

MDMA ON THE SCALES OF JUSTICE

A REPORT ON THE DRUG ENFORCEMENT ADMINISTRATIONS' MDMA HEARING

THE OPENING MEETING-FEBRUARY 1, 1985

REPORTED ON BY RICK DOBLIN
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The First Hearing- Blind Justice begins to weigh MDMA

On February 1, 1985, in the hearing room on the twelfth floor of the Washington, D.C. Drug Enforcement Administrations' offices, the legal status of MDMA was at issue. The hearing that had been requested by several physicians and researchers on August 27, 1984, was finally beginning, the first clear example of the exceeding slowness with which this particular branch of the federal government sometimes operates. It was my great delight to discover some of the causes of the length of this particularly long drawn out process, reasons which became apparant within the first few minutes of the hearing. Examples will follow, but the basic time delaying factor in this process is the chief attorney for the Drug Enforcement Administration himself!

The DEA initiated legal action against MDMA without expecting opposition, particularly reputable opposition. Their case about the abuse potential of MDMA is weak, there have been no emergency room Drug Abuse Warning Network(DAWN) mentions of MDMA since 1981, and only one medical examiner report involving a person with a "preexisting physiological condition" of some unspecified sort (case currently under investigation by Ann).

The animal studies designed to determine drug dependence liability and abuse potential of new compounds have not been done for MDMA, and so the DEA attorney cannot put forward an affirmative case concerning MDMA's alledged "high potential for abuse" other than comparing MDMA to MDA, which some of the governments own experts say is not a valid comparison.

The strict interpretation of "accepted medical use" to mean only drugs having completed the FDA process is under challenge from the pharmaceutical industry as well as the research and therapeutic community, and may also be contrary to the legislative intent behind the creation of the FDA.

Given a weak case, the DEA attorney has adopted the strategy of fighting on every issue, of attempting to stop every motion that might give the slightest advantage to the group working to avoid having MDMA placed in Schedule 1. He objects just for the sake of objecting, in order to show that he is being tough. He confuses the exercise of power with strength. He does not respect reason and principles of fairness and has totally lost sight of the traditional, constitutional role of the prosecuter as the "White Knight" of the system, the only party that must impartially search for truth since the defense is not seeking truth but freedom. Matters that should be settled simply and in a moment become battles and the process ginds forward more slowly than necessary. By choosing to fight all the battles, he inevitable chooses some losing battles, weakens his credibility and thins out his energy. This DEA attorney is one of our greatest assests.

On the other hand, there could be a very successful "grand plan" behind his actions. His time delays have created the situation wherein the World Health Organizations' Expert Committee on Drug Dependency will give their recommendations concerning the international scheduling of MDMA prior to those issues being raised in the more open forum of the DEA hearing. If the WHO Committee recommends Schedule I, this would create a precedent and would make US control action of a different nature more difficult. Perhaps he knows that the recommendations of the WHO Committee are likely to be that MDMA be placed in Schedule I? But, just perhaps he is not counting on our efforts to place accurate and intellectually challenging information in the hands of each representative to that meeting.

Even before Freud, psychological sophisticates (and their grandmothers) have known that off-hand comments and jokes often reveal a great deal about the person who says them. Prior to the start of the hearing, some of the about a dozen people present were gathered in a group talking. The author of both a forthcoming article in Psychology Today concerning MDMA and another on synthetic heroin substitutes appearing in this month's Science 85, Jack Shafer, was at the hearing and was handing out copies of his article. Jack reported that some of the synthetic heroins were deadly and that some addicts had died from their use. The DEA attorney responded "Now that some of these addicts are dying from their use of these drugs, maybe we finally have a solution to the addiction problem." In all fairness to the group, it must be said that the joke was not well received.

Present at the hearing were two attorneys representing both Hofmann-LaRouche and MacNeil Labs, one of whom was Mr. Bob Angerola, two DEA attorneys, Mr. Steven Stone and Ms. Charlotte Johnson, Richard Cotton representing the researchers, both Howard McClain and Frank Sapienza of the DEA, Jack Shafer, myself, a court reporter, the DEA hearing clerk Mrs. Baltz, and the administrative law judge Francis Young. The case is docket number 84-48.

After the various parties identified themselves, the judges' first comments restored my faith in the ability of honorable men to retain their integrity while working within the system. Judge Young spoke out on a procedural matter that he felt should be cleared up. He noted that the files for this case included a letter from Richard Cotton briefing the DEA staff on the legal necessity to have a hearing when requested. The judge felt that such a letter was unnecessary, since his reading of the statute led him to conclude that a hearing was to be automatically granted if requested. He spoke to the DEA attorney, Mr. Steven Stone, and said that the public interest was not served when the public had to spend good money to make the case for their rights to a hearing when such a hearing was plainly required by law.

Judge Young said that this problem had happened before in another case. He required Mr. Stone to straighten out this problem by talking to the legal staff who actually write the DEA notices in the Federal Register and letting them know that future notices should be written making plain the obligation of the DEA to hold hearings if requested. It was at this point that hope began stirring within me, and I began to see the delaying tactics of the DEA legal staff as actually helping our case, and giving us months extra to work and prepare.

The next matter at hand was a brief review of the various parties that had requested a hearing, their location and possible locations for future meetings in this case. Judge Young suggested that perhaps it would be in order to have several locations and he asked the various lawyers their opinions. Mr. Stone objected to the idea of having more than one location, citing the budget problems of the DEA, their need to conserve on travel funds, and he gave an analogy of multi-state class action suits that have the actual trial in only one location. Judge Young found this attitude a bit unfair, said the analogy only went so far since only in one case are lawyers working on contingent fees with large sums involved. Also, the federal courts have regional jurisdiction, and are not national in scope as is this DEA hearing.

Judge Young read the statute book to Mr. Stone, citing the passage that requires the DEA to give all witnesses a chance to participate in the hearing process without undue hardship. He offered that he had read the same memorandums as Mr. Stone had encouraging budgetary restraint, that he tried to run his office with as little expense as possible, but that still the public must be served. He then went on to remind Mr. Stone that within the next several months hearings on other matters were going to be held in San Francisco, Kansas City as well as several other locations, and that the MDMA hearings could be scheduled on a day following one of those hearings in order to conserve travel expenses. Judge Stone further went on to pose a hypothetical case of witnesses not being able to attend the hearings, the judge siding with the DEA's recommendation, and an appeal being filed by Richard Cotton which would reopen the hearings after months of needless delay. He asked Richard Cotton if this was a realistic scenario, and he replied that it was. Judge Young then turned to Mr. Stone and said it seems it would just be simpler to take the testimony for a day or so and so have all the information on the record.

Mr. Stone then reiterated that one hearing was best, but that instead of Washington it could perhaps be held in the "heartland" of the country, making everyone travel only a little. Needless to say, this matter was not resolved at this time, but left up in the air for the judge to consider later.

Turning to Mr. Angerola, attorney for the two pharmaceutical companies, Judge Young asked for a statement of his clients interests in this case. Mr. Angerola replied that his clients have no interest whatsoever in MDMA but that they were concerned about a procedural matter discussed in the Federal Register notice about this hearing. The DEA legal staff had asked the administrative judge to rule on the statutory requirements of the Controlled Substances Act. The DEA legal staff wanted the judge to decide if substances could be put in other than Schedule 1, even if there was no currently accepted medical use. The pharmaceutical companies that Mr. Angerola represented felt that the DEA does have such discretion. Mr. Angerola went on to describe why this issue was important to his clients, and spoke clearly and directly. He said that his clients have some medicines that are marketed in Europe but not yet in the U.S. In several cases their medicines have been placed in Schedule 1 in the U.S., and then later approved for marketing in the U.S. Sometimes years are required for some of the states to change their scheduling to permit marketing. About half the states automatically follow the federal governments scheduling, but half permit changes in drug scheduling to be done only by a bill passed through their legislatures. Both the American public and the profit-making drug company suffer in these cases. Also, there is a stigma attached to substances in Schedule 1, research is much harder and European sales are often affected.

Mr. Angerola stated that he was planning to call no witnesses and asked that the hearing be bifurcated into two areas, those that concern MDMA directly on the one hand, and on the other hand the procedural issue concerning the latitude given by the statute to the DEA in their scheduling decisions. Furthermore, Mr. Angerola asked that the procedural issue be dealt with first and that then the MDMA issues might be clearer and easier to discuss. Mr. Angerola then said that in his opinion the DEA does have clear discretion to place substances in whatever schedule they wish.

Judge Young then asked Richard Cotton for his presentation of the issues important to his clients. He began by mentioning that the witnesses cluster both on the East Coast and the West and he requested two hearings, one in D.C. and the other somewhere in California. He then defined three major issues. First, what is accepted medical use? Is it to be determined narrowly to mean only those substances approved by the FDA or is it to mean something broader involving some form of peer review and informed consent, procedures which seem more in harmony with the legislative intent of the FDA laws. He mentioned that the laws were not intended to regulate doctors practicing medicine but were designed to protect the public from pharmaceutical companies selling unsafe or worthless substances.

Secondly, what is accepted safety under medical supervision? Compounds must have no accepted medical use to be placed in schedule 1, as well as a lack of accepted safety under medical supervision. MDMA seems very safe when used under medical supervision.

The third issue Richard Cotton raised was the procedural one, can a substance with some potential for abuse, but not high, be placed in other than schedule 1?

Mr. Stone was asked his perception of the issues and he added the question concerning the abuse potential of MDMA, high, moderate or low?

He also objected to separating the hearing into parts, saying that the definition of "currently accepted medical use" should be settled first before they would be able to address the question of the ability of the DEA to place something without "currently accepted medical use" in any schedule other than 1. It was here that I saw Mr. Stone's grasp on logic being replaced by his desire to object and delay. Whatever the definition of "currently accepted medical use", it is irrelevant to questions concerning the case where there is no "currently accepted medical use".

I saw Judge Young getting a bit exasperated and he asked Richard Cotton for his view. After reviewing the various issues, Richard Cotton said that he could see no reason not to take the procedural question first, since the definition of "currently accepted medical use" was not required prior to deciding the procedural issues.

The procedural matter was not resolved, and left for later.

Judge Young said that this hearing could take up to a year, and that he had hopes to expedite this matter but that his hopes were fading. After reading the transcript of this hearing the next week, the judge said he would issue an order asking each lawyer to write him short briefs discussing what they think the issues are, in what order they should be addressed, which ones can be handled by the lawyers writing briefs and which ones require witnesses, and where the hearings should take place.

By general agreement, five issues were mentioned. First, is there accepted medical use of MDMA? Second, is there lack of accepted safety for MDMA when used under medical supervision? Third, what is the relative abuse potential of MDMA? Fourth, if there is no accepted medical use of MDMA, can it be placed in other than schedule 1? Fifth, if MDMA can be placed in other than schedule 1, where should it be scheduled, if at all?

About a month has been added to the hearing process for this written clarification process, and all of these issues could have been dealt with at this hearing, if the DEA lawyer had been more reasonable. Judge Young will almost certainly agree to several hearings, one in D.C. and one in California. He will almost certainly agree to decide the procedural issue first. We can only continue preparing, wait and see.

Strategy Suggestions-Additional Actions to set in Motion

Assumption 1-The administrative judge will rule that the DEA does have discretion in placing substances with no currently accepted medical use in schedules other than 1. These substances will most probably be those that are "in the pipeline", that are currently being investigated under FDA permission.

Action 1-To ride on the coattails of the pharmaceutical industry seems our safest course of action. Therefore, we should try to initiate some Investigational New Drug applications. In order for permission to be granted, a certain minimum amount of animal studies need to be done. These studies will cost \$20,000 at a research lab, perhaps less at a University. Fundraising should begin again for animal studies. If they are completed, both a protocol modeled on Franco Di Leo's LSD study and one designed specifically for MDMA could be submitted to the FDA, and the FDA must reply within 30 days. In the current political climate, with a growing professional support and a lack of MDMA mentions in the DAWN system, one of the protocols would likely be approved.

Assumption 2:

Hearings which will involve witnesses will probably not take place until this summer, well after the April 22-29 meeting of the World Health Organizations Expert Committee on Drug Dependence which will consider MDMA and 26 other phenylethylamines for placement in the International Convention on Psychotropic Substances. The Committee recommendation will therefore be strongly considered by the DEA as a guideline for scheduling decisions within the United States.

Action 2:

Educational materials should be sent to every member of the committee. Such material will be sent by the WHO to the committee members within a few weeks. Included already is the bibliography of all papers written about MDMA updated to August, 1984, and George Greers study and protocol. Still to be included are all the letters sent to the DEA requesting a hearing, the physiology study, an updated bibliography of MDMA mentions in print, W.-Eberhard Mehling's letter to Dr. Khan at the WHO, and later whatever relevant documents are created during the US hearing.

Today, a potentially very fortuitous contact was initiated in search of a list of all the participants in the WHO Expert Committee. Dr. Charles O'Brien is one of the few members of that committee from the United States, and he works at the Veterans Hospital in Philadelphia, the same place that Lance Wright works. Dona is attempting to contact him, referred by a colleague of Dr. O'Brien's from Harvard School of Public Health. Dr. O'Brien knows Lance Wright and perhaps we can see if the two of them can discuss MDMA, and if Dr. O'Brien would like to come to the conference.

Assumption 3

The more witnesses the better.

Action 3

Continue to seek more physicians to speak about abuse potential of MDMA, and about therapeutic use.