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George Greer?

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MEMORANDUM FOR INTERESTED PARTIES

George Greer

The purpose of this memorandum is to describe (1) what has been accomplished so far in the scheduling proceeding involving MDMA, and (2) the need for additional financial support. These new funds would be put to two uses. First, these funds are needed to allow the participation in the MDMA scheduling proceeding to come to a successful conclusion. Second, these funds are needed to support lobbying activities in the Congress to seek to assure that appropriate provisions are included in proposed designer drug legislation (now called the Controlled Substances Analog Act) in order to avoid deterring or hindering research in the area of drugs potentially useful as adjuncts to psychotherapy.

The final portion of this memorandum will describe the nature of the activities that remain in the MDMA proceeding; it will also describe the nature and plan for activities with respect to the lobbying activity concerning the designer drug bill.

MDMA Proceeding to Date

By almost any measure, the scheduling proceeding affecting MDMA has gone far better than anyone could have foreseen when we first undertook this project. (It is only unfortunate that

the substance of the proceeding has not been reflected in the press.) The most dramatic and striking evidence in the record bears on the importance that the consciousness effects of MDMA have for medicine and for psychotherapy in particular. The Government's own witness, Dr. John Docherty, a psychiatrist who was for many years the Chief of the Psycho-social Treatment Research Branch at the National Institute of Mental Health, was one of the most eloquent witnesses on the potential importance of MDMA. The following are excerpts from Dr. Docherty's testimony concerning MDMA:

- o "It is an interesting compound, one of potentially great importance to the field that ought to be investigated within a research framework."
- o "One of the important developments in the field [of psychotherapy] has been the moving together of psychopharmacology and psychotherapy and their combined use to relieve psychiatric problems. A drug which could particularly enhance the psychotherapeutic process is sort of at the next stage in that whole development. From a scientific development point of view, which is an interesting one especially at this time in the history of the field, it [MDMA] represents a drug which could potentially have an impact on the psychotherapeutic process itself."

- o "This drug [MDMA] since it focuses direction [on the combined effect of a drug and psychotherapy] is a useful one because it really points the field where it ought to be headed."
- o "MDMA is an agent that offers the possibility of moving us into an understanding of some disturbance in interpersonal processes, which is an important aspect of psychiatric disorder, but one which we have really not addressed specifically with our drug treatment."
- o "The anecdotal reports of the effect of MDMA on what I would call attachment behavior, the degree to which two people form some kind of a bonding between them, . . . is the aspect of [MDMA] that may have psychotherapeutic importance."

In addition, the record contains testimony from the following witnesses that we have put on:

- o Dr. Lester Grinspoon, a psychiatrist on the faculty of the Harvard Medical School and Former Chairperson of the Council on Research of the American Psychiatric Association, has testified that in his judgment MDMA has important therapeutic potential, and that research into its therapeutic potential was important.

- o Dr. Morris Lipton, Director of one of the nation's leading biomedical research laboratories and the Deputy Editor of the American Journal of Psychiatry, which is published by the American Psychiatric Association and is the leading journal in the field of psychiatry, testified that research into MDMA's potential therapeutic uses is important, and that MDMA "deserves thorough investigation." Dr. Lipton specifically testified that MDMA's "reported mechanism of action suggests that it might have clinical utility in several . . . serious psychiatric conditions for which treatment is currently not very effective." Dr. Lipton called for research into MDMA's possible use in the treatment of autistic children, cocaine abusers, and individuals suffering from post-traumatic stress syndrome.
- o Dr. Robert Lynch, the psychiatric consultant to the California Department of Rehabilitation, testified that he believes MDMA has important therapeutic potential and that he would like to see further research conducted. He further testified that he had received approval from his department to carry

out a research clinical trial with clients of the Department of Rehabilitation, but that such research will not go forward now that MDMA has been placed in Schedule I.

