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7/1/85

July 1, 1985

Senator Paula Hawkins
Chair, Subcommittee on Alcoholism
and Drug Abuse
U.S. Senate
Washington, D.C. 20510

Dear Senator Hawkins:

I have been authorized to transmit to you the enclosed letter on behalf of the seven physician signatories. Geographical separation made it impossible for the physicians to sign the letter personally, and still deliver it to you by July 1, 1985.

Thank you for your consideration of the enclosed letter.

Sincerely,

Richard Cotton

Enclosure

July 1, 1985

Senator Paula Hawkins
Chair, Subcommittee on Alcoholism
and Drug Abuse
U.S. Senate
Washington, D.C.

Dear Senator Hawkins:

Effective today, the Drug Enforcement Administration (DEA) is acting on an emergency basis to place the substance, 3, 4-methylenedioxymethamphetamine (MDMA) into Schedule I of the Controlled Substances Act. We are a group of psychiatrists and researchers who believe that MDMA may be a potentially valuable drug and that research into MDMA's potential therapeutic use should be facilitated, not discouraged by the Government. We support DEA's effort to make street use and recreational use of MDMA illegal. However, DEA's emergency placement of MDMA into Schedule I will impose such severe restrictions on MDMA that all use of MDMA by psychiatrists and virtually all research into its medical potential will be significantly retarded.

We are writing to you to request a Congressional review of the DEA's emergency scheduling action, and the apparent failure of the Department of Health and Human Services to advise DEA of the shortcomings of DEA's medical and scientific evidence. The actions by the DEA and HHS/FDA indicate the need for legislative or oversight action to clarify Congressional intent in this area. We request the opportunity to meet with you or your staff at a mutually convenient time in the near future to discuss this request in more detail.

Based on our review of the evidence cited by the DEA, we believe the DEA's action was precipitate and not justified by current scientific and medical information. The appropriate course for DEA would have been to expedite the placement of MDMA into Schedule III of the Controlled Substances Act -- an action which would allow medical research to continue, but would provide DEA the authority to control street use and recreational use of MDMA.

To understand our concern, it is necessary to set out briefly the background of the DEA's emergency scheduling action. The Controlled Substances Act provides a careful and orderly procedure for imposing appropriate control on substances that have a potential for being abused. The DEA initiated proceedings in July, 1984, to consider what controls should be imposed on MDMA. Psychiatrists and researchers participating in those proceedings have voiced their view that MDMA may have important therapeutic potential, and that the evidence to date has not indicated either a high potential for abuse, or that MDMA cannot be safely used under medical supervision. Similarly, the evidence to date does not indicate that MDMA causes either physical or psychological dependence. These psychiatrists and researchers have been urging DEA to place MDMA in Schedule III. By the end of May, 1985, all direct testimony had been submitted into the record in this proceeding.

It is our understanding that the Congress did not intend the DEA to use its emergency scheduling authority routinely or to use it to circumvent ongoing scheduling proceedings. The DEA is to invoke its emergency authority only when a drug has a high potential for abuse, has no medical utility, and poses "an imminent hazard to the public safety." Based on the evidence already in the record of the ongoing proceeding, the DEA could not properly make any of the findings required by statute for exercising its emergency scheduling power. The evidence submitted to date suggests that MDMA has a relatively low potential for abuse, not a high potential for abuse. For example, out of approximately 750,000 hospital emergency room episodes involving drug abuse reported to the government from 1977 through 1983, only eight have involved MDMA.

The question of whether MDMA has an accepted medical use is a central one in the on-going scheduling proceedings. The Administrative Law Judge conducting that proceeding publicly criticized the DEA for pre-judging that issue before all the evidence was in. Attached to this letter is an excerpt of the transcript showing the criticism voiced by the Administrative Law Judge of the DEA staff's pre-judging of this issue.

Finally, we do not believe the animal studies cited by the DEA support a finding that MDMA is an "imminent hazard to public safety," a finding that is required in order for the DEA to exercise its emergency scheduling power. We base our conclusion on four factors. First, none of the studies cited by DEA involve MDMA. All involve different drugs. Second, the primary study cited by the DEA specifically states it would be premature to extrapolate the results of that study to humans. Third, all the studies cited by the DEA involve direct injection of the substances studied into animals. Humans take MDMA orally, and the different route of administration makes it imperative to again exercise caution in the extrapolation of these data to humans. In fact, preliminary results recently available from the first animal studies involving the oral administration of MDMA indicate that MDMA is significantly safer when administered orally rather than by injection. Fourth, the animal studies cited by the DEA involved injections of large amounts of the substance being studied; humans take much smaller doses orally. Even more importantly, the studies cited by the DEA as justifying extrapolation to humans did not find any indication of neurotoxicity at low doses comparable to those taken by humans.

We are, of course, concerned about reports that there may be as yet undiscovered adverse effects of MDMA. We want to see research done to determine both the risks and benefits of MDMA. Placing MDMA in Schedule III would allow such research to proceed expeditiously.

The DEA's action in placing MDMA into Schedule I is an abuse of its emergency scheduling power, and raises serious questions about the proper administration of the Controlled Substances Act. The Controlled Substances Act prohibits judicial review by the federal courts of action taken by the DEA under its emergency scheduling authority. We therefore believe it is important for Congress to carefully scrutinize this DEA action. We urgently request an opportunity to discuss these questions with you in detail.

Richard Cotton at the law firm of Dewey, Ballantine, Bushby Palmer & Wood in Washington, D.C., will be available to work out a mutually convenient time with your staff, or to assist in providing you with any additional

information you may desire. Mr. Cotton's telephone number is 862-1004.

Thank you for your consideration.

Sincerely,

Lester Grinspoon, M.D.,
Boston, Mass.
George Greer, M.D.,
Santa Fe, New Mexico
Joseph Downing, M.D.,
San Francisco, Calif.
Richard Ingrasci, M.D.,
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