10-5-85

ADDITIONAL TESTIMONY BY RICK J. STRASSMAN, M.D.

Rebuttal to testimony of Dr. Docherty

Dr. Docherty raises objections to Dr. Greer's scientific methodology in Dr. Greer's paper. Dr. Greer's paper, however, begins by stating that it does not represent a rigorously controlled, double-blind, placebo-controlled study. Rather, he clearly indicates the report's preliminary and anectodal nature of MDMA's therapeutic effects, and suggests that these indicate the need for further, more rigorous, research. Dr. Greer's paper addresses the question: "What are the mental and interpersonal effects of MDMA, and are they possibly therapeutic?" It is not, nor is it meant to be, a definitive test of MDMA's efficacy as either a sole or adjunctive treatment agent in the psychotherapy of psychiatric patients.

Dr. Greer states in the first paragraph of his paper that his study is not meant to be a definitive research paper on MDMA. Dr. Docherty is quite correct and helpful in describin the makings of a well-controlled study in this regard. But to state that because of the paper's lack of critical research methodology, it is possible to state that MDMA has no currently accepted medical use is not correct. Many interventions in medicine are administered in accordance with the standards of practice in the community in which the physician operates. Dr. Greer's practice of administering MDMA was sanctioned by the California medical board and was monitored by a peer review board. As a member of his peer review board in New Mexico, I have reviewed his inclusionary and exclusionary criteria for entrance into the protocol, informed consent forms, protocol for administration of MDMA (with a Dr. Greer or his wife, a master's level psychiatric nurse with extensive training in working with subjects using MDMA), the setting in which sessions occur, his results of follow-up, etc. In my opinion, he has included appropriate safeguards and has not experienced significant adverse reactions to this form of treatment, and that all individuals have experienced significant benefit. Therefore, within the standards of practice set forth by the physician's community, MDMA has a currently accepted medical

use in the hands of a qualified clinician (e.g. Dr. Greer).

The data supports continued investigatory action into its therapeutic effects. The fundamental basis of clinical medicine is established on studying interventions and drugs that "appear to work," and then refining and specifying their therapeutic applications over time, with rigorously performed studies as described by Dr. Docherty.

Rebuttal to testimony of Prof. Siegel

I have several comments on Prof. Siegel's testimony.

Prof. Siegel describes himself as a psychopharmacologist, but does not appear to have an appointment with the Department of Pharmacology at UCLA. His work, training, and background are in psychology and the behavioral sciences, and do not appear to allow him to make definitive statements regarding the pharmacology of MDMA. To wit, he includes THC and marijuana as hallucinogens, going against the standard terminology and classification as described, e.g. in Goodman and Gilman's standard reference text (1980). Also, to assert that street drug users are actually taking MDMA is fraught with difficulties, especially without toxicologic documentation. As shown in my review of the literature on adverse reactions to psychedelic drugs, not one of the 14 studies of adverse reactions to "street LSD" was able to clearly demonstrate that LSD was actually taken. In the case of a newly described drug as MDMA, verification of its identity is of the utmost importance.

My major concern with Prof. Siegel's statements regarding the use and abuse of MDMA is that he provides no data to support his assertions. For example, he provides no data to support his assertion that in man, the acute physical and psychological effects of MDMA are not substantially different than those seen with the classic psychedelic drugs. He presents no reports of the intoxicatory effects of street doses of MDMA, and then asserts that these (unstated effects) are not significantly different from low doses of mescaline.

He presents no data to support his assertion that the phenomenology and incidence of "intoxication effects" of higher doses of MDMA are similar to the effects of LSD. All clinical research to date, as described by Drs. Greer and Downing, and Ms. Kueny, refutes these assertions with presented clinical data. Hallucinations, ego-disruption, disorientation, or transient delusional states do not occur with MDMA,as detailed by Greer, Downing, and Kueny. Pre-clinical and pharmacologic studies, as described by Prof. Nichols, also bear out the assertion that MDMA differs significantly and substantively from the classic hallucinogens.

He does not define "long-term effects," which may imply either effects of chronic repetitive use, or the effects of one exposure that may not manifest for some time. In any event, he suggests "caution" with respect to those non-defined long-term effects based on his contention (unsupported by any data) that there is a relatively high incidence of acute toxic effects. These acute toxic effects are neither descibed nor quantified.

He presents no data with respect to the "untoward and unsafe physical and psychological reactions" (pg. 7) occurring with pure MDMA (as proven by toxicological analyses). He states "they" cannot be controlled in non-medical settings, but does not describe "them," and then extrapolates these baseless assertions to carefully monitored, supervised, clinical settings, where much clinical data has been presented demonstrating minimal and easily managed, transient side-effects.

The paucity of reports of MDMA in the DAWN system, especially with regard to Prof. Siegel's use of the rather large figures of MDMA dosage distribution, supports the assertion that adverse reactions to MDMA are extremely rare, even with street-quality "MDMA." In fact, Prof. Siegel proposes that MDMA's use in his sample of street users is not, by his definition, abuse, as shown by the absence of compulsive, escalating-dosage, personal-escape type of self-administration. As described by those with clinical experience in the supervised use of MDMA, increasing frequency of use decreases its beneficial effects,

and increases its negative effects--providing an almost endogenous anti-addicting factor.

Prof. Siegel asserts that MDMA is potentially as abusable as the classic psychedelic drugs. There is no evidence for this. The scarcity of DAWN reports, in the face of apparently increasing nonmedical use, refutes this assertion, as do qualitative phenomenological and basic biological studies, describing the differences between MDMA and the classic psychedelics. MDMA is not a classic hallucinogenic drug, and to assert so is not substantiated by current data, nor by the (lack of) data presented by Prof. Siegel.

His assertion that MDMA has no acceptable medical use is also not supported by available data. I address this issue at great length in my rebuttal to Dr. Docherty's testimony. Briefly, it is correct that no rigorously administered clinical trials of MDMA's therapeutic effect have occurred, but pilot data by Drs. Greer, Downing, Ingrasci, and Wolfson are unanimous in their demonstration of positive effects within the context of these physicians' communities of practice.

Rebuttal to testimony of Dr. Tocus

The pharmacological and biochemical differences between MDMA and MDA have been extensively reviewed by Prof. Nichols. As presented by Dr. Lipton in his testimony, chemical similarity does not mean biological and/or clinical similarity. To assert that because MDMA and MDA differ by only a single chemical grouping, they are equally "abusable," is too simplistic a proposition, and ignores existing data. Even the relevance of the similar behavioral effects in animals, as described by Dr. Tocus, is unclear, especially as Dr. Tocus does not include in his comments the findings of distinct differences between MDMA and MDA. For example, because LSD and caffeine can increase an animal's heart rate, this does not mean the two drugs have identical behavioral effects in man. Similarly, in Dr. Tocus' remarks concerning Hardman's work (pg. 7), he again does not include findings of differences between MDMA and the classic hallucinogens. For example, MDMA produced "hallucinogenic" behavior in the monkey, but mescaline did not, contradicting known

clinical effects. This finding bespeaks the difficulty in extrapolating animal behavior data to human subjective effects, a point I emphasize in my original testimony.

I am unaware of "tests in humans showing MDMA to be similar to MDA." No studies I have seen compare the effects of these two drugs in the same individual. The criteria he uses to declare them similar: "...a change in consciousness without hallucinations, a decrease in tension, a heightening of mood, and an increase in acoustic, visual and tactile perception....Both MDMA and MDA cause increased heart rate and mydriasis" (pg. 7) are too general to draw meaningful conclusions from regarding their similarities viz. abuse potential and medical use. This level of generalization would cause caffeine and over-the-counter cold remedies to be included in this vaguely alluded-to "class" of drugs.

The question of nonmedical abuse has been addressed in my response to Prof. Siegel. To reiterate, however, eight mentions in the DAWN system in 13 years does not indicate a high level of abuse. The seizures of illicitly manufactured MDMA also does not directly concern the issues of high levels of abuse and lack of acceptable medical use, and are not relevant to the discussion of these issues.

Dr. Tocus provides no relevant data supporting his assertion that "MDMA can produce harm to the public health" (pg. 8). His statement that MDMA is more toxic than mescaline in animals does not address the issue of its non-toxic, therapeutic use in humans. The relevance of such a statement to clinical practice is comparable to stating that digoxin is more toxic than penicillin in animals, and therefore, digoxin should not be available for treatment and study in people. Toxic effects of MDMA, when used in a clinically supervised setting, are noticeable by their absence. Rather, its safe use has been repeatedly documented within the clinical setting by Drs. Greer, Downing, Ingrasci and Wolfson's testimonies. No data is provided by Dr. Tocus to document toxic effects in man.

His assertion that MDMA has a high potential for abuse is not supported by findings of clinical researchers, the DAWN system's remarkably low ratio of apparent dosage distribution to adverse incidence reports, nor the existence of seizures of MDMA by the DEA.

His concerns about medically acceptable use do not address the issue that this is an area of concern for the physician's community's standard of practice to determine, which has already had a precedent established, e.g. in the case of Dr. Greer.

In conclusion, it appears that MDMA is a promising agent for future psychiatric research, has not been shown to have a high abuse potential, and within certain physicians' communities, has been demonstrated as safe and helpful in currently accepted medical practice. Further research, which would effectively be precluded by scheduling it in the I or II category, is necessary to increase our knowledge and application of its actual therapeutic effects.

I declare, under penalty of perjury, under the laws of the United States of America, that the foregoing is true and correct.

Executed on the 16th day of May, 1985.

Rick J. Strassman, M.D.