UNITED STATES DEPARTMENT OF JUSTICE

Drug Enforcement Administration

In The Matter Of	)	Docket No. 84-48
MDMA SCHEDULING	)	

HOFFMANN-LA ROCHE INC.'S
PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ARGUMENT

In this document, Hoffmann-La Roche Inc. (Roche) will only discuss the proper resolution of issue number 2 in this proceeding.1/ That issue reads as follows:

> What constitutes "currently accepted medical use in treatment in the United States" within the purview of 21 U.S.C. §812(b)?

1/ Hoffmann-La Roche Inc. and McNeilab, Inc. jointly filed a brief on issue number 1, the question of whether a substance with no currently accepted medical use in treatment in the United States can be controlled in a schedule other than schedule I. Roche also submitted the testimony of Dr. Dziewanowska on issue number 2, the meaning of the term "currently accepted medical use in treatment in the United States." This brief is submitted on behalf of Roche to explain its interpretation of this term in light of Dr. Dziewanowska's testimony.

Because issue number 2 is predominantly a matter of statutory interpretation,[2/] its resolution requires little, if any, citation to the facts regarding MDMA developed in this proceeding. As we have stated previously, Roche has no interest in MDMA per se, but is participating in this proceeding in order to help clarify the legal issues relating to interpretation of several statutory provisions of the Federal Controlled Substances Act (CSA). Our presentation therefore will be in the form of a brief rather than as numbered findings of fact and conclusions of law.

In this brief, Roche first takes issue with the interpretation of the phrase "currently accepted medical use in treatment" advanced by Drug Enforcement Administration (DEA) counsel. Then, we propose a definition of that phrase which is consistent with the language of the statute, the interests of the medical and scientific community, and the public health.

I. DEA's Position

Roche finds itself in the anomalous position of trying to convince a federal regulatory agency that it has more flexibility in interpreting its authorizing statute than it apparently believes it has. DEA's position on the issue under consideration

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2/ Although Roche will not discuss issue number 3 -- the meaning of "accepted safety for use under medical supervision" -- the resolution of issue number 2 will plainly affect the Administrative Law Judge's decision with respect to issue number 3.

has the same characteristic as its position on issue number 1. DEA contended with respect to issue number 1 that a drug with no currently accepted medical use in treatment in the United States could be placed only in schedule I of the CSA. This approach would preclude the agency from having to consider critically important issues such as relative abuse potential and levels of psychological dependence liability. DEA could mechanically control a drug in schedule I solely on the basis of its having no medical use. DEA's proffered resolution of issue number 2 is the product of the same simple, inflexible approach.

DEA counsel argue that the term "currently accepted medical use in treatment in the United States" means only that the drug is lawfully marketed under the Federal Food, Drug, and Cosmetic Act (FFDCA). Therefore, according to DEA, a drug does not have a currently accepted medical use in treatment in the United States unless the Food and Drug Administration (FDA) has determined that it can be lawfully marketed in the United States pursuant to an approved new drug application (NDA) under Section 505 of the FFDCA, 21 U.S.C. §355, or that it satisfies the requirements for lawful marketing under either the exemption from the definition of "new drug" in 21 U.S.C. §321(p) or one of the two

"grandfather" provisions.[3/] Under the DEA analysis, therefore, drugs which are being investigated under an investigational new drug (IND) exemption can never have a currently accepted medical use in treatment in the United States, regardless of how extensive those investigations are or how widely such drugs are being used in therapy.

The inflexible DEA approach is wrong as a matter of both statutory interpretation and public policy. Roche believes that drugs may have currently accepted medical uses even though they do not have an approved NDA or are otherwise lawfully marketed under the FFDCA. With regard to IND and in some instances pre-IND drugs, however, the CSA requires DEA and FDA to make a fuller inquiry into the state of scientific and medical knowledge relating to a particular substance and then to decide whether that substance has an accepted medical use.

