THE LEGAL, SAFE AND EFFECTIVE USE OF MDMA

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MDMA (3,4-methylenedioxymethamphetamine) is a psychoactive substance that has great potential as a tool for human development and consciousness research. It can enhance psychotherapy and personal growth, and occasionally relieve psychosomatic symptoms, when taken in a supportive setting with an open and willing attitude.

The purpose of this document is to promote the legal, safe and effective use of MDMA by experienced practitioners. Only this kind of use can support the integration of MDMA into our society in a responsible and useful way.

LEGAL ISSUES

MDMA is not an FDA-approved prescription drug, nor is it a DEA-specified controlled substance. In California, it is legal for a licensed physician to manufacture or compound any substance (except a Schedule I controlled substance) and dispense or administer it to any patient he or she has examined.[1] The patient must be informed both verbally and in writing about several issues related to the use of an experimental drug. The physician must also have peer review and some supporting scientific literature justifying the use of MDMA with the patient. The Board of Medical Quality Assurance can provide the necessary information. No special permission from any governmental agency is necessary, but the physician's license is in jeopardy if a complaint is made and the BMQA guidelines have not been followed.

It is also legal, in California, for a licensed pharmacist to dispense any drug he or she has manufactured to any patient who has a legal prescription.[2,3] It is not legal for anyone to give or sell any substance that alters physical or mental function to anyone outside the above guidelines, except for FDA-approved drugs. Other states may have different laws, or their laws may not address the above issues. However, the regulations regarding the manufacture and distribution of drugs are generally meant to protect the consumer from the manufacturer and are not intended to interfere in the legal practice of medicine.[4] Interested physicians should contact their state board of medical examiners for information on local regulations.

SAFETY ISSUES

In regard to physical safety, MDMA has not been formally tested in humans, though a pilot project is underway. In a study of the subjective reports of 29 people receiving 50-200 mg doses,

there were no serious side effects, and minor side effects lasted no more than a few days.[5] The one person who received 200 mg reported no significant additional benefit over lower doses and had many uncomfortable side effects.

In animals, MDMA was found to be most toxic in dogs, with a dose of 8 mg/kg being lethal to 5% of the dogs tested and 14 mg/kg lethal to 50% of them.[6] 8 mg/kg is equivalent to 3.6 mg/lb or 360 mg in a 100 lb human. (MDMA was also given to mice, rats, guinea pigs and monkeys in the same study.) It is difficult to extrapolate as to what the minimum lethal dose would be in humans, but one should certainly use the minimum dose necessary to allow one to experience the state of mind that MDMA offers. In any case, 150 mg should be the maximum dose used, and that only in healthy young people.

MDMA should not be taken by people with the following physical conditions: hypertension, heart disease, seizures, hyperthyroidism, diabetes mellitus, hypoglycemia, glaucoma, diminished liver function, actual or possible pregnancy, and breast feeding. It could cause an exacerbation of the condition, birth defects, or unknown effects in a breast-fed infant. It should not be taken with other sympathomimetic drugs (caffeine, diet pills, bronchodilators for asthma or hay fever, cold remedies, etc.) and especially not with MAO-inhibitors (Nardil, Parnate, Eutonyl, etc.) It's safety with other antidepressants is unknown and should be avoided.

People may experience a recurrence of any psychological problems they have ever had in the past. Those with a history of panic attacks have had recurrances both during and after sessions. For this reason, MDMA is not recommended for people who have ever been unable to function socially or vocationally due to psychological problems, unless 24-hour care by trained people is available. The person should also fully be willing to experience whatever may happen during or after the session. This is the most important factor in screening clients. People who are not ready for anything to happen should not take MDMA because that mental set predisposes one to having a difficult time without benefitting from the experience.

The most common side effects of MDMA are: jaw tension, fatigue for a day or two afterward, insomnia, muscle tension in general, nausea, and decreased appetite. Other side effects are: upset stomach, difficulty walking, chills, sweating, biting the inside of the cheek, jittery vision, headache, fainting, inability to reach orgasm, vomiting, blurred vision, and geometric visual hallucinations. In addition, any psychosomatic symptom can occur. Blood sugar level, pulse and blood pressure can rise or fall. There is also a decreased sensitivity to pain so that the clients may bite their cheek or swallow incorrectly and aspirate something if they are not attentive. Dehydration is possible if clients urinate a large volume, and liquids should be encouraged if this occurs. All side effects increase with the

dose taken.

The most common undesirable emotional symptom is anxiety. Depression, emotional lability, racing thoughts, confusion, and grandiose thoughts can also occur during or after the session. Though other symptoms are not common, it is safe to assume that any psychological disturbance could occur. The facilitator running the session should be very experienced at handling such reactions and helping clients use them for therapeutic growth. Any physical or psychological reaction can be utilized beneficially if all parties are committed to that endeavor.

EFFICACY ISSUES

Each person who administers or takes MDMA will discover what procedure works best for yielding the desired results. Within a safe setting of shared purpose by both facilitator and client, desirable changes almost always occur. The following are a few guidelines that have been developed over years of experience by a number of therapists using MDMA. Responsible and safe experimentation is encouraged to find more optimum ways of using MDMA with a wide variety of people with different kinds of problems and goals.

