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## THERAPEUTIC MDMA (ECSTASY): THE FEDERAL GOVERNMENT: A CLOUDY PAST & A HOPEFUL FUTURE

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**THERAPEUTIC MDMA (ECSTASY) & THE FEDERAL GOVERNMENT: A CLOUD**

Donald David Lewis

*There is something very special about illicit drugs. If they don't always make the drug user behave irrationally, they certainly cause many non-users to behave that way.*<sup>1</sup>

**INTRODUCTION**

The debate over the legalization of drugs in the United States has been a core issue for well over a century.<sup>2</sup> Within this debate, the most intriguing issues arise when the medical community clashes with the government and legal system regarding whether or not a drug should be legalized for therapeutic purposes. The debate with the loudest voice to date is over medicinal marijuana, however there is another drug, ecstasy<sup>3</sup>, whose proponents are pressing for its legalization. Advocates of MDMA are mostly physicians who champion its therapeutic value as an adjunct to psychotherapy.<sup>4</sup> Their opponents are the federal government, led by the Drug Enforcement Agency, who permanently banned ecstasy in 1988 by placing it in the most restrictive schedule, Schedule I, of the Controlled Substances Act<sup>5</sup>, determining that MDMA lacked a currently accepted medical use and safety, and possessed a high potential for abuse. The Schedule I categorization is paramount because it results in a sit-

<sup>1</sup>Lester Grinspoon & James B. Bakalar, *Marihuana, the Forbidden Medicine*, at xi (1997).

<sup>2</sup>See Nicole Dogwill, *The Burning Question: How Will The United States Deal With the Medical-Marijuana Debate?*, 1998 Det. C.L. Mich. St. U. L. Rev. 247 (1998).

<sup>3</sup>"Ecstasy" is the most commonly used nickname for MDMA, which is the acronym for the chemical structure that bears the structural configuration of 3,4-methylenedioxymethamphetamine. Ecstasy and MDMA are used interchangeably in medical and legal literature and will be used interchangeably in this paper.

<sup>4</sup>See Lester Grinspoon and James B. Bakalar, *Can Drugs Be Used to Enhance the Psychotherapeutic Process?*, *American Journal of Psychotherapy*, (1986) (hereinafter Grinspoon and Bakalar).

<sup>5</sup>21 U.S.C. §§ 801-848 (1994).

uation of extremely limited ability to use MDMA in research and an inability to prescribe ecstasy for medical use.<sup>6</sup> The rigid and narrow research exception<sup>7</sup> creates an immense obstacle for physicians trying to conduct research in order to validate their claims regarding the therapeutic value of MDMA. The problem is not inherent in the regulations themselves but in the fact that the FDA can act arbitrarily regarding the approval of research with Schedule I drugs. FDA risk/benefit calculations used to evaluate the safety of studies in human subjects can be heavily skewed toward exaggerating risk and ignoring benefit, with the decision to place a research proposal on Clinical Hold virtually impossible to appeal outside of the FDA. In the past (mid-1960s to 1989), FDA blocked all psychedelic research, with some outrageous examples from the 1980's in which MDMA research was placed on Clinical Hold. Since 1989, when the FDA reorganized and formed the Pilot Drug Evaluation Staff, with the notable exception of the brief period from 1997 to mid-1999 when Dr. Cynthia McCormick, the Food and Drug Administration's ("FDA") Director of Anesthetics, Critical Care and Addiction Products, blocked Dr. Charles Grob's proposal for MDMA research, psychedelic research and medical marijuana research have been approached in a fair and balanced manner. This shift was due to internal FDA policies, with the same set of regulations as in the previous decades. Advocates of ecstasy would claim the government acted and continues to act "irrationally" with regards to the Schedule I placement of MDMA. I would agree. Recently however, the

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<sup>6</sup>21 U.S.C. § 812(b)(1) (1994).

<sup>7</sup>21 U.S.C. § 823 (1994). Schedule II-V substances are only available through a physician's prescription whereas Schedule I substances are prohibited from distribution with a narrow exception made for research purposes. See *id.*

government appears to be lessening its previously irrational stance concerning ecstasy.

This Paper will present a comprehensive review of the evolution of MDMA including the historical, legal and medical issues. Part I will present the history of ecstasy prior to its criminalization in 1986. Part II will analyze the legal issues and proceedings that resulted in MDMA's Schedule I placement. Part III will discuss recent clinical studies on ecstasy. Part IV will present several anecdotal reports from patients who have successfully used MDMA therapeutically. Part V will discuss the future prospects for MDMA research and will conclude that the societal and political concerns that have so hindered research into the therapeutic benefits of MDMA are beginning to crumble and that although the government has acted "irrationally" in the past with regards to MDMA's potential as a therapeutic adjunct there is hope for the future.

