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STATEMENT BY:

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The issue in the present proceeding is whether medical research into MDMA's therapeutic potential will be encouraged or whether that research will be significantly discouraged by excessively restrictive government action.

We emphasize that we support the DEA's efforts to make street use and recreational use of MDMA illegal. We do not believe that MDMA should be available for use except to physicians and to medical researchers. But we strongly believe that MDMA has important therapeutic potential. We are participating in the current proceedings to urge that MDMA be controlled in a way that will encourage medical research into its therapeutic potential and not obstruct research.

In our judgment, current clinical reports from physicians about MDMA suggest that research is warranted to assess its therapeutic potential in several areas, including: 1. Individual psychotherapy, where fear of emotional injury prevents the individual from dealing with psychiatric issues; 2. Individual and family therapy for people who face a severe personal crisis such as terminal illness, or who have suffered severe trauma such as rape; 3. Individuals

suffering from chronic pain; 4. Marital counseling. Further experience may suggest other therapeutic uses.

We support placing MDMA in Schedule III under the Controlled Substances Act. Under Federal law it is a felony (up to five years in jail and a \$50,000 fine), to manufacture, sell, or distribute a Schedule III substance without proper government authorization. Unauthorized possession is a misdemeanor under Federal law, punishable by up to one year imprisonment.

Placing MDMA in Schedule III will give the DEA full power to use its investigative and criminal enforcement authority to seek to control the street use of MDMA. Street use or recreational use is not the issue in these proceedings.

The issue is medical research into MDMA's therapeutic utility as well as possible adverse effects. Placing MDMA on Schedule I as the DEA seeks to do, will drastically curtail medical research, if not eliminate it altogether. Both Federal and State governments impose such severe and draconian restrictions on carrying out research on substances in Schedule I that the expense and delays these restrictions create, serve as powerful obstacles to research.

Two respected pharmaceutical companies -- Hoffman-LaRoche, and McNeil Labs, neither of which has any interest in MDMA -- are participating in this proceeding. They have emphasized the disincentives to medical research -- even

for well-funded drug companies -- that are created by placing substances in Schedule I. These two companies have urged the DEA to adopt policies that would more carefully distinguish substances that should properly be placed in Schedule I from substances with important therapeutic potential, that can properly be placed in other schedules.

We believe that the DEA's action on May 31, 1985, in placing MDMA in Schedule I on an emergency basis was precipitate and not supported by appropriately careful scientific and medical analysis. We support all research efforts on MDMA. We, as all responsible doctors and researchers, are concerned about any reports of potential adverse effects. We believe research on adverse effects should be continued and their results published in accordance with normal research procedures. Assessment of these results should also meet standard norms of medical and scientific analysis.

The DEA justified its emergency action on the basis of the results of certain animal tests in which chemically related but different substances had been injected into animals. Extrapolation from animal data to humans is always difficult. But when the data in question involves both different chemicals, different routes of administration (animals are injected; humans take it orally), and the animals appear to metabolize the substances differently than humans, extrapolation is particularly difficult and fraught with uncertainty. If the tests relied on by the DEA can

properly be extrapolated to humans, these tests have equal implications for the safety of amphetamine and methamphetamine which continue to be approved for marketing by the FDA including for long term use in young children. We have called on the Department of HHS to convene an emergency meeting of the appropriate FDA Advisory Committee to assess the animal studies involved in a careful, scientific manner and to consider their implications, not just for MDMA but for amphetamine and methamphetamine as well. Attached to this statement is the letter our counsel has submitted to HHS.

MDMA was originally patented by Merck in Germany in 1914. That patent has expired, and MDMA is not under patent and cannot be patented. There is no financial incentive to research MDMA.

If MDMA is placed in Schedule I, research into its therapeutic potential will be stymied. The evidence in this proceeding suggests that MDMA has a relatively low potential for abuse and does not cause dependence. Indeed, MDMA appears to have built-in protections against abuse -- higher doses only exaggerate unpleasant side effects and repeated doses eliminate the desired effect. Schedule III will provide the DEA with the legal restrictions it needs to do its job, yet medical research will be able to go forward.

We see no justification for the DEA's extreme position. We would hope that the DEA itself would reconsider, since the statute under which it operates seeks to

strike an appropriate balance between law enforcement concerns and medical research concerns. In this case, the DEA has failed to strike this balance. -