is the possibility of lethal effects. Can the drug cause death?

4. Nearly all medicines have toxic, potentially lethal effects. But marijuana (cannabis) is not such a substance. There is no record in the extensive medical literature describing a proven, documented cannabis-induced fatality.

5. This is a remarkable statement. First, the record on cannabis encompasses 5,000 years of human experience. Second, cannabis is now used daily by enormous numbers of people throughout the world. Estimates suggest that 20-million to 50-million Americans routinely, albeit illegally, smoke marijuana without the benefit of direct medical supervision. Yet, despite this long history of use and the extraordinarily high numbers of social smokers, there are simply no credible medical reports to suggest that consuming cannabis has caused a single death.

6. By contrast aspirin, a commonly used, over-the-counter medicine, causes hundreds of deaths each year.

7. Drugs in medicine are routinely given what is called an LD-50. The LD-50 rating indicates at what dosage fifty percent of test animals receiving a drug will die as a result of drug induced toxicity. A number of researchers have attempted to determine cannabis’s LD-50 rating in test animal, without success. Simply stated, researchers have been unable to give animals enough cannabis to induce death.

8. At present it is estimated that cannabis’s LD-50 is around 1:20,000 or 1:40,000. In layman terms this means that in order to induce death a marijuana smoker would have to consume 20,000 to 40,000 time as much cannabis as is contained in one marijuana cigarette. NIDA-supplied marijuana cigarettes weigh approximately .9 grams. A smoker would theoretically have to consume nearly 1,500 pounds of cannabis within about 15 minutes to induce a lethal response.

9. In practical terms, cannabis cannot induce a lethal response as a result of drug-related toxicity.

10. Another common medical way to determine drug safety is called the therapeutic ratio. This ratio defines the difference between a therapeutically effective dose and a dose capable of inducing adverse effects.

11. A commonly used over-the-counter product like aspirin has a therapeutic ratio of around 1:20. Two aspirins are the recommended dose for adult patients. Twenty times this dose, forty aspirins, may cause a lethal reaction in some patients, and will almost certainly cause gross injury to the digestive system, including extensive internal bleeding.

12. The therapeutic ratio for prescribed drugs is commonly around 1:10 or lower. Valium, a commonly used prescriptive drug, may cause very serious biological damage if patients use 10 times the recommended dose.

13. There are, of course, prescriptive drugs which have much lower therapeutic ratios. Many of the drugs used to treat patients with cancer, glaucoma and multiple sclerosis are highly toxic. The therapeutic ratio of some of the drugs used in anti-neoplastic therapies, for example, are regarded as extremely toxic poisons with therapeutic ratios that may fall below 1:1.5. These drugs also have very low LD-50 ratios and can result in toxic, even lethal reactions, while being properly employed.

14. By contrast, marijuana’s therapeutic ratio, like its LD-50, is impossible to quantify because it is so high.

15. In strict medical terms marijuana is far safer than many foods we commonly consume. For example, eating 10 raw potatoes can result in toxic response. By comparison, it is physically impossible to eat enough cannabis to induce death.

16. Marijuana, in its natural form, is one of the safest therapeutically active substances known to man. By any measure of rational analysis cannabis can be safely used with a supervised routine of medical care.

18. There have been occasional instances of panic reaction in patients who have smoked marijuana. These have
(Continued on next page.)

(Continued from previous page.)

occurred in cannabis-naïve persons, usually older persons, who are extremely anxious over the forthcoming chemotherapy and troubled over the illegality of their having obtained the cannabis. Such persons have responded to simple person-to-person communication with a doctor and have sustained no long term mental or physical damage. If cannabis could be legally obtained, and administered in an open, medically-supervised session rather than surreptitiously, the few instances of such adverse reaction doubtless would be reduced in number and severity.

19. Other reported side effects of cannabis have been minimal. Sedation often results. Sometimes mild euphoria is experienced. Short periods of increased pulse rate and of dizziness are occasionally experienced. Cannabis should not be used by persons anxious or depressed or psychotic or with certain other health problems. Physicians could readily screen out such patients if cannabis were being employed as an agent under medical supervision.