## **I. HISTORY OF MDMA PRIOR TO CRIMINALIZATION**

MDMA was synthesized in 1912 and patented in 1914 by Merck, a pharmaceutical company.<sup>8</sup> A common present day misconception is that MDMA was created as an "appetite suppressant", however the reality is ecstasy was a precursor agent possessing properties deemed to contain primary constituents for

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<sup>8</sup>See Grinspoon and Bakalar, *supra* note 4 at 399.

therapeutically active compounds.<sup>9</sup> Merck's decision not to market ecstasy resulted in the drug being largely ignored until 1953 when MDMA was used in a series of animal studies, supported by the US Army, the results of which were not declassified and published until 1973.<sup>10</sup> The studies were designed to determine the dose at which half the animals died, called LD 50 studies for the lethal dose at which 50% of the test animals die. LD 50 Studies are used to measure toxicity and hence the toxicity of MDMA was a forgone conclusion, the only unknown was the dose.

The primary signs of human consumption of ecstasy for therapeutic and non-therapeutic use was in the early 1970's.<sup>11</sup> From the 1970's through the 1980's MDMA was used as an adjunct to psychotherapy by psychiatrists and other therapists in the United States and Europe. While there were strong suggestions that ecstasy could be helpful in the therapeutic process<sup>12</sup>, the reports of therapeutic results were anecdotal, unpublished and unverified.<sup>13</sup> A primary and prophetic reason for the lack of published results was the fear of ecstasy advocates that drawing attention to MDMA would result in its criminalization despite the lack of evidence of harm.

The major obstacles for advocates of MDMA as a therapeutic device began

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<sup>9</sup>Hardman H., Haavik C., and 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, 299-309 (1973).

<sup>10</sup>See id.

<sup>11</sup>Grinspoon and Bakalar, *supra* note 4, at 399.

<sup>12</sup>See Richard S. Cohen, *The Love Drug: Marching to the Beat of Ecstasy* (1988) at 8 (citing to Gallagher, W., "MDMA: Is there ever justifiable reason for getting high?", *Discover* (1986) 7:34. (Psychiatrists reported that a single MDMA-assisted therapy session could be as helpful as six months or more of conventional psychotherapy.)

<sup>13</sup>See id.

to form as careless recreational use of the drug began to increase. “The very properties that suggested MDMA might be therapeutically useful - its capacity to diminish anxiety and depression and promote easy emotional communication - may also create a danger of unconstructive use.”<sup>14</sup> Exacerbating this problem were the early media accounts in the mid-1980’s which sensationalized and “advertised” the euphoric qualities of MDMA.<sup>15</sup> The increased media attention and recreational use of ecstasy was highly unfortunate for those sincerely searching for the therapeutic uses of MDMA. Recognizing the dichotomous use of MDMA, as a therapeutic adjunct in the medical field and as a recreational drug used in some, but certainly not all, cases irresponsibly by thrillseekers is incredibly important in understanding the legal history surrounding ecstasy. Beginning with the Nixon Administration and the federal governments antagonism regarding legitimate medical uses for marijuana, it became clear that the government strongly wished to prohibit and discourage recreational drug use.<sup>16</sup> This “war on drugs” climate continued through the Reagan Administration, and with the political climate as such in the 1980’s it was inevitable that law enforcement and government officials would intervene to eliminate the expanding recreational use of ecstasy which would also result in the criminalization of MDMA’s use therapeutically.

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<sup>14</sup>Grinspoon and Bakalar, *supra* note 4, at 399.

<sup>15</sup>Marsha Rosenbaum and Rick Doblin, The Drug Legalization Debate: “Why MDMA Should Not have Been Made Illegal.” (1991) at 12 (“The popular media loved MDMA. They loved the name “Ecstasy”... And they wrote glowing reports about it in nearly every popular publication, including Newsweek, Time, and the Washington Post. This was not the first time the media helped to advertise a “new” drug.”).

<sup>16</sup>See Laretta Higgins Wolfson, *A Quality of Mercy: The Struggle of the Aids-Afflicted to Use Marijuana as Medicine*, 22 Thomas Jefferson L. Rev. 1, 10 (1999).

