DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

JUL 8 1985

Mr. Richard Cotton
Dewey, Ballantine, Bushby, Palmer & Wood
1775 Pennsylvania Ave., N.W.
Washington, D.C. 20006

Dear Mr. Cotton:

I am writing in response to your letter of June 5 to Secretary Heckler. In your letter, you raised what you view as issues that Secretary Heckler should be aware of concerning the Drug Enforcement Administration (DEA) initiative to place 3,4-methylenedioxymethamphetamine (MDMA) into Schedule I on an emergency basis. As you know, the Controlled Substances Act was recently amended to provide DEA with the authority to place a substance, like MDMA, in Schedule I on a temporary basis, should DEA find that the substance presents an imminent hazard to the public safety. The Secretary has the opportunity to comment on any DEA proposal to invoke the temporary emergency scheduling process.

The Department will consider the points and comments you raise in your letter in its deliberations as to whether and to what extent it will comment on DEA's notice concerning MDMA. We wish to point out, however, that the imminent hazard standards under the Controlled Substances Act and under Section 505 of the Food, Drug, and Cosmetic Act differ significantly and are designed to address different factual situations presented by the marketing of drug substances. I should note that placement of a drug into Schedule I does not prohibit its use in research or development as a drug. Thank you for sharing your concerns with us.

Sincerely yours,

James O. Mason

James O. Mason, M.D., Dr.Ph.
Acting Assistant Secretary for Health

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July 18, 1985

James O. Mason, M.D., Dr.Ph.
Acting Assistant Secretary for Health
Department of Health & Human Services
Public Health Service
Washington, D.C. 20201

Dear Dr. Mason:

Thank you for your letter dated July 8, 1985, responding to my letter to Secretary Heckler of June 5, 1985. In your letter, you indicated that the Department was still considering its comments on the Drug Enforcement Administration's invocation of DEA's emergency scheduling power with respect to MDMA.

I want to amplify the point that I made in my original letter of June 5, 1985. The basis for the DEA's conclusion that an "imminent hazard to the public safety" existed was the experimental results of a study at the University of Chicago, indicating that MDA (not MDMA) when injected into rats at several times the human therapeutic dose on a milligram/kilogram basis produced some evidence of changes in the biochemistry of the brains of the rats. My original letter pointed out that amphetamine and methamphetamine have produced the same experimental results and were still on the market in the United States.

Enclosed with this letter is a chapter from a book recently published which contains results and findings by the same University of Chicago group with respect to fenfluoramine. (See p. 276 of enclosed chapter.) As you know, fenfluoramine is approved for marketing in the United States. What is striking about the University of Chicago group's findings about fenfluoramine is that fenfluoramine produces the changes in the biochemistry of rat brains at the effective therapeutic dose. Thus, if there is reason for concern about these experimental findings in rats, fenfluoramine is more dangerous than MDA. Of course, MDMA itself has yet to be tested.

Further, I also enclose the preliminary results of animal toxicology studies done by Intox Laboratories in Redfield, Arkansas -- a laboratory whose results have been accepted by the FDA on many occasions. The results of the Intox Lab tests (which are admittedly preliminary) reflect that the laboratory could find no histological evidence of brain lesions in rats who had been dosed orally with increasing daily doses up to 300 mg/kg -- more than 100 times the human therapeutic dose.

The Department of HHS should discharge promptly its statutory responsibilities and provide comments to the DEA concerning the scientific and medical bases for DEA's invocation of DEA's emergency scheduling powers. We do not see how the effects detected by these University of Chicago experiments can be said to have medical and scientific validity in the case of an extrapolation to MDMA, when these same results have been detected in the case of drugs (in particular fenfluoramine) which are approved for marketing in the United States. If they have validity for an extrapolation to MDMA, then FDA should act promptly at least with respect to fenfluoramine.

Thank you for your consideration of this matter.

Sincerely,

Richard Cotton

cc: Dr. Frank Young, Commissioner, Food & Drug Administration
Edward Tocus, Chief, Drug Abuse Staff,
Center for Drugs and Biologics