A. Statutory Language

An analysis of the meaning of the phrase "currently accepted medical use in treatment in the United States" requires a review

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3/ A "new drug" is one that is not generally recognized among qualified experts as safe and effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. §321(p)(1). Drugs that are generally recognized as safe and effective (GRAS/GRAE) are not required to have approved NDAs. In addition, the FFDCA contains two grandfather exemptions for certain drugs that were on the market prior to 1938 (21 U.S.C. §321(p)(1)) and prior to 1962 (Drug Amendments of 1962, Pub. L. 87-781, §107, 76 Stat. 788-89 (1962)). Drugs which are subject to these grandfather exemptions are not required to have approved NDAs in order to be marketed lawfully.

of two statutes, the FFDCA and the CSA. Under Section 505 of the FFDCA, 21 U.S.C. §355, a new drug may not be commercially marketed in interstate commerce unless FDA has approved an NDA for the product. An NDA is a license that allows a specific manufacturer to market and ship a product in interstate commerce.4/

Each manufacturer must obtain its own NDA to market a drug even if FDA has already approved other NDAs for the same product. The NDA process is extremely rigorous. A manufacturer must not only demonstrate that a product is safe and effective, usually on the basis of controlled, double-blind clinical investigations, 21 C.F.R. §§314.50 and 314.126, but it must also show that it has the manufacturing capability to produce the product.5/

The NDA approval process, however, does not, and is not intended to, regulate the practice of medicine. Physicians are free to prescribe any drug for any use that they wish regardless

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4/ Since the Act prohibits the shipment of new drugs in interstate commerce, 21 U.S.C. §355(a), new drugs that are produced wholly intrastate and that are shipped only within that state are not subject to the requirement for an NDA.

5/ Among other things, the NDA must include "the method of synthesis (or isolation) and purification of the drug substance; the process controls used during manufacture and packaging; and such specifications and analytical methods as are necessary to assure the identity, strength, quality, and purity of the drug substance, including, for example, specifications relating to stability, sterility, particle size, and crystalline form." 21 C.F.R. §314.50(d)(1)(i). Such information obviously goes well beyond the medical usefulness of the product.

of whether a drug is labeled for that use. United States v. Evers, 643 F.2d 1043 (5th Cir. 1981); FTC v. Simeon Management Corp., 532 F.2d 708, 717 (9th Cir. 1976); 37 Fed. Reg. 16,503 (Aug. 15, 1972). Moreover, physicians who compound drugs for use in their own practice are not considered manufacturers under the FFDCA and do not need to register with FDA. 21 U.S.C. §360.

As a consequence of such therapeutic use of drugs by physicians, it often happens that new uses are discovered and become accepted in the medical profession long before those uses are ever the subject of FDA approvals. United States v. Evers, 453 F. Supp. 1141, 1149 (M.D. Ala. 1978). Therefore, the fact that FDA licenses a manufacturer to sell a drug for a particular purpose is not a limit on the medical usefulness of the substance for other purposes.

This conclusion has important implications when one examines the CSA in light of the provisions of the FFDCA. The CSA was passed in 1970, long after passage of the FFDCA.6/ Had Congress intended that the phrase "currently accepted medical use in treatment" be synonymous with FDA approval of a new drug application or otherwise lawfully marketed under the FFDCA, Congress could easily have said so. Indeed, Congress in enacting the CSA did use this formulation. Congress specifically restricted DEA's

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6/ The FFDCA was originally enacted in 1938 to require proof of safety before a new drug could be marketed. The Act was amended in 1962 to require that efficacy be demonstrated as well.

In the section of the CSA immediately preceding the one under consideration, Congress prohibited DEA from controlling any non-narcotic substance "if such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold over-the-counter without a prescription." 21 U.S.C. §811(g)(1).[7/]

Although it certainly could have, Congress did not impose the criterion of lawful sale under the FFDCA to determine whether a drug has an accepted medical use. Rather, it directed DEA, in conjunction with the Department of Health and Human Services, to consider the eight factors set forth in 21 U.S.C. §811(c) when determining whether and in which schedule to control a substance. FDA approval of a drug is not one of these eight factors.

It is an elementary principle of statutory construction that a statute should be interpreted "so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant ... [and] that the same words used twice in the same act have the same meaning."[8/] Because Congress did not make lawful marketing under the FFDCA synonymous with currently accepted medical use, it is clear that, as a matter of statutory interpretation, DEA's position is incorrect

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7/ The CSA contains several other direct references to the FFDCA. For example, Congress defined the term "drug" is the CSA, 21 U.S.C. §802(12), as having the same definition as under the FFDCA.