Discussion of Legal Obligations

The Act, at 21 U.S.C. 812(b)(1)(C), requires that marijuana be retained in Schedule I if “there is a lack of accepted safety for use of [it] under medical supervision, then it is unreasonable to keep it in Schedule I. The only proper question for the Agency here is: Have a significant minority of physicians accepted cannabis as safe for use under medical supervision?

The gist of the Agency’s case against recognizing cannabis’s acceptance as safe is to assert that more studies, more tests are needed. The Agency has presented highly qualified and respected experts, researchers and others, who hold that view. But, as demonstrated in the discussion in Section V above, it is unrealistic and unreasonable to require unanimity of opinion on the question confronting us. For the reasons there indicated, acceptance by a significant minority of doctors is all that can reasonably be required. This record makes it abundantly clear that such acceptance exists in the United States.

Findings are made above with respect to the safety of medically supervised use of cannabis by glaucoma patients. Those findings are relevant to the safety issue even though the administrative law judge does not find accepted use in treatment of glaucoma to have been shown.

Based upon the facts established in this record and set out above one must reasonably conclude that there is accepted safety for use of cannabis under medical supervision. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious.

IX. Conclusion & Recommended Decision

Based upon the foregoing facts and reasoning, the administrative law judge conclude that the provisions of the Act permit and require the transfer of cannabis from Schedule I to Schedule II. The judge realizes strong emotions are aroused on both sides of any discussion concerning the use of cannabis. Nonetheless it is essential for this Agency, and its Administrator, calmly and dispassionately to review the evidence of record, correctly apply the law, and act accordingly.

Marijuana can be harmful. Marijuana can be abused. But the same is true of dozens of drugs or substances which are listed in Schedule II so that they can be employed in treat-

ment by physicians in proper cases, despite their abuse potential.

Transferring cannabis from Schedule I to Schedule II will not, of course, make it immediately available in pharmacies throughout the country for legitimate use in treatment. Other government authorities, federal and State, will doubtless have to act before that might occur. But this Agency is not charged with responsibility, or given authority, over the myriad other regulatory decisions that may be required before cannabis can actually be legally available. This Agency is charged merely with determining the placement of cannabis pursuant to the provisions of the Act. Under our system of laws the responsibilities of other regulatory bodies are the concerns of those bodies, not of this Agency.

There are those who, in all sincerity, argue that the transfer of cannabis to Schedule II will “send a signal” that marijuana is “OK” generally for recreational use. This argument is specious. It presents no valid reason for refraining from taking an action required by law in light of the evidence. If cannabis should be placed in Schedule II, in obedience to the law, than that is where cannabis should be placed, regardless of misinterpretation of the placement by some. The reasons for the placement can, and should, be clearly explained at the time the action is taken. The fear of sending such a signal cannot be permitted to override the legitimate need, amply demonstrated in this record, of countless sufferers for the relief cannabis can provide when prescribed by a physician in a legitimate case.

The evidence in this record clearly shows that cannabis has been accepted as capable of relieving the distress from great numbers of very ill people, and doing so with safety under medical supervision. It would be unreasonable, arbitrary and capricious for the DEA to continue to stand between those sufferers and the benefits of this substance in light of the evidence in this record.

The administrative law judge recommends that the Administrator conclude that the cannabis plant considered as a whole has a currently accepted medical use in treatment in the United States, that there is no lack of accepted safety for use of it under medical supervision and that it may lawfully be transferred from Schedule I to Schedule II. The judge recommends that the Administrator transfer cannabis from Schedule I to Schedule II.

— by Francis L. Young,
Administrative Law Judge

Upheld by the Federal Appeals Court

April 1991: Docket No. 90-1020:

“The DEA Administrator exercised with a vengeance his prerogative to reject the recommended decision.”

“... [T]hree of the factors in the Administrator’s eight factor test appear impossible to fulfill and thus must be regarded as arbitrary and capricious. ... Since the government did not respond clearly to the argument, we are left in doubt as to the argument’s validity.” Under our governing cases, we must remand for the requisite explanation.”

— *Silberman, Buckley and Henderson, Circuit Judges*

Reversed — not on facts, but over a technicality

In a subsequent DEA appeal, a federal court ruled that the Food and Drug Administration (FDA) should also have been involved in the argument and set the case back to its starting point: a 20 year setback over a mere technicality.

Presented by the Family Council on Drug Awareness
www.fcda.org