- o The World Health Organization wrote as follows about MDMA:

It should be noted that the Committee held extensive discussions concerning the reported therapeutic usefulness of MDMA. While the Committee found the reports intriguing, it was felt that the studies lacked the appropriate methodological design necessary to ascertain the reliability of the observations. There was, however, sufficient interest expressed to recommend that investigations be encouraged to follow up these preliminary findings. To this end, the Committee urges nations to use the provisions of Article 7 of the Convention on Psychotropic Substances to facilitate research on this interesting substance.

In addition, four practicing psychiatrists testified at length about the therapeutic utility they had observed in using MDMA in their private practice.

Five other psychiatrists who had not used MDMA in their practice, but who were familiar with its use by other practitioners or who were familiar with the literature on MDMA testified that in their judgment a psychiatrist's decision to use MDMA on appropriately selected patients for appropriate indications would, in their judgment, constitute good medical practice.

In short, the record is quite extraordinary in describing the therapeutic potential of MDMA.

Research Disincentive of Schedule I

The record is also quite remarkable in emphasizing the disincentive that placement in Schedule I creates for research. The following appears in the record that has been compiled:

- o The clinical director of Hoffman-LaRoche, one of the nation's leading pharmaceutical houses, testified that Hoffman-LaRoche would not conduct research upon and develop a substance that was placed in Schedule I unless it was a lifesaving substance.

- o Dr. Grinspoon, as an author in the area of psychedelic drugs and as a professor at the Harvard Medical School, testified that it was his opinion that Schedule I classification of MDMA would seriously discourage research. He specifically testified that it had already had an adverse impact on researchers at Harvard. He testified that there was little current writing in the scientific literature about Schedule I drugs and that he believed that the amount of research being done on Schedule I drugs was being strongly discouraged by the Schedule I status of these drugs.
- o Dr. Norman Zinberg, another well-known psychiatrist on the faculty of the Harvard Medical School, testified that Schedule I status severely and strongly discouraged research.
- o The chief of the Drug Abuse Section of the U.S. Food and Drug Administration testified that only 20 to 40 clinical trials per year were approved on Schedule I drugs, and that virtually all of these approvals related to research on THC and marijuana.

He specifically testified that in the past five years only one research protocol had been approved for research into the psychotherapeutic potential of a Schedule I drug.

- o A letter from Dr. Alfred Kurland at the Maryland Psychiatric Research Institute was admitted into the record recounting Dr. Kurland's difficulties in obtaining approvals to carry out research on a Schedule I drug.

Integrity of Administrative Law Judge

One of the most striking aspects of the proceeding to date has been the independence and integrity demonstrated by the Administrative Law Judge conducting the proceeding. In the Judge's first ruling which was issued in June, the Judge rejected wholly the legal position urged upon him by the DEA and held that the legal position that we urged was one of two that he found legally justified.

But perhaps even more striking has been the seriousness with which the Administrative Law Judge has treated the issue of whether medical research into MDMA will be discouraged. Set out below are quotations from the Judge on the issue of research:

JUDGE YOUNG: Ms. Johnson, what is your basis in this case [for taking the position that the law forecloses consideration of] such practical problems as may exist for researchers resulting from placement in Schedule 1?

MS. JOHNSON: Your Honor, the Drug Enforcement Administration is conducting a scheduling action under a statute that was passed by the United States Congress, and we used the criteria for scheduling substances that are listed in the statute.

Congress has not provided, nor given any leeway to consider issues such as research.

* * *

JUDGE YOUNG: But when you take that position, you're saying okay, we're on this island here, and this decision will be based only on the factors stated in this very small island, and a vast sea of reality which may surround us is not to be considered.

Now, to my mind that's just not a reasonable position for any government agency or anyone to take in a case like this. It seems to me -- perhaps a hypothetical statement -- it seems to me perhaps the reason we are here conducting this proceeding may very

well be when you get down to the rock bottom of it, the fact that some people find it enormously difficult to get approval to do experimentation with substances in Schedule 1.