8/ Sutherland Stat. Const. §46.06 (4th Ed.) (footnotes omitted).

and that lawful marketing under the FFDCA cannot be the only criterion for determining accepted medical use.

B. Judicial Interpretation

The inflexible approach advocated by DEA was also rejected by the Court of Appeals in National Organization for Reform of Marihuana Laws (NORML) v. Drug Enforcement Administration, 559 F.2d 735 (D.C. Cir. 1977). In that case, DEA argued unsuccessfully that a drug with abuse potential and with no currently accepted medical use was required to be placed in schedule I. In attempting to establish that marihuana lacked a currently accepted medical use, DEA relied upon a letter from the Acting Assistant Secretary for Health that said in part:

> There is currently no accepted medical use of marihuana in the United States. There is no approved New Drug Application for Cannabis sativa L. (marihuana) or tetrahydrocannabinol, the active principle in marihuana. There are Investigational New Drug Applications on file to determine possible therapeutic uses and potential toxic effects of the substance.

559 F.2d at 743 n. 41. The court rejected this letter as failing to meet the requirements of the CSA, stating that:

> The one-page letter makes conclusory statements without providing a basis for or explanation of its findings. It is unclear what Dr. Cooper means when he writes that marihuana has no currently accepted medical use. As a legal conclusion his statement cannot be doubted: Placement in Schedule I creates a self-fulfilling prophesy ... because the drug can be used only for research purposes ... and therefore is barred from general medical use. But if Dr. Cooper's statement is meant to reflect a scientific judgment as to the medicinal potential of marihuana, then the basis for his evaluation should be elaborated. Recent studies have yielded findings to the contrary: HEW's Fifth

> his evaluation should be elaborated. Recent studies have yielded findings to the contrary: HEW's Fifth Annual Report to the U.S. Congress, Marihuana and Health (1975), devotes a chapter to the therapeutic aspects of marihuana discovered through medical research.... Possible uses of marihuana include treatment of glaucoma, asthma, and epilepsy, and provision of "needed relief for cancer patients undergoing chemotherapy." ... Accordingly, recognizing that it is our obligation as a court to assure that the agency acts within statutory boundaries, we hold that Dr. Cooper's letter was not an adequate substitute for the procedures enumerated in Section 201(a)-(c).

559 F.2d at 749-750 (footnotes and citations omitted). In other words, the court determined that medical usefulness cannot be determined simply on the basis of whether a drug has an approved NDA.

DEA's focus on the FDA's new drug application approval system unfortunately confuses economics with medicine. Several examples will demonstrate the incorrectness of this approach. Assume arguendo that a manufacturer had demonstrated to FDA's satisfaction that a drug was safe and effective for a particular use and had obtained FDA approval to market the product. Assume also that the product turns out to be unprofitable, either because of a limited patient population or because of the availability of alternative therapies. If the manufacturer decides that it no longer wishes to market the drug and therefore withdraws its NDA, presumably under DEA's theory the drug would no longer have an accepted medical use and, if it had even low abuse potential, would have to be placed in schedule I.

A real example of this conflict between accepted medical use and NDA approval involves the drug Bendectin. Bendectin was marketed for many years for the treatment of nausea associated with pregnancy. Because of the enormous costs associated with hundreds of product liability lawsuits brought against the company in which it was alleged that the product caused birth defects, the manufacturer withdrew the product from the market despite the fact that FDA and most of the medical community agreed that the product was safe and effective.9/ Under DEA's theory, Bendectin would not now have an accepted medical use.

There are numerous examples that demonstrate that a drug can have an accepted medical use even if it cannot be lawfully marketed under the FFDCA. For example, tetrahydrocannabinol (THC) was recently approved by FDA for use as an antiemetic, 50 Fed. Reg. 42,186 (Oct. 18, 1985), and therefore, under DEA's definition, THC now has a currently accepted medical use. As the NORML v. DEA case demonstrates, there has been a longstanding battle between NORML and DEA regarding the scheduling of marihuana, and in particular its medical usefulness. At one stage of this battle, FDA, in a lengthy Federal Register publication, discussed the development of medical information on THC, particularly its use in cancer treatment. 47 Fed. Reg. 10,080 (March 9, 1982). The agency noted that THC had been

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9/ See New York Times, June 19, 1983, §4, at 7, col. 3; Washington Post, June 10, 1983, §A, at 1.