## II. THE CRIMINALIZATION OF MDMA: LEGAL ISSUES AND PROCEEDINGS

Wary of the expanding recreational use of ecstasy<sup>17</sup>, in January of 1984 the Drug Enforcement Agency (“DEA”) prepared a document entitled “Schedule I<sup>18</sup> Control Recommendations under the Controlled Substances Act (“CSA”)<sup>19</sup> for (MDMA).”<sup>20</sup> The CSA was enacted by Congress in 1970 to combat the problem of illicit drug use in the United States. The Act placed all controlled substances into five categories, called schedules. Table 1 contains the entire list of CSA classifications and category criteria for the different schedules (Schedule I - Schedule V).

Table 1. Controlled Substances Act Classifications

Schedule I	a. The drug or other substance has a high potential for abuse.
	b. The drug or other substance has no currently accepted medical use in treatment in the United States.
	c. There is a lack of accepted medical use for safety of the drug or other substance under medical supervision.
Schedule II	a. The drug or other substance has a high potential for abuse.
	b. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
	c. Abuse of the drug or other substances may lead to severe physical or psychological dependence.

<sup>17</sup>Conversation with Rick Doblin, MAPS Founder (May 12, 2000). (“In January 1984 the DEA had not yet heard anything at all about possible neurotoxicity. That didn’t happen until a spring, 1985 Phil Donahue television show on MDMA during which Dr. Schuster mentioned the preliminary findings of Dr. Ricuarte. Mr. Gene Haslip of the DEA was also a guest on the same show and realized that Dr. Ricuarte’s research could help justify emergency scheduling.”)

<sup>18</sup>21 U.S.C. § 812(b)(1)(1994).

<sup>19</sup>21 U.S.C. § 801-848 (1994).

<sup>20</sup>Grinspoon, M.D. v. Drug Enforcement Administration, 828 F.2d 881, 883 (1<sup>st</sup> Cir. 1987).

Schedule III	a. The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
	b. The drug or other substance has a currently accepted medical use in treatment in the United States.
	c. Abuse of the drug or other substance may lead to moderate physical dependence or high psychological dependence.
Schedule IV	a. The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
	b. The drug or other substance has a currently accepted medical use in treatment in the United States.
	c. Abuse of the drug or other substance may lead to limited physical or psychological relative to the drugs or other substances in schedule III.
Schedule V	a. The drug or other substance has low potential for abuse relative to the drugs or other substances in schedule IV.
	b. The drug or other substance has a currently accepted medical use in treatment in the United States.
	c. Abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule IV.

In March of 1984, the DEA recommendation was submitted to the Assistant Secretary for Health of the Department of Health and Human Services (“HHS”) for an HHS recommendation as to whether or not MDMA should be controlled.<sup>21</sup> The HHS evaluation was conducted by Dr. Charles Tocus, Chief of the Drug Abuse Staff of the FDA and his research found of an absence of any reference to MDMA in FDA files. Upon reviewing the information contained in the DEA control recommendation and applying the requisite eight-factor analysis<sup>22</sup> (Table 2) for drug scheduling Dr. Tocus agreed that MDMA be placed in Schedule I.<sup>23</sup>

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<sup>21</sup>See id.

<sup>22</sup>21 U.S.C. § 811(c)(1994).

<sup>23</sup>Grinspoon, 828 F.2d at 883.



Table 2: DEA’s Eight-Factor Drug Scheduling Analysis

(1)	[The drug’s] actual or relative potential for abuse.
(2)	Scientific evidence of its pharmacological effect, if known
(3)	The state of current scientific knowledge regarding the drug or other substance.
(4)	Its history and current pattern of abuse.
(5)	The scope, duration, and significance of abuse.
(6)	What, if any, risk there is to public health.
(7)	Its psychic or physiological dependence liability.
(8)	Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

The Schedule I recommendation of the DEA required all three Schedule I criteria be met. Most notably a Schedule I placement would mean that ecstasy did not have any accepted medical use in the United States. Unbeknownst to the DEA at this early stage in the debate was widespread support of MDMA in the psychiatric community and hence the DEA was surprised by the strong opposition to the Schedule I recommendation.<sup>24</sup> The stage was set for a battle between the federal government spearheaded by the DEA and those in the psychiatric community who advocated MDMA as a therapeutic drug.

As a result of a request for a hearing filed in August, 1984 by advocates for the medical use of MDMA, in November 1984, Administrative Law Judge (“ALJ”), Francis L. Young, was asked by the Administrator of the DEA, John Lawn, to conduct hearings, gather factual evidence, and expert opinion and

<sup>24</sup>Jerome Beck and Marsha Rosenbaum, Pursuit of Ecstasy: The MDMA Experience (1994) at 20 (citing to Adler, J., “Getting High on Ecstasy”, *Newