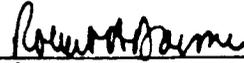


Respectfully submitted,

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April 25, 1985

UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

In the Matter of)
)
MDMA Scheduling)
_____)

Docket No. 84-48

STATE OF NEW JERSEY)
) ss:
COUNTY OF ESSEX)

Statement of Zofia Dziewanowska, M.D., Ph.D.

Zofia Dziewanowska, M.D., Ph.D., being first duly sworn,
deposes and says:

1. My name is Zofia Dziewanowska, M.D., Ph.D.
2. I am currently employed by Hoffmann-La Roche Inc. (Roche) in the capacity of Director of Clinical Research and Assistant Vice President.
3. My curriculum vitae is attached.
4. I have been employed by Roche since 1976 and during that time have been involved in the direction of medical research on investigational drugs. I have also been involved in drug research for Merck Inc. International Division from 1972 to 1976.
5. I have been asked to address the question as to what constitutes "currently accepted medical use in treatment in the United States." It is my professional scientific opinion that substances which are the subject of Investigational New Drug Exemptions (IND) and even substances at the pre-IND stage of development must be considered as belonging to the category of substances having "currently accepted medical use in treatment in the United States" as that phrase is used in the Federal Controlled Substances Act, since they have the potentiality for becoming approved drugs. Such substances have the potentiality for receiving approved New Drug Applications (NDA) from the FDA. All substances must pass through the pre-IND and IND stages of development prior to final approval. This potentiality for medical use must be considered a critical

factor in determining what constitutes "accepted medical use in treatment in the United States."

6. IND substances are considered to have a therapeutic potential, and may be useful for more than merely the clinical data obtained as a result of their administration. To illustrate this point, many substances under investigation are being used on a "compassionate plea" basis in patients for whom no other therapy exists. Because such substances are medically essential to the well-being of certain patients, they may be provided to such patients on an emergency basis for therapeutic purposes, even without NDAs.

7. Inappropriate early regulation of substances under the Controlled Substances Act would have a chilling effect upon the pharmaceutical research process.

8. If an investigational substance were to be placed in Schedule I, it is my understanding that a Schedule I registration would have to be obtained. A separate detailed Protocol for each Schedule I substance would have to accompany the registration application. Moreover, any change or addition to the Protocol would be subject to a formal amendment. It is my understanding that the registration application process could take as long as 6-8 months.

9. If an investigational substance is placed in Schedule I, individual physician-investigators studying the substance would need to seek separate DEA registrations. Although most physicians possess DEA registrations to prescribe controlled substances, they would not possess Schedule I research registrations. Moreover, such investigators would need to seek individual state controlled substance registrations.

10. It is my understanding that substances that are placed in Schedule I cannot be transferred without official order forms. This order form requirement for all transfers of investigational substances whether to physicians or others represents another burdensome procedure on the research process.

11. If an investigational substance were to be scheduled under the Controlled Substances Act, that substance would be subject to highly detailed inventory and accountability requirements, necessitating the expenditure of additional time, and the generation of additional paperwork during the various steps in the research function on the part of physician investigators as well as the company. Additionally, these substances would be subject to the security controls associated with controlled substances.

12. The time delays and increased administrative work of this nature would discourage incentive for pursuing research on such a substance. I agree that scheduling of substances with abuse potential is an important and necessary process. I also recognize that, in recent years, the government has in certain instances attempted to make it easier for researchers to obtain Schedule I registrations. Nevertheless, scheduling substances, particularly in Schedule I, during the investigational phases of pharmaceutical development would substantially slow down the development process, and would definitely inhibit a company's incentive to invest in research on many potentially important substances, thereby affecting negatively the development process.

13. The fact that a substance has been placed in Schedule I of the Controlled Substances Act may very well need to be included in the patient consent form which, under Federal Food and Drug Administration regulations, must be signed by patients administered investigational drugs pursuant to an IND. This requirement could have a chilling effect upon patient recruitment for important substance studies, and could needlessly frighten potential volunteers who may be lead to believe, because of the Schedule I treatment, that a substance has greater abuse potential than it actually does. Because the Schedule I treatment is only an "interim" placement until the substance is approved, in reality, the Schedule I classification is actually a "misclassification."

14. Clearly, upon approval of the investigational drug, which, during the investigational period has been placed in Schedule I, a descheduling or rescheduling process must take place, resulting in additional paperwork, potential hearings, and substantial time delays. Since it is my understanding that state legislatures and administrative agencies typically schedule substances in accordance with the federal schedules, such rescheduling must also take place on an individual state-by-state basis, resulting in an even greater expenditure of time (often over one year) and resources. Assuming the rescheduling or descheduling at the state and federal levels does not become effective immediately upon approval of the substance, there could be a substantial delay in the actual marketing of a potentially important therapeutic substance.

15. In any event, it is my understanding that a substance cannot be placed in Schedule I unless it possesses a "high" potential for abuse. Unless an investigational substance has been shown to have such a high abuse potential, placement of the substance in Schedule I would be inappropriate.

16. The added expenditure of time, paperwork and administrative delays for a pharmaceutical company caused by the inclusion of an investigational substance in Schedule I would result in significant increased economic costs associated with the cost of research. These additional financial costs and time delays would constitute a major disincentive to a pharmaceutical company to pursue the development of many potentially important drugs. Costs and time are a key factor in a pharmaceutical company's determination as to whether to commit itself to a particular area of research. The increased costs of research associated with the imposition of Schedule I controls upon an investigational substance would have a deterrent effect upon pursuit of research of new promising drugs.

15. Therefore, in my opinion, in order to avoid inappropriate scheduling actions which would negatively affect the development of needed pharmaceuticals, the phrase "currently accepted medical use in treatment in the United States" should be understood to include IND substances and those pre-IND substances whose pharmacological and other scientific profiles would lead to the conclusion that they may receive NDAs in the future or may be otherwise used therapeutically.

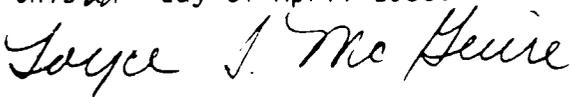


Zofia Dziewanowska, M.D., Ph.D.

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0547C

Sworn to and subscribed before me
this 23rd day of April 1985.



JOYCE S. MCGUIRE
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES NOV. 16, 1989