And a message that I frequently get "blipping" up to me through the evidence is that if we didn't have all these problems, we wouldn't care what schedule you put it in.

Now, if there is validity to this, if there is, and I'm not saying there is, but if there is validity to that point, I ought to consider it and so should this Administrator, and the statute, I don't think precludes that.

* * *

I think this Administrator would close his eyes to reality if he did not consider this and I think I would be doing him a disservice if, with what I have heard about it so far, I didn't consider the difficulty of experimenting with a Schedule 1 substance, and address the subject in my recommended decision to him.

* * *

Ladies and gentlemen, just one comment further with respect to this matter that we were discussing before we left, you know, it could very well be that

this matter of the difficulty of researchers with Schedule 1 substances, maybe that's the way it has to be and maybe that's the way it ought to be, but I want to be satisfied with respect to that.

You know, there was a time when all the established wisdom and the best available scientific knowledge said the world is flat, and Mr. Columbus, you're out of your mind, and there was a time when all the established knowledge said to Galileo that he was out of his mind.

You know, I just want to see to it that people do not look back at us a hundred years or so down the road in the same way that we now look back at the Holy Inquisition in Spain as the period of the Renaissance.

Abuse Potential

The record now contains evidence demonstrating the relatively low abuse potential of MDMA which would, if objectively evaluated, prove that MDMA should not be held to have "high" abuse potential and should not be placed in Schedule I.

- o MDMA has been mentioned on only eight occasions in the entire 12-year period that that DAWN data has been collected by the government on visits to hospital emergency rooms associated with drug abuse. From 1972 to 1983, there have been approximately

1.5 million drug mentions recorded by DAWN. Eight mentions out of 1.5 million is obviously insignificant and, if anything, evidence of low abuse potential.

- o There has been only one mention of MDMA in connection with a medical examiner's report of a drug abuse-related death. (The record reflects that there is substantial controversy over whether the drug in question was MDMA.) But this one isolated report must be compared to 3,000 medical examiner drug abuse deaths reported to DAWN each year (i.e. approximately 30,000 to 40,000 from 1972 to 1984).
- o The DEA reported that MDMA had been found in approximately four laboratories which had been seized for producing other illicit drugs since 1972. During the period of time in question, the DEA seized approximately 2,600 laboratories. Four out of 2,600 cannot be said to demonstrate "high" abuse potential.
- o The DEA reported that 44 "exhibits" of MDMA have been recorded in the DEA's computerized STRIDE data collection system from 1972 to 1984. This system tabulates all drugs seized by the DEA or other law enforcement agencies and submitted to DEA

laboratories for chemical analysis. This system records somewhere between 30,000 to 40,000 "exhibits" per year. Therefore, for the period 1972 through 1983, this system recorded between 400,000 and 500,000 "exhibits" of drug evidence -- of which only 44 involved MDMA.

- o The DEA's only witness from a drug abuse treatment program (Dr. Inaba from the Haight-Asbury Free Clinic) testified that significantly less than one-half of one percent of the Free Clinic's case load involved MDMA.

NEXT STEPS FOR WHICH FUNDING IS NEEDED

1. MDMA Scheduling. The hearings in the DEA scheduling proceeding have now concluded. All witnesses have been cross-examined, and all documents have been submitted into evidence. The DEA legal counsel will file their legal brief setting out the DEA's argument on December 10, 1985.

Our brief is due on January 15, 1986, as is the brief of the two drug companies (Hoffman-LaRoche and McNeil Laboratories) which are participating in the proceedings. The DEA will file a reply brief on February 10, 1986. An oral argument on legal issues by lawyers for all sides may be

held later in February. The Judge will then issue his recommended decision, sometime in the spring of 1986. The lawyers for all sides will file written comments on the Judge's recommended decision. At that point, the Judge's recommended decision along with the lawyers' written comments will go to the DEA Administrator, who will make the final decision about what schedule MDMA should be placed in. The Administrator's decision will probably be announced sometime in the summer of 1986.