placed in the National Cancer Institute's "Group C" system because clinical research had progressed sufficiently that the drug should be made widely available to physicians.10/ The agency noted that under the Group C distribution system, THC would be made available to an estimated "4,000 cancer specialists for use in combating nausea and vomiting in cancer patients undergoing chemotherapy." 47 Fed. Reg. at 10,085. Whatever definition of "currently accepted medical use in treatment" is adopted by the Administrative Law Judge, we submit that when an IND drug is being used in treatment by 4,000 physicians in the United States, it is inconceivable that such use is not accepted by the medical community and the government, regardless of whether an NDA has yet been approved for the product.

A second example of unapproved drugs that can have accepted medical uses involves "orphan drugs."11/ Congress recognized

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10/ See 47 Fed. Reg. at 10,083 for a description of NCI's Group C system. FDA takes the position that Group C drugs have "accepted medical use with severe restrictions." Id. at 10,085. Roche believes that such use also constitutes "currently accepted medical use in treatment" and that FDA, like DEA, has improperly focused on the FDA approval process in assessing medical use.

11/ "Orphan drugs" are drugs intended to be used in the treatment of rare diseases or conditions. A "rare disease or condition" is one which "(A) affects less than 200,000 persons in the United States or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." 21 U.S.C. §360bb(a)(2).

that because the new drug approval system was based on the incentive for economic reward, manufacturers in the past had been unwilling to do the necessary testing and research to obtain FDA approval for substances where there was no reasonable likelihood of making a profit. Therefore, in 1982 Congress amended the FFDCA to encourage the development and marketing of drugs for the treatment of rare diseases or conditions. 21 U.S.C. §§360aa-360ee. Despite the past unwillingness of manufacturers to seek approval for orphan drugs, physicians were treating their patients with such drugs.12/ In surveying this situation, a congressional committee concluded in 1980 that there were 134 drugs being used to treat a variety of rare diseases and that only 47 of these drugs were approved by FDA. One of the conclusions of this survey was that there are "many drugs for rare diseases which are not approved and on the market."13/ The use of such drugs by physicians to treat rare conditions, where alternative approved therapy does not exist, constitutes medical acceptance of the drugs.

In addition to orphan drugs, FDA has recognized that there are other circumstances where unapproved drugs should be made

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12/ In many instances FDA has allowed physicians to obtain unapproved drugs for such treatment use even though its regulations do not yet specifically authorize such a practice. See 48 Fed. Reg. 26,720, 26,728-9 (June 9, 1983). FDA has proposed to amend its regulations to permit such use. Id.

13/ H.R. Rep. No. 97-840, 97th Cong., 2d Sess. 7 (1982).

available for treatment purposes. FDA has proposed to make certain unapproved drugs available under "treatment INDs" if three conditions are satisfied:

1) the proposed use is intended for a serious disease condition in patients for whom no satisfactory approved drug or other therapy is available;

2) the potential benefits of the drug's use outweigh the potential risks; and

3) there is sufficient evidence of the drug's safety and effectiveness to justify its intended treatment use.

48 Fed. Reg. at 26,729. Clearly, it would be difficult for DEA to contend that this type of treatment was medically unaccepted, even though such drugs have yet to be approved by FDA.

II. DEA's Position Would Negatively Affect Research

In addition to his duty to control illicit drug trafficking and abuse, the Administrator of DEA has the responsibility to ensure that he does not unduly restrict access to and research on drugs which are "necessary to maintain the health and general welfare of the American people." 21 U.S.C. §801(c); see also 21 U.S.C. §801(a)(3) relating to the Congress' concern that the Convention on Psychotropic Substances not interfere with bona fide research activities. DEA's approach in this proceeding may well have a detrimental impact on research, and could affect the

development of needed medications by requiring that the agency control in schedule I any IND or pre-IND drug it deems potentially abusable. Such drugs, under DEA's definition, would have no currently accepted medical use and could only be placed in schedule I.

It is clear that DEA will not move to schedule a substance before it uncovers actual abuse or trafficking. It is entirely appropriate for the agency to institute control procedures under 21 U.S.C. §811(a)-(c) under such circumstances. However, if that substance is under investigation by a pharmaceutical manufacturer or other legitimate researcher, placement in schedule I would almost certainly ensure that research would be discontinued. This means that a narrow interpretation of the term "currently accepted medical use" could result in therapeutically useful drugs not receiving NDAs and not being made available to patients who need them.

