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August 22, 1984

Administrator
Drug Enforcement Administration
1405 I Street, NW
Washington, D.C. 20537

Attention: DEA Federal Register Representative

re: Federal Register Notice # 21 CFR Part 1308

Dear Sirs:

I am requesting a hearing on the following issues regarding the proposed placement of 3,4-methylenedioxymethamphetamine (MDMA) into Schedule I: 1) MDMA does have a legitimate and accepted medical use; 2) There is accepted safety for the use of MDMA under medical supervision; 3) Placement into Schedule I will have a significant deleterious impact upon my small business as a psychiatrist, whose interest must be considered under the Regulatory Flexibility Act (Pub. L. 96-354); and 4) I am a legitimate user and manufacturer of MDMA.

1) The legitimate use of MDMA is described in the accompanying report which I have recently written, "The Legal, Safe and Effective Use of MDMA." Its acceptance in medical practice is evidenced by the concurrence of my peer review committee, and of almost all of the local psychiatrists in Santa Fe, N.M., that my work with MDMA is acceptable medical practice. The enclosed paper, "MDMA, A New Psychotropic Compound and Its Effects in Humans," lists the members of the peer review committee. The paper describes the useful and beneficial effects of MDMA when used under medical supervision. Neither of these reports were available to the DEA in the analysis of MDMA entitled: "Schedule I Control Recommendation Under the CSA for 3,4-Methylenedioxymethamphetamine (MDMA)." Apparently the representatives of the Department of Health and Human Services reporting to the DEA in the report entitled: "Evaluation of the DEA Recommendation to Control 3,4-Methylenedioxymethamphetamine (MDMA) in Schedule I of the CSA" were not aware of the paper either, though copies of it had been sent to Dr. Edward N. Brandt, Jr., M.D., Assistant Secretary for Health, and Dr. Joseph Contrera, Ph.D., Supervising Pharmacologist, Division of Neuropharmacology, Food and Drug Administration.

From a recent telephone conversation with Mr. Frank Sapienza, the DEA Federal Register Representative, I understand that

HHS currently defines "accepted medical use" of a drug as existing only when the drug is approved for marketing by the FDA in a New Drug Application. This standard of "accepted medical use" is incorrect because the FDA has no role in defining or setting standards for medical practice. The enclosed "Opinion of Evelle J. Younger" dated May 2, 1978, at the bottom of page 23, states:

> "The FDA Drug Bulletin of October 1972 contains the following statement reflecting the position of the agency:
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> `Congress did not intend the Food and Drug Administration to interfere with medical practice. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.'"

This means that no federal laws, or agencies, have any role in defining "accepted medical use". Only physicians in a local community can determine what is "accepted medical use" and "the standard of practice in the community."

Given the above facts, MDMA does not qualify for placement in Schedule I of the Controlled Substance Act, though it may qualify for placement in Schedules II-V.

2) The fact that my peer review committee approved my protocol for the use of MDMA is evidence that it is accepted as safe when used under medical supervision. The results reported in the enclosed paper, "MDMA: A New Psychotropic Compound and Its Effects in Humans," further substantiates the safety of the use of MDMA under medical supervision.

3) My small business as a psychiatrist in private practice will suffer both professionally and economically if MDMA is placed into Schedule I. The FDA regulations that are currently applied to large pharmaceutical manufacturers will be inappropriately applied to my practice of medicine. It is my understanding that the DEA is required by law to follow the recommendations of HHS in all matters of scientific judgment when granting permits to use Schedule I controlled substances. I also understand that current HHS policy requires all researchers, even physicians, to obtain an Investigational New Drug permit from the FDA before approving research protocols involving Schedule I substances. (However, an IND is not required for physicians using drugs in Schedules II-V, even if that use is experimental.)

In order to obtain an IND for MDMA, the FDA requires that certain animal research be completed. This research would cost $1,500,000 from the estimates of commercial laboratories. Once clinical trials are approved, FDA approval of my protocol for using MDMA would still be required. I have received verbal estimates from the pharmaceutical industry that $40,000,000 to $80,000,000 in research expenses must be spent in order to gain

FDA approval for marketing a new drug. As mentioned above, current HHS policy equates FDA marketing approval with "accepted medical use," a necessary criteria for allowing a substance of abuse to be placed in Schedules II-V. This approval would be necessary before I could resume my practice of medicine using MDMA without interference from the FDA, even though the FDA is mandated by Congress not "to interfere with medical practice."

