



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Drug Abuse
Bethesda, Maryland 20892

NOV 18 2003

Rick Doblin, Ph.D.
President, Multidisciplinary Association
for Psychedelic Studies
3 Francis Street
Belmont, Massachusetts 02478-2218

Dear Dr. Doblin:

Thank you for your recent inquiries to the Secretary of Health and Human Services (HHS); the Director of National Institutes of Health (NIH); and to myself, the Director of the National Institute on Drug Abuse (NIDA), regarding a number of issues that are relevant to NIDA. On behalf of my colleagues, I will respond to your two major areas of concern: the licensing of an alternative facility to provide marijuana for research purposes; and additional information and investigation into the research of Drs. Ricaurte and McCann on the dopaminergic neurotoxicity of MDMA.

In your letter, you stated that you had planned to ask the National Advisory Council on Drug Abuse (Council) to make a recommendation on each of these issues. As you know, the Council serves a crucial role in advising NIDA, the NIH Director, and the Secretary of HHS to support the highest caliber of scientific research. The legislatively mandated function of Council is to provide a secondary level of review for research grant applications. The Council also advises NIDA on programmatic and policy matters by providing input on ways to better carry out its knowledge development and knowledge dissemination mission. While you are free to raise these issues during the open session of the next meeting of Council, please keep in mind that although we value the advice of Council, it is only one of many avenues from which we receive scientific input to establish our research priorities. The ultimate responsibility for setting the Institute's research agenda lies with the Director of NIDA in consultation with the Director of NIH.

In regard to your request that Council endorse the establishment of a DEA-licensed privately funded facility to produce marijuana for federally approved research, it is not NIDA's mission to study of the medicinal uses of marijuana, and therefore, it also is not NIDA's role to advocate for the establishment of facilities to support this research. NIDA will, however, continue, on behalf of the U.S. Government, to provide supplies of well-characterized cannabis for both NIH and non-NIH funded research, including research into putative medical applications. This will be done according to the procedures established in 1999 by HHS for obtaining access to marijuana for research purposes. To date, several researchers, primarily from the Center for Medicinal

Cannabis Research at the University of California, San Diego, have received marijuana and have begun clinical trials. As you noted, the DEA is responsible for licensing facilities for marijuana production, and is currently reviewing the proposal of Dr. Craker for the establishment of an additional production facility. We await the results of that review.

In response to your recommendation that Council ask NIDA to disclose more information regarding the retraction issued in the journal *Science* by Dr. George Ricaurte, we believe that information has been made available to a variety of sources, including the NIH and the affected journals. In fact, Dr. Ricaurte is to be commended for his efforts in bringing this incident to the attention of the public and the scientific community. In addition, NIDA program staff have formally requested that Dr. Ricaurte inform us of any additional retractions or other research publications that may be impacted by this incident.

As for the actions already taken by NIDA in this matter, there have been several. Prior to the retraction, Dr. Ricaurte notified NIDA of his concern about possible mislabeling, and NIDA worked with Dr. Ricaurte to uncover the facts. NIDA has no reason to believe that the mislabeling of drugs was anything other than human error. Although NIDA can never be certain where the error occurred, we have taken additional steps to ensure the highest attainable quality assurance standards for our Drug Supply Program. We have also invited a team of outside consultants to review current procedures for all drugs that are distributed by NIDA's Drug Supply Program.

As to your specific questions about doses, routes of administration, etc., for all experiments conducted by Dr. Ricaurte using MDMA or methamphetamine, I encourage you to contact Dr. Ricaurte directly for this information. I also understand you will be receiving any responsive documents on these issues that are available under the Freedom of Information Act (FOIA).

I would like to make clear that the retraction of the scientific paper, "Severe Dopaminergic Neurotoxicity in Primates After a Common Recreational Dose Regimen of MDMA (Ecstasy)," published in *Science* on September 27, 2002, does not negate previous research in animals that demonstrates MDMA's neurotoxic properties in serotonergic neurons, another key neurotransmitter system in the brain. MDMA can produce both short- and long-term physiological and psychological consequences that can be detrimental to an individual's health. In addition, there is accumulating animal and human data suggesting that chronic abuse may also produce long-lasting effects in the brain. Thus, despite the retraction of this particular paper in *Science*, the research to date still leads NIDA, as a public health agency, to conclude that MDMA can be harmful.

You also expressed concern for NIDA's credibility in its educational messages concerning MDMA. I would point out that the dopaminergic neurotoxicity findings published by Dr. Ricaurte were not incorporated by NIDA into its publications or educational efforts. NIDA's information has been based mostly on the large volume of studies in animals examining MDMA's impact on the serotonin system. It is NIDA's practice that its public health messages be based on a consensus or an emerging theme in the constantly evolving world of science.

When Dr. Ricaurte's paper was published in the fall of 2002, it was the only report of dopamine neurotoxicity in monkeys. The exploration of the impact of MDMA on the dopamine system, nonetheless, remains an important research question that should and will continue to be addressed.

NIDA will continue to support and share information about MDMA and other drugs of abuse with the scientific and public community. Maintaining our position as the Nation's resource for credible, science-based information on all drugs of abuse is and will always be one of NIDA's highest priorities.

Sincerely,

A handwritten signature in black ink, appearing to read 'Nora D. Volkow', written over a horizontal line.

Nora D. Volkow, M.D.
Director