Placement of an investigational substance in schedule I would impose added expenditures of time, additional paperwork, and administrative delays for a pharmaceutical company and would result in significant increased economic costs associated with such research. (Dziewanowska, direct, p. 4.) But these considerations are of secondary concern. More important, such scheduling requires a researcher to inform volunteers in the patient consent form that the government has determined that the drug under investigation has a high abuse potential, does not

have accepted medical use, and does not have accepted safety, even under medical supervision. (Dziewanowska, cross, p. 102.) This requirement could have a chilling effect upon patient recruitment for important drug studies and could needlessly frighten potential volunteers and physician-investigators who may be led to believe, because of schedule I status, that a substance has a greater abuse potential or risks than it actually has. (Dziewanowska, direct, p. 3.)

The increased cost of research associated with imposition of schedule I controls upon an investigational substance and the need to inform potential volunteers of the supposed dangers of taking a substance which is controlled in the same schedule as heroin and LSD would have a deterrent effect upon the pursuit of research on new promising drugs. (Dziewanowska, direct, p. 4.) Dr. Dziewanowska, testifying for Roche, stated that her company would not develop a schedule I drug, even if it was promising, unless it was a lifesaving substance (Dziewanowska, cross, p. 110). It was her belief that a schedule I designation would deter many investigators from researching a compound unless it was of vital importance (Dziewanowska, cross, p. 119) and that

other pharmaceutical companies shared this view. (Dziewanowska, cross, p. 122.)[14/]

The DEA position requires the placement of any abused IND or pre-IND drug in schedule I, even if it has a low abuse potential, because it is not lawfully marketed under the FFDCA. However, the CSA requires that schedule I drugs must be found to have a "high potential for abuse." 21 U.S.C. §812(b)(1)(A). Placing a drug with a lower abuse potential in this schedule would be a misclassification and contrary to the language and intent of the CSA. In addition, this misclassification would be repeated in each of the states, requiring state authorities to reschedule the

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14/ DEA might argue that extensive research has been conducted on the schedule I substance tetrahydrocannabinol (THC) and that two THC compounds have recently been approved for use by the FDA. 50 Fed. Reg. at 42,186; The Pink Sheet, Jan. 6, 1986, at T & G 3. There are two principal reasons for this: (1) As early as 1975, the government recognized the potential efficacy of THC in the treatment of nausea and vomiting associated with cancer chemotherapy. See HEW's Fifth Annual Report to the U.S. Congress, Marihuana and Health (1975). Research on this compound was actually fostered by the government, with the National Cancer Institute according THC Group C status in 1982. (2) The approved indication for THC derivatives is for the treatment of nausea and vomiting associated with chemotherapy in terminally ill cancer patients. If the drug was used as an anti-depressant or an anti-convulsant rather than for the treatment of the terminally ill, research on those compounds would in all probability not have received such government support.

It is clear that a schedule I investigational drug which does not receive active governmental research support and is not indicated for use by a group of patients such as the terminally ill would be treated a great deal differently by researchers than THC was.

drug once it is approved for marketing. Rescheduling can take well over one year and substantially delay the marketing of a potentially important therapeutic substance. (Dziewanowska, direct, p. 3.)

There are many investigational drugs being used safely and effectively in treatment by physicians which do not have approved NDAs. If DEA uncovers actual abuse and trafficking in any of these substances, the CSA gives the agency the flexibility to determine, in conjunction with FDA and other appropriate authorities, whether that substance has been accepted by the medical or scientific community for use in treatment, even if it cannot yet be marketed under the FFDCA. Once this is done, DEA can then decide on the appropriate schedule for control. This flexibility would not unnecessarily impede medical research and would allow for the development of many therapeutically useful compounds which would not otherwise have been investigated if they were in schedule I.

Therefore, in order to avoid inappropriate scheduling actions which would negatively affect the development of needed pharmaceuticals, the phrase "currently accepted medical use in treatment in the United States" should be understood to include certain IND substances and those pre-IND substances whose pharmacological or other medical or scientific profiles and whose current use by the medical and scientific community would lead to the conclusion that they are "accepted" therapeutically.