In regard to the Regulatory Flexibility Act, the placing of MDMA into Schedule I would "impose unnecessary and disproportionately burdensome demands ... upon [my] small business" (Sec. 2, Paragraph (3)); would "discourage innovation" (Paragraph (4)); would "discourage potential entrepreneurs from introducing beneficial products" (Paragraph (5); and would "lead to ... actions inconsistent with the legislative intent [as described above and below] of health, safety, environmental and economic welfare legislation" (Paragraph (6)). Furthermore, an "alternative regulatory approach which do[es] not conflict with the stated objectives [prevention of substance abuse] of applicable statutes ... [is] available which minimize[s] the significant economic impact of rules on small businesses" (Paragraph (7)). This alternative approach is to place MDMA into Schedule II, III, IV, or V of the CSA.

4) According to the enclosed "Opinion of Evelle J. Younger" I am a legitimate user of MDMA even though it is not recognized by the FDA as an approved prescription drug. As explained above, FDA regulations have no effect on my legitimacy as a user of any drug within my medical practice. The argument is lengthy, but important: page 21, line 4 states the following: "The purpose of the Federal Food, Drug and Cosmetic Act viewed in its broadest sense is to protect the uninformed consumer." (My informed consent document is enclosed.) Page 22, line 19 states:

> "... where a licensed practitioner in an exercise of his or her independent judgment decides to prescribe a drug for a use which, as to that use, would make the drug a new drug ... the practitioner ... is not promoting a drug in a <u>commercial</u> setting in which a drug manufacturer operates."
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> "Senator Royal Copeland, when introducing Senate Bill No. 2800 on the subject, stated that the Bill [the Federal Food, Drug and Cosmetic Act] was drafted so as to make `certain that the medical practitioner shall not be interfered with in his practice.' (78 Cong. Rec. 2728 (1934).)... Both Senate Bill No. 2800 and Senate Bill No. 5 said that the term `drug' was defined therein `for the purpose of this act and <u>not to regulate the practice of medicine</u>.' (Emphasis added.) The House Committee on Interstate and Foreign Commerce in consideration of Senate Bill No. 5 omitted the latter clause because the words were thought to be unnecessary and might create confusion. [p. 23] The committee further stated that the bill `does not undertake to regulate

> the practice of the healing arts.' (H.R. Rep. No. 2755, 74th Cong., 2d sess. (1936).) ... In explaining the 'new drug' provisions [added in the 75th Congress], the Committee stated that the section was intended 'to prevent incompetent or irresponsible manufacturers from causing wholesale deaths.'"

The enclosed opinion of Mr. Bion M. Gregory, Legislative Counsel of California, also speaks to the general issue.

My legitimacy as a manufacturer of MDMA is described in the enclosed report, "The Legal, Safe and Effective Use of MDMA." This legitimacy is upheld by the enclosed copy of a portion of the California Health and Safety Code, Division 21: Sherman Food, Drug and Cosmetic Law, Chapter 6: Drugs and Devices, Article 6: Licenses, Paragraph 26693: "The licensing provisions of this chapter shall not apply to any of the following: ... (d) Any person who is licensed by law to administer drugs or devices and who manufactures, prepares, propagates, compounds, or processes drugs or devices solely for use in the course of his professional practice." This statement implies that any licensed physician is a legitimate manufacturer of any drug manufactured "solely for use in the course of his professional practice." I am a physician licensed to practice medicine in California and I manufactured in California the supply of MDMA that I use in my practice. Therefore I am a legitimate manufacturer of MDMA. (The manufacturing procedure is mentioned in the enclosed paper, "MDMA: A New Psychotropic Compound and Its Effects In Humans," on page 1 under the heading, "METHOD.")

I will be happy to appear at the hearing I have requested to further address the above issues. If further evidence is needed to support the objections I have outlined above, please let me know what is required and I shall obtain and present it.

Sincerely,

George Greer, M.D.

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