It should also be noted that this whole issue could get even more complicated when MDMA is formally placed in Schedule 1 internationally -- an event which is likely to occur sometime between February and June of 1986. At that point, there will be further legal arguments about the impact of that action on the current proceeding.

Funds are needed to continue to pay the legal expenses of the scheduling proceedings. The briefing required for the scheduling proceedings will be very substantial. The legal issues are complicated. The hearing record is lengthy. The documentary material placed into evidence is voluminous. Preparation of the briefs will require substantial research, extensive review of medical materials, and extensive drafting.

There are currently about \$12,000 of outstanding unpaid legal bills connected with the scheduling proceeding. We anticipate a need for approximately another \$25,000 in addition to the outstanding bills to be able to complete the scheduling proceeding successfully and in a professionally competent manner. Thus the total needed is \$37,000 - \$40,000.

2. Designer Drug Bill. In August of this year, the Reagan Administration proposed a new law which it said was needed to control trafficking in so-called designer drugs. The most well-publicized examples of these drugs are the synthetic heroins which are said to be responsible for a significant number of overdose deaths and serious medical complications -- primarily in California.

The Senate Judiciary Committee has already reported out a bill which is likely to be passed by the Senate before the end of 1985. The House of Representatives will hold hearings on the Senate bill and on the Administration bill in early 1986. It is almost certain that the House will pass some bill before June 1986. The House bill and the Senate bill will then go to a Joint Conference Committee to resolve any differences between the two bills, and the Conference Committee bill will likely become law roughly in mid-summer 1986.

The language in the current Senate bill is quite vague. This vagueness as well as one specific provision which was added to the Senate bill could raise a serious question about the legality of work being done by a number of ethical, legitimate researchers working with psychoactive drugs that could be therapeutically useful in psychotherapy.

The Senate bill is, at this point, a fait accompli. The most promising approach is to work with the House Judiciary Committee to seek to convince that Committee of the need to assure that the bill does not discourage legitimate research. This would require the services of a lobbyist, and it would require participation in the House hearings (involving preparation of testimony and witnesses traveling to Washington, D.C.). In addition, it would require careful work with the staff of the House Judiciary Committee and with the staff of individual members of the House Judiciary Committee. It would further require high level contacts with the individual Congressmen who are members of the Committee.

If the House bill can be influenced to incorporate the necessary protections for research, it will then be necessary to persuade the Senate to accept the House amendment in the Conference Committee. Again, this will require work with the

staff of the Senate Judiciary Committee. It will also require high level contacts with Senators who are on the Senate Judiciary Committee. If the Senators can be convinced and the Conference Committee accepts the House amendment, the final law will then contain the needed protection for research.

The key to a successful effort will be credibility on Capitol Hill. In particular, a spokesman is needed who can convince Congressmen and Senators (and even perhaps the DEA) that the legitimate law enforcement concerns reflected in the designer drug bill of the Administration and of the Controlled Substance Analog Act of the Senate can be preserved while at the same time legitimate research interests are protected.

We have identified an individual we believe has these credentials. This individual has received wide recognition for his role in drug enforcement efforts and has, therefore, substantial credibility in the law enforcement world, and particularly in the drug law enforcement world.

This individual and his lobbying firm have indicated they would be prepared to take on the lobbying campaign outlined above. We believe that it would have a good chance of success with their participation. In addition, an effort that gave credibility to the claims that certain drugs may have serious therapeutic potential in a psychotherapeutic setting could favorably affect indirectly the MDMA proceeding itself as well as public perceptions on these questions generally.

The lobbyist has estimated that the effort outlined above would cost approximately \$10,000 per month from January through June, 1986, for a total of \$60,000.

Conclusion

In view of the need to move quickly on both of these efforts, we need to ascertain our ability to raise the necessary funds to support these efforts as soon as possible. If funds can be raised, we need to get them in hand rapidly and start to work immediately. If not all these funds can be raised, difficult choices will need to be made and priorities set.