III. A Proposed Solution

If the term "currently accepted medical use in treatment" is not entirely a function of NDA approval, what is the proper definition of that phrase? Roche believes that FDA's approval of an NDA is not, and should not be, the only definition of accepted medical use.

DEA's inflexible and narrow definition of the term, which allows the agency to determine mechanically that one substance has accepted use (i.e., it has an NDA) while another does not (i.e., it is an IND or pre-IND drug used by physicians in their practice or studied by pharmaceutical companies), should be rejected. Rather, whether a substance has a currently accepted medical use depends upon a number of factors that must be examined on a case-by-case basis.

It is important to examine the scientific and medical evidence on a substance in light of the disease condition being treated and the availability, or lack, of alternative therapies. For example, in the case of a disease such as AIDS, a drug which demonstrates the ability to halt the progression of the disease in one or two patients might be considered by the medical community to have an accepted use in treatment, even if it is in an early investigational stage. The medical community might accept the substance because the disease has proven universally fatal and there is no known cure or effective treatment. On the

other hand, it is unlikely that a new pain medication to treat headaches would be so accepted by the medical community without extensive clinical trials.

If accepted medical use is to be determined on a case-by-case basis, how is that determination to be made within the context of the FDA/DEA relationship under the Controlled Substances Act? The Court of Appeals in NORML v. DEA suggested the proper approach. 559 F.2d at 749 n. 59.

FDA has at its disposal a Drug Abuse Advisory Committee which is intended to provide a forum whereby FDA "can hear from interested persons, the medical and scientific community, and the public." Id. In addition to the Drug Abuse Advisory Committee, FDA also receives advice from a series of other advisory committees with expertise in various specialty areas. See 21 C.F.R. §14.100. For example, there are advisory committees for anti-infective drugs, arthritis drugs, gastrointestinal drugs, and oncologic drugs. Each of these committees, and others, could be used by FDA for advice on whether a particular substance, in light of the risk-benefit issues involved in its use, has an accepted medical use in treatment. In this way, FDA can make a determination whether a particular substance has an accepted medical use within the medical community, independent of whether the product is the subject of an approved NDA.

Roche suggests that the Administrative Law Judge define "currently accepted medical use in treatment" in the following manner:

> The term "currently accepted medical use in treatment in the United States" means that the medical and scientific community in the United States, after considering the particular risks and benefits of the drug, the disease condition to be treated, and the drug's potential medical significance, concludes that use of the drug for that purpose constitutes acceptable treatment. "Currently accepted medical use" can be demonstrated by FDA's approval of a new drug application, by clinical testing, by reports in the scientific literature, by the informed judgment of members of the medical community, and by other relevant means.

The Food and Drug Administration, through its advisory committees, should solicit and obtain the views of the medical community and recommend to DEA whether the use of a drug in the treatment of a particular medical condition is "currently accepted." Roche believes that this definition is consistent with the FFDCA and the CSA, and that such an approach adequately protects the public health without needlessly hindering legitimate medical practice and scientific research.

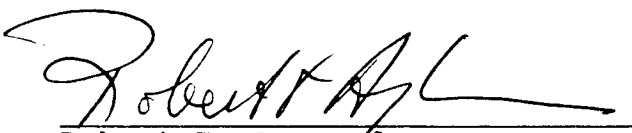
If medical use is limited to what FDA has approved, in contrast to what is accepted in the medical community, then FDA will effectively have control over medical practice in this country. Congress did not give FDA or DEA this power and it is one for which both agencies are woefully ill-equipped. The <u>medical</u> community, not FDA or DEA, should determine what constitutes an accepted <u>medical</u> use in treatment. Roche's

definition accomplishes this; DEA's does not. Therefore, our definition is preferable and should be accepted by the Administrative Law Judge.

IV. Conclusion

In conclusion, Roche believes that the concept of "currently accepted medical use" is more flexible than DEA believes. Both the statutory language and the Court of Appeals' decision in NORML v. DEA demonstrate that DEA and FDA must evaluate the actual medical usefulness of a substance and that they may not rely on FDA approval for marketing as the only measurement of a drug's acceptance by the medical community.

Respectfully submitted,



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TO Dr. Shulgin

I thought you might be interested in the drug company's brief.

Rick Cotton

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