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September 12, 1984

Francis M. Mullen, Jr.
Administrator
Drug Enforcement Administration
Department of Justice
1405 I Street, N.W.
Washington, D.C. 20537

Re: 49 Fed. Reg. 30210, Proposed Placement of 3, 4-Methylenedioxymethamphetamine Into Schedule I

Dear Mr. Mullen:

This firm has been retained by several physicians and professors */ who filed comments in the above-entitled proceeding. They asked us to review the comments that they and others had filed with DEA in response to DEA's Federal Register notice of July 27, 1984 and to express our opinion, based on that review, whether a hearing was required under 21 U.S.C. § 811 in light of the comments that DEA had received.

We have completed that review and reached the conclusion that a hearing is legally required. At the request of our clients, we are providing our conclusions to you in this letter in an effort to assist the agency in considering what course of action it should follow in discharging its statutory responsibilities. Our clients do not necessarily oppose the placement of MDMA into any schedule. Rather they believe that a hearing would assist in developing information that would allow DEA to consider the appropriate schedule for this substance, in light of its current and potential medical uses.

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*/ Professor Thomas B. Roberts, Ph.D., George Greer, M.D., Professor Lester Grinspoon, M.D. and Professor James Bakalar.

I. Relevant Statutory Provisions

21 U.S.C. § 811 empowers the Attorney General to add substances to the five schedules of controlled substances created by 21 U.S.C. § 812. However, § 811 specifically provides that any such addition of substances to these schedules must be effected by the Attorney General "by rule" and that:

> Rules of the Attorney General under this subsection shall be made on the record after opportunity for a hearing pursuant to the rulemaking procedures prescribed by subchapter II of chapter 5 of Title 5. [Emphasis added]

By its terms, this statutory requirement is not discretionary. Rather it specifies without qualification the procedural requirements that the agency must follow in promulgating a rule to control a particular substance under the provisions of the Act.

The provisions of Section 811(c) are also important in assessing whether a hearing is required. In that section, Congress provided as follows:

> . . . the Attorney General shall consider the following factors with respect to each drug or other substance proposed to be controlled or removed from the schedules:
>
> (1) Its actual or relative potential for abuse.
>
> (2) Scientific evidence of its pharmacological effect, if known.
>
> (3) The state of current scientific knowledge regarding the drug or other substance.
>
> (4) Its history and current pattent of abuse.
>
> (5) The scope, duration, and significance of abuse.
>
> (6) What, if any, risk there is to the public health.
>
> (7) Its physical or physiological dependence liability.

(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

The legislative history of § 811 sheds some additional light on what Congress intended the agency to consider in its scheduling decisions and the purpose of this consideration. The bill ultimately passed by the Congress was essentially the House bill. The House report specifically commented on a number of factors that are particularly relevant to MDMA:

> . . . potential for abuse [should not] be determined on the basis of "isolated or occasional nontherapeutic purposes." The committee felt that there must exist "a substantial potential for the occurrence of significant diversions from legitimate channels, significant use by individuals contrary to professional advice, or substantial capability of creating hazards to the health of the user or the safety of the community."
>
> In speaking of "substantial" potential the term "substantial" means more than a mere scintilla of isolated abuse, but less than a preponderance. Therefore, documentation that, say, several hundred thousand dosage units of a drug have been diverted would be "substantial" evidence of abuse . . .
>
> * * *
>
> Misuse of a drug in suicides and attempted suicides, as well as injuries resulting from unsupervised use are regarded as indicative of a drug's potential for abuse.
>
> * * *
>
> . . . (3) Its history and current pattern of abuse.
>
> To determine whether or not a drug should be controlled, it is important to know the pattern of abuse of that substance, including the social, economic, and ecological characteristics of the segments of the population involved in such abuse. . .

(4) The scope, duration, and significance of abuse

In evaluating existing abuse, not only must the Attorney General know the pattern of abuse, but he must know whether the abuse is widespread. He must also know whether it is a passing fad, or whether it is a significant chronic abuse problem like heroin addiction. . . .

(5) What, if any, risk there is to the public health

If a drug creates no danger to the public health, it would be inappropriate to control the drug under this bill.

In view of the twin Congressional directives -- (1) that the Attorney General shall hold a hearing and (2) that the Attorney General shall consider a list of specified factors -- it seems clear that a hearing is required to the extent that facts or interpretations bearing on any of the factors set out in the statute have been contested or any new information has been provided that might affect the agency's findings with respect to those factors.

In light of this statutory scheme, we turn to the written comments that have been submitted to the agency.

II. Comments Submitted

To facilitate this discussion and put it into the statutory context, we set out below six of the eight statutory factors listed above -- as well as the three specific findings required to place a substance in Schedule I -- and identify briefly the comments submitted which raise important questions about the appropriate conclusions to be reached with respect to that factor.

(1) Actual or Relative Potential for Abuse

Greer paper */ : MDMA distinguished from other drugs of abuse by diminished pleasurable effects

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*/ Full citations to the comments are set out in Appendix A.

and markedly increased side effects when taken in either larger doses or with greater frequency;

Shulgin comment: Differences between MDMA and MDA "became striking" at effective levels, citing two papers Shulgin himself co-authored in 1980 (papers relied upon by DEA in its original analysis);

Grinspoon & Bakalar comment: MDMA does not resemble MDA in its effects;

Nichols comment: Notes relatively mild effects and short duration.

2. Scientific Evidence of its Pharmacological Effect

Nichols comment: Not at all clear that the toxicity associated with MDMA will in any way necessarily resemble that produced by MDA, with discussion of "very distinct effects on pharmacology" of the chemical differences between the two drugs. Author expresses professional opinion that literature cited by DEA "is inadequate to firmly conclude a similarity between the known toxicity of MDA and the expected toxicity of MDMA."

Roberts comment: Questions propriety of relying on studies based on injection while human administration is oral.

3. State of Current Scientific Knowledge Regarding MDMA

Greer paper: Not cited or discussed by DEA or HHS, yet plainly represents one of the latest and most extended discussions of MDMA.

4. and 5. History and Current Pattern of Abuse/Scope, Duration and Significance of Abuse

Greer, Shulgin, Grinspoon & Bakalar, Nichols comments:

> These commentators expressed disagreement on one or more scores with DEA's interpretation of the scientific literature in terms of the conclusion that MDMA has a high potential for abuse. All these commentators are professionals with relevant scientific expertise.

6. What, if any, risk there is to the public health.

DEA's and HHS' analysis rests substantially on extrapolation from MDA to MDMA. As noted above, Greer and Shulgin disagree on similarity with respect to documented effects; Nichols disagrees with similarity on basis of pharmacology; Roberts questions propriety of relying on studies utilizing injection methodology.

With respect to the ultimate findings made to place a substance in Schudule I, the comments disagree with DEA's tentative conclusions as follows:

1. High Potential for Abuse

See description of comments regarding factor 1 above.

2. Current Accepted Medical Use

Greer paper, Houghton comment, Greer comment, Shulgin comment, Reidlinger comment -- all suggest that there is currently accepted medical use of MDMA as adjunct to psychiatric medical practice in U.S.

3. Accepted Safety for Use Under Medical Supervision

Greer paper and comment; Shulgin comment; Houghton comment; Darling comment; Robinson comment: All disagree with finding that there is not accepted safety for use under medical supervision. These comments are particularly important in light of the fact that Dr. Greer's paper was apparently not available to DEA's and HHS's reviewers when the scheduling analysis was carried out (Dr. Greer's paper was, however, submitted to HHS before scheduling was considered by either agency).

III. Need for a Hearing

It is clear that the comments have raised important questions for DEA to consider with respect to the findings concerning MDMA. These questions involve both (1) the ultimate findings required to be made before a substance can be placed in Schedule I and (2) the findings concerning the several factors set out in 21 U.S.C. § 811 that DEA must consider before making a decision with respect to scheduling.

These questions fall into three categories.

- In the case of the Greer paper, the agency has been presented with critical factual evidence -- central to many of the determinations that it must make -- which the agency did not have available to it when it made its initial recommendations.

- Second, substantial issues with respect to the interpretation of -- and the conclusions to be drawn from -- the scientific literature have been raised. These issues have been raised by individuals with substantial scientific credentials and reputations.

- Third, in some instances, authors of papers that DEA itself has relied on question whether DEA has drawn the proper inferences from their data.

Section 811 contains a non-discretionary directive to the agency to issue rules on the record after opportunity for a hearing. The Supreme Court has consistently affirmed that this wording requires a trial-type hearing. See United States v. Allegheny-Ludlum Steel Corp., 406 U.S. 742, 757 (1972); 2 K. Davis, Administrative Law Treatise, § 10.7 (2d ed. 1979). There would be an extraordinary burden on the agency to justify proceeding without such a hearing. In this case, the comments made and questions raised about findings and interpretations central to the scheduling decision raise such fundamental issues that a hearing is plainly required.

Moreover, a hearing appears particularly important in the case of MDMA. There have only been eight mentions of MDMA in the DAWN data since 1972 and one medical examiner report. This level of reporting represents an extraordinarily low number of

mentions. It tends to suggest an absence of actual current abuse and certainly tends to negate a finding that a high potential for abuse exists. In light of this minor number of mentions in the DAWN data, the agency's analysis and inferences become particularly important in considering the appropriate scheduling for MDMA. Therefore, under these circumstances, the agency would appear, in our opinion, required to hold a hearing under § 811(a) of Title 21 on its proposal to schedule MDMA as a controlled substance. It is clear that a hearing would offer DEA an important opportunity to develop a full understanding of uncertain facts and interpretations. This should allow a more informed and better decision by the agency on this issue.

IV. Conclusion

For the reasons set out above, we believe that a hearing is required and would substantially assist DEA in discharging its obligations under the Act.

Sincerely,

Richard Cotton

COMMENTS CITED

Letter of August 13, 1984 to DEA from Professor Thomas B. Roberts, Ph.d.

Letter of August 15, 1984 to DEA from Lieutenant Commander Donald L. Darling, USN

Letter of August 17, 1984 to DEA from Professor David E. Nichols, Ph.D.

Letter of August 21, 1984 to DEA from Rodney A. Houghton, M.D.

Letter of August 22, 1984 to DEA from George Greer, M.D. [Greer comment], enclosing Greer, MDMA: A New Psychotropic Compound and its Effects in Humans (1983) [Greer paper]

Letter of August 26, 1984 to DEA from June E. Riedlinger, R.Ph.

Letter of August 28, 1984 to DEA from Professor Lester Grinspoon, M.D. and Professor James Bakalar

Letter of August 29, 1984 to DEA from Alexander T. Shulgin, Ph.D.