

MDMA-DEA Strategy Reconsidered

Schedule 1, 2 or 3?

by Rick Doblin—November 10 / 1985

This paper is a review of what has transpired during the more than a year since the Drug Enforcement Administration (DEA) announced in the Federal Register their intentions to place methylenedioxymethamphetamine (MDMA) in Schedule 1 and in response James Bakalar, George Greer, Lester Grinspoon, and Tom Roberts (BGGR) requested a hearing and suggested as an alternative that MDMA be placed in Schedule 3. This paper is also a rethinking, in light of subsequent events, of the continued efficacy of BGGR requesting that MDMA be placed in Schedule 3. I conclude that the goals of BGGR would well served if they now requested that MDMA be placed in Schedule 2, instead of 1 or 3.

It is early November, and the testimony in the MDMA scheduling hearings has already been presented to Judge Young, the Administrative Law Judge of the DEA. The final legal briefs are due very soon. The DEA will submit their brief by mid-December, and the BGGR brief needs to be submitted by mid-January. The DEA final rebuttal brief is due early February, and then Judge Young will make his recommendation to the Administrator of the DEA, John Lawn.

The International Convention on Psychotropic Drugs will also meet in February and vote on the international scheduling of MDMA, and their decision will most likely precede that of Judge Young's. Their Expert Committee on Drug Dependence has formally recommended that MDMA be placed in Schedule 1, though the Chairman of that Committee, Dr. Paul Grof, dissented.

After examining the proposition that the basic strategy of the MDMA research and therapy group be changed from requesting that MDMA be placed in Schedule 3 to requesting that MDMA be placed in Schedule 2, several main points emerge. 1) At this point, most of the original objectives of the research and therapy group's hearing request have already been met. 2) There are practical political realities to accept that make an eventual Schedule 3 decision extremely unlikely. 3) Most importantly, Schedule 2 may actually offer more specific opportunities than Schedule 3 for the advancement and integration of psychedelic medicine into our culture, primarily through providing a context for American Psychiatric Association and Food and Drug Administration cooperation.

Strategically, there were several benefits to be gained from requesting a hearing, regardless of which particular Schedule MDMA ended up in. The case for psychedelic research could get a fair hearing, and as a result therapists and researchers might be able to work more effectively within the FDA and within the culture. Also, the criminalization of MDMA would be delayed so that research and treatment could continue.

All of these objectives have been met, more fully than many people expected. Judge Young of the DEA is a fair man, and observations of the hearings strengthen my faith in democracy. The FDA is now publically committed to permitting research applications. Two compassionate INDs have already been granted for work with MDMA,

one to Dr. Greer for a 73 year old male cancer patient and the other to Dr. Franco Di Leo for an 81 year old female chronically depressed patient. Physician groups at several Universities in the U.S. and in Germany, Panama, and Guatemala are preparing to initiate MDMA research, looking at it's physiological effects, it's subjective effects, it's therapeutic potential, it's use in treating alcohol abuse, and it's addictive potential.

A potentially fundamental form of support for MDMA research has become clearer in discussions with the Orphan Drug Products Office of the FDA and through study of their guidelines. I'm left with the conclusion that it is very possible that MDMA could get Orphan Drug Designation, making further research much more likely.

MDMA animal toxicity studies, done in conformity with FDA regulations, are to conclude in January and will enable Phase 1 and Phase 2 human studies to begin. Dr. Schuster's U. of Chicago MDMA neurotoxicity study is being expanded on and replicated by a cooperative effort of Toxicology Pathology Associates working at the University of Arkansas Medical Center, and the National Center for Toxicological Research. The project is being funded by Earth Metabolic Design.

Another effect of the request for a hearing was that criminalization of MDMA was delayed about ten months. Treatment was able to continue for many patients, as well as training for many therapists. Several important conferences were held that significantly broadened the base of support for MDMA research within medical and governmental circles. And funds were raised to support the animal studies.

I've identified many gains from having the hearing itself, and now will look at the effects of requesting a specific schedule. Reviewing the practical aspects of requesting a Schedule 2 placement instead of a Schedule 3 placement begins with an assessment of the chance for success for a Schedule 3 placement of MDMA. Since I have been referred to as an eternal optimist, it may be a bit surprising when I say that there is no chance at all that MDMA will be placed in Schedule 3 by the DEA. A quick look at a few factors should make my opinion clearer.

Firstly, an offhand comment made by the council for the DEA during the hearing held on October 8-11 in Washington sheds a great deal of light on the political realities of this case. Judge Young was reprimanding the DEA council, who had stated that the difficulty of conducting research with Schedule 1 compounds was irrelevant to the purpose of the hearing. Judge Young, in an imaginative flourish, suggested by way of metaphorical allusion that the DEA was ignoring the Sea of Reality which surrounded the little island on which they stood, and that such narrow vision was not good policy for any government agency, nor for any individual for that matter. And if considering the practical implications of placing MDMA in Schedule 1 was not part of this case, then Judge Young felt it should be. In the recess following this exchange, Mr. Steven Stone, the DEA attorney, told me that he didn't care what the Judge said, the DEA was going to do what they wanted to no matter what Judge Young recommended.

Needless to say, administrative law is filled with case law concerning the authority of the Administrative Law Judges. They have independence, and their rulings must be considered by the administrator of their respective agencies. Their rulings become part of the record of the case, and carry a certain significant legal weight. However, they can only make recommendations and their rulings are not final.

In this hearing, there has already been a useful example of the dynamic between Judge Young and John Lawn, the Administrator of the DEA. One of the claims of the DEA is that they were legislatively bound to place MDMA in Schedule 1, since there is no currently accepted medical use for MDMA. This issue of law was challenged by both Richard Cotton and by the Robert Angerola, the lawyer for Hoffman LaRoche and MacNeil pharmaceutical corporations. Judge Young reviewed the briefs and made his recommendation to John Lawn, suggesting several different policy alternatives. On the morning of the opening hearing in Washington, months after the Judge's recommendations were finalized, Judge Young announced that he had received a letter from John Lawn concerning those recommendations. John Lawn had declined to make any choice at all, postponing the decision indefinitely. Judge Young felt that this was unfortunate, but that there was nothing further he could do.

Another piece of evidence for my conclusion that MDMA will not be placed in Schedule 3 at this point in time comes from a discussion that I had with Gene Haislip, the DEA official who was primarily responsible for invoking the Emergency Scheduling of MDMA. He told me that Schedule 3 was unacceptable to him because the legal penalties for manufacture, sales, and possession of MDMA were significantly less in Schedule 3 than in Schedule 1. The penalties for crimes involving Schedule 1 and 2 compounds are roughly three times as harsh as penalties for crimes involving Schedule 3 compounds.

The opinion of Richard Cotton, the man most in touch with the legal case, adds yet another piece of evidence. He also feels that there is virtually no hope that MDMA will be placed in Schedule 3 by the DEA. However, he does feel that the case for a Schedule 3 placement has been well made and that Judge Young has truly listened to the testimony.

The final piece of evidence for the conclusion that MDMA has no chance to be placed in Schedule 3 comes from observation of the International Convention on Psychotropic Drugs. They will meet in February to vote on the recommendation that MDMA be placed in Schedule 1. Since the US is a party to this treaty, we are bound to comply with decisions made by the Convention. While there is some "slippage" between Schedule 1 internationally and Schedules 1 and 2 nationally, as evidenced by the DEA requesting that THC be placed nationally in Schedule 2 even though it is in Schedule 1 internationally, this "slippage" cannot be stretched to include Schedule 3.

Part of the initial hope of MDMA placed in Schedule 3, and then remaining there, came from the anticipated timing of Judge Young's recommendations. If he recommended Schedule 3, and if the DEA administrator complied, then the Convention might have been influenced to overrule the Schedule 1 recommendation of their Expert Committee on Drug Dependence (ECDD). However, it is now clear the decisions will be at best simultaneous, and more likely the Convention will vote before Judge Young issues his recommendation.

At this time there is no international constituency for modifying the Schedule 1 recommendation of the ECDD. In discussions a few days ago with Howard McClain, liaison to the Convention from the DEA Diversion Control Office, I mentioned that I assumed that MDMA would be placed in Schedule 1 in February. He replied that while it

was likely, it was still not settled, and that the DEA doesn't check to see how the wind is blowing until late December. However, I see absolutely no signs of change blowing in the wind, nor is anyone working to produce such change.

Taken in total, the various clues concerning the likelihood of MDMA actually being placed in Schedule 3 add up to a uniformly negative conclusion. Yet we knew this from the very beginning, and it should be no surprise now. Rather than continuing to request an unlikely outcome, after all of the main realistic objectives have already been met by our present strategy, it is worth reconsidering strategy and objectives to see about ways in which additional progress might be made.

A Schedule 2 placement, in contrast to a Schedule 3 placement, is conceivable. The International treaties would not preclude such a placement. The penalties for crimes involving Schedule 2 compounds would satisfy the DEA. There is a structural potential for government controlled distribution in Schedule 2 which does not exist within Schedule 3. A request for a Schedule 2 placement thus has some hope of success, and would at the same time show the willingness of the therapists and researchers to empathize with some of the concerns of the DEA and to compromise. Perhaps such leading behavior would encourage the DEA to also compromise.

When our view is broadened to include the developing situation in regards to the new Designer Drug Law, it becomes clear that a two-pronged approach to opening up psychedelic medicine could be developed which would provide more options and a greater likelihood of success. There is the possibility that the new Designer Drug Law will provide an avenue for new drugs to be developed and used by physicians at the discretion of the physician, as long as the ethical standards of good medicine are being followed. This means that if the Designer Drug Law is written to include the right of physicians to practice medicine with the new compounds as they see fit, in effect all the new compounds would be available to physicians without requiring specific FDA permission. This is precisely what having MDMA in Schedule 3 would permit.

George Greer is attempting to have psychedelic medicines made legally available directly to physicians, by his work focusing on effecting the outcome of the Designer Drug Law. By abandoning an unwinnable position as regards to MDMA, the basic attempt to have psychedelic medicines available to physicians without specific FDA approval is not abandoned.

So far, I have described how many of the objectives of initially recommending Schedule 3 have been met, and how further progress is unlikely if the present course is followed. It has been made clear that there exists at least the potential for a Schedule 2 ruling. It has also been shown that the basic goal of having MDMA in Schedule 3, of having psychedelic medicines available to physicians, can still be worked towards in the context of lobbying on the Designer Drug Law.

What remains to be reviewed is the potential advantages of having MDMA in Schedule 2 over having it in Schedule 3. It is obvious that having it in Schedule 2 is better than having it in Schedule 1. While I have left it for last, this is one of the most important elements in the strategy reconsideration. To begin the review of how it might actually be better if MDMA is in Schedule 2 rather than 3, a review of long term goals is in order.

The work with MDMA is only one aspect of the field of psychedelic medicine. The

long term goal is the development of the field, not the development of one particular medicine or another. For psychedelic medicine to develop, there will need to be acceptance by psychiatry in general. There will also need to be acceptance by governmental agencies, and the public. There will need to be training programs for physicians interested in practicing this specialty and there will need to be a great deal of research. Basically put, there needs to be a transition for psychedelic medicine from fringe to center, and a transformation of the perception of its practitioners from renegades to pioneers. All of this will emerge through actual therapeutic successes, and through visible cooperation with the authorities that be. The fear and the concern of the government and the public must be accepted and dealt with directly.

Schedule 2 requires the creation of administrative structures of control, supervision and management. Having MDMA in Schedule 2 would require codification of integrative systems of social control. Faced with the opportunity of having MDMA more easily available for research and treatment, simultaneous with possible efforts to make it an FDA approved Orphan Drug, the FDA would want to assure themselves that such a development would be properly managed, necessitating a medical review board that could be given certain oversight responsibilities.

What needs to occur is a shift in the locus of control from government to psychiatry. The government is fully willing to cooperate in this process, and in fact this is the precedent in law. The FDA is not meant to interfere with the practice of medicine, but rather is empowered to regulate the drug manufacturers and advertisers. What we have here is not only a case of government repression, but also a situation of psychiatric abdication of responsibility due to lack of experience and fear.

The possible regulatory system of control for MDMA, if it were placed in Schedule 2, could take several forms. Dr. Thomas Ling wrote that for LSD research in England, during the 1960's, LSD was sold directly to mental hospitals, and to approved psychiatrists by the manufacturer. "The manufacturer's medical staff satisfy themselves that the individual psychiatrist is reliable and really knows how to use the drug. The company reserves the right to sell or withhold the drug from any psychiatrist, and it is never on sale through any ordinary pharmacist, or to lay psychologists."

This procedure would not work in the case of MDMA, since there is no manufacturer with exclusive rights to market MDMA as yet. If a company is given Orphan Drug status for MDMA, then such a procedure might be possible. However, it seems preferable for the field of psychiatry to take the responsibility directly.

Methadone is in Schedule 2, and both a clinic and a physician need to be approved prior to physicians being able to administer it. This is probably a very fine solution in the long term for the field of psychedelic medicine, since the creation of psychedelic clinics in various locations offers the possibility of interdisciplinary staffing, specialized training programs for the staff, inpatient treatment in a supportive setting, and government monitoring. But the field is now in its infancy and setting up clinics might be prohibitively expensive. Also, MDMA does not seem to need a clinic setting as much as the major psychedelics. Still, the setting where MDMA therapy takes place is very important, and a certain minimum set of standards could be established that would not make the clinics prohibitively expensive and would still assure a certain supportive setting.

The definition of the requirements for physician approval also needs to be codified, and would need to be different for MDMA than for the major psychedelics. Additionally, since there are so few physicians who have experience with MDMA, some procedure needs to be created to train physicians.

For the approval of settings and physicians, the FDA is more than willing to cede responsibility to psychiatry, since such work is actually outside of the FDA mandate. It is thus precisely in the area of the training of physicians and of accrediting them that psychiatry must make the first moves, and it is precisely there that psychiatry is most qualified to act.

Thus, to be taken seriously by Judge Young, the DEA and the FDA, a proposal for placement of MDMA in Schedule 2 must specify the procedures and requirements that will be put in place. Also, the proposal must have some connection with the American Psychiatric Association.

The most obvious Association to take the lead role in specifying training procedures and clinic settings is the American Association of Physicians for the Advancement of Psychedelic Medicine(AAPAPM). Perhaps an interim approval could be granted to them by the APA, to be formalized at APA conventions. It should be possible, with the combined efforts of the physicians who already care about MDMA, to make telephone appeals for membership, and to get about 100 psychiatrist members. If the fee for membership is placed at \$100 or less, such an organization could probably be established within a month and have some funds to support the actual writing of the proposals. With the participation of Lester Grinspoon, Morris Lipton and Bob Lynch, some tie in to the APA could possibly be established.

As far as specifics go, it seems that any physicians who want to work with MDMA should have two of their own experiences with it at a minimum, under the supervision of one of the eight or so physicians who have the most clinical experience with it. Such a training group would include Franco Di Leo, Jack Downing, George Greer, Stan Grof, Rick Ingrasci, Rick Strassman, Phil Wolfson, and Lance Wright, basically those physicians that have testified about their use of MDMA. Training sessions should be paid for by the physicians who want them.

The requirements for the clinic or setting should be relatively minimal but include a private room with music and a couch or bed, and easy access to a bathroom. Various medical provisions should be readily available in case of need. The sessions could occur within a physician's office, or in a specially provisioned home. A hospital setting would not be required.

A request for placing MDMA in Schedule 2 would require significant organizational activity within a relatively short period of time. However, if the time is ripe for such an effort, the network of interested physicians could fairly easily be established. Dr. Franco Di Leo and an assistant would probably need to work full time, more or less, for the next month or so on the development of the AAPAPM so that it could strongly endorse the training program and link up in some fashion with the APA.

The most necessary and most uncertain aspect of this plan involves the participation of the APA. They seem to be a conservative body with little enthusiasm for psychedelic psychotherapy. However, there may be just enough interest in MDMA to

carry such a proposal through. For essentially what is being proposed is to the benefit of the APA, empowering them to regulate and investigate what even Dr. Docherty, until recently Chief of Psychosocial Research and Treatment of the National Institute of Mental Health, called, during the DEA hearings, one of the most promising areas of psychiatric research.

There are two decisions to be made if this plan is to be implemented. Firstly, is it theoretically beneficial? I think it is. I have spoken about this idea with Howard McClain of the DEA and he understood the objectives but thought that I would get little support from the MDMA group since it would feel like changing horses in mid-stream.

The second decision concerns its practicality. Would the APA find it in their advantage to assume the responsibility of regulating this area of medicine in cooperation with the FDA, or would they continue to abdicate responsibility? Could the AAPAM get 100 or more members? While I am not certain, it seems that we have a window of opportunity here, one that is worth trying at least. And if this opportunity is passed up now, it may not be available again for many, many years, until the research with MDMA or another compound reaches the point of FDA approval and it will need to be scheduled in such a manner as to permit physicians to use it.

For all the above reasons, I propose that James Bakalar, George Greer, Lester Grinspoon and Tom Roberts explore the possibility of APA cooperation in allowing the American Association of Physicians for the Advancement of Psychedelic Medicine to be the official body sanctioned by the APA to train and accredit physicians in the use of MDMA, and to approve the setting in which such therapy will take place. If such approval is possible from the APA, then I propose that the BGGR group formally request the DEA to place MDMA in Schedule 2. After that, it would be in the hands of the Judge.

The time frame for such action is two months, short but sweet.

After thought: I'm not so sure APA cooperation is essential ~~AS~~ A prerequisite for requesting Schedule 2.