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6/5/85

June 5, 1985

Secretary Margaret Heckler
Department of Health and Human
Services
200 Independence Avenue, S.W.
Washington, D.C.

Dear Madam Secretary:

It is my understanding that John Long, Acting Administrator of the Drug Enforcement Administration, has written to you with respect to DEA's temporary placement of the drug 3,4-methylenedioxymethamphetamine (MDMA) into Schedule I under the Controlled Substances Act. This firm represents two psychiatrists and two professors who have been participating in the DEA proceeding concerning MDMA, and have been urging DEA to place MDMA into Scnedule III, rather than into Schedule I. My clients support DEA's effort to make street use and recreational use of MDMA illegal. But my clients strongly believe that MDMA has important therapeutic usefulness. They have been urging DEA to schedule MDMA in such a way as to facilitate, not to obstruct, medical research into its therapeutic potential. Special care not to block research is necessary in the case of an unpatented drug in the public domain such as MDMA.

In order to invoke its emergency scheduling authority, DEA was required to find that MDMA posed an "imminent hazard to the public safety." DEA rested its finding on certain research findings which DEA claimed suggested that MDMA might have neurotoxic properties. DEA cited one study on a different substance, MDA, that has not yet been published. The MDA study, however, specifically noted that, "Given differences in species, dose, frequency, and route of administration, as well as differences in the way in which rats and humans metabolize amphetamine, it would be premature to extrapolate our findings to humans." Therefore, the DEA's extrapolation of the animal data to humans rested

primarily on the results of studies involving amphetamine and methamphetamine. In particular, DEA wrote that "the neurotoxicity of amphetamine and methamphetamine has been shown in five diverse mammalian species. This strongly suggests that the substances would be neurotoxic to humans." As you know, amphetamine and methamphetamine are currently approved for marketing by the FDA. It is our understanding that Smith, Kline & French and Rexar market amphetamine, and that Abbott Laboratories and Rexar market methamphetamine. It is our understanding that currently approved (FDA) indications for these drugs include hyperactivity in children, weight loss therapy under medical supervision, and the treatment of narcolepsy. It is our further understanding that millions of doses of amphetamine and methamphetamine are prescribed in this country each year, and that a substantial number of these doses go to children.

Either the neurotoxicity tests cited by DEA are properly extrapolated to humans or they are not. DEA has submitted evidence in the current DEA scheduling proceeding that the pattern of use of MDMA is either (1) use of ten times or less in a lifetime, or (2) one to four times per month. These usage patterns involve significantly less use than is often prescribed for amphetamine and methampnetamine.

Simply put, DEA's finding that MDMA poses an "imminent hazard to public safety" appears to be inconsistent with the FDA's failure to remove amphetamine and methampnetamine from the market. Furthermore, if DEA's action is justified under such a severe standard (imminent hazard to public safety), then FDA's continued approval for marketing methamphetamine and amphetamine which involve more frequent usage patterns appears to raise serious public health concerns.

The Department of Health and Human Services (HHS) has two related responsibilities at stake in this matter. It has the primary responsibility for scientific and medical judgments under the Controlled Substances Act. It also has important responsibilities under the Food, Drug and Cosmetic Act. If HHS concludes that DEA's action with respect to MDMA was scientifically justified, such a finding appears to have important implications for the continued marketing of amphetamine and methamphetamine. If HHS concludes that DEA's scientific and medical extrapolations were not justified, it has the responsibility to make that judgment clear and to communicate it to DEA.

In view of DEA's conclusion that an imminent hazard to the public safety exists, we believe that HHS should convene an emergency meeting of the relevant FDA Advisory

Committee to consider whether the studies that DEA cited are properly extrapolated to humans, whether amphetamines, methamphetamines and MDMA do in fact constitute an imminent hazard, and what action FDA should take in this area.

Sincerely,

Richard Cotton

cc: Assistant Secretary of Health
Commissioner, Food & Drug Administration
Edward Tocus, Chief, Drug Abuse Staff,
Center for Drugs and Biologics