Thorough psychological preparation before the session cannot be overstressed. The first and most important question to be answered is, "Why do I want to take MDMA at this time in my life?" This is the most important preparatory step. This conscious purpose, along with the open willingness mentioned above, is the foundation of a client's mental set for the session.

In regard to the setting, clients must feel free to lose complete emotional and behavioral control, within ethical and safe limits. To this end, a confident and trusting relationship among all parties must be developed as much as possible. At least one in-depth interview should be held a few days or more before the session. It is helpful if the facilitators divulge their personal histories and experiences as they relate to their reason for doing experimental work with MDMA. A set of explicit agreements should be made to establish everyone's roles and responsibilities: 1) Everyone will remain on the premises until all agree that the session is over and that it is safe to leave (including safe to drive); 2) Clients will engage in no destructive activities toward self, other or property; 3) There will be no sexual contact between facilitators and clients or between clients who are not already sexually involved; and 4) The clients agree to follow any explicit instruction given by any facilitator. This last agreement is rarely invoked, but is of crucial importance. It tests the level of trust clients have for the facilitators, and it allows the clients to let go of the need to stay in control of the situation for survival reasons.

On the day of the session, the clients should have fasted

overnight, or at least 6 hours, to make sure the MDMA is fully absorbed and to prevent unnecessary nausea or vomiting. Clear juices can be drunk up until about 2 hours before taking MDMA.

The dose of MDMA depends on several factors, especially the clients' history of sensitivity to other psychoactive compounds. For individual sessions, 75 - 125 mg is a good range for the first session. Clients can choose a "low, medium or high" dose as desired, and be given 75, 100 or 125 mg, respectively. The effect of MDMA begins 15-60 minutes after ingestion and begins to wear off 1-2 hours later. An additional 50 mg can be given at that time to prolong the session. When this is done, the effect has mostly subsided after 2 more hours. A phase of relaxed tiredness follows, usually lasting about 3 hours. By 6-8 hours after the initial dose, physical and psychological functioning is almost always back to normal.

For repeat sessions, the response to the initial session can be used to gauge the effect of different doses. However, the dose should not be raised more than 50 mg above the highest dose previously taken. For sessions that will involve interpersonal contact, 25 mg less than the above doses should be used so that social judgment is not overly impaired.

Many people feel they learn more from lower doses than higher ones. This could be because their state is only slightly altered so that the insights gained are more realistic and applicable to their usual state of consciousness. Inderal (proprano-lol), 40 mg can be given every 4 hours (up to 120 mg total dose) to partially relieve some of the side effects such as muscle tension. Inderal prevents the heart from beating faster during physical exertion, so clients may feel short of breath if they exert themselves.

During the session, the best results are generally obtained if clients lie down and listen to instrumental music while wearing headphones and eyeshades. This prevents distractions and promotes an inner exploration. If the session involves a couple or group who have a mutually important ongoing relationship, the early part is best spent alone, with a coming together after an hour or so after the MDMA has taken effect. This way they can get in touch with themselves before going out to relate with others.

If clients get into a rambling monologue with facilitators, they can be asked to stop talking or to talk into a tape recorder. They should also not hold themselves or others to any commitments made while in an altered state because their expectations of their abilities and needs after the session may be distorted. No activity with people outside of the setting should be allowed, such as making phone calls or going to public places. Clients should be informed of these possibilities during a pre-session interview.

In special cases, facilitators may want to take MDMA with clients, but at least one facilitator should not take any in order to maintain appropriate social judgment. In general, the facilitators should be available for contact and interaction, but not initiate such contact except to check on the comfort or safety of clients. The less facilitators intervene, the more clients experience responsibility and credit for the results of their session.

Clients should have no scheduled work or social obligations for at least one day after the session. This is usually enough time to recover from any fatigue that may result, and allows time for psychological integration. Follow-up contact can occur as needed, but at least one facilitator should be available on a 24-hour basis for the following 3 days. Repeat sessions should be at least 4 weeks apart to allow for full psychological integration into clients' everyday lives. Some people have reported that more frequent use of MDMA leads to a diminishing of its beneficial effects. There seem to be no obvious physical dangers to more frequent use, but, being a relatively untested drug, it is difficult to know what the actual risks are.

This protocol is not to be seen as a do-it-yourself manual on giving MDMA sessions. Every facilitator should be trained by someone who has had experience giving many sessions successfully. All facilitators should also have had a few MDMA sessions at different doses themselves to understand the range of its effects and to work through any psychological issues that may arise. All such issues should be fully resolved before taking MDMA with clients, or else the psychological issues of the facilitator may be confused with those of the client.

REFERENCES

1. California Health and Safety Code, Division 21: Sherman Food, Drug and Cosmetic Law, Chapter 6, Article 6: Licenses, #26693d: Exceptions to drug manufacturing licensing regulations. Department of Health Services, Food and Drug Section, 714 P Street, Room 400, Sacramento, Ca. 95814.

2. Ibid.

3. Opinion of Evelle J. Younger, Attorney General of California, in reply to California State Board of Pharmacy question, May 2, 1978.

4. Ibid, p.22.

5. Greer, G.: MDMA: A new psychotropic compound and its effects in humans. Unpublished manuscript, 1983.

6. Hardman, H. Haavik, C. & Seevers, M.: Relationship of the structure of mescaline and seven analogs to toxicity and behavior in five species of laboratory animals. Toxicology and Applied Pharmacology 25(2):299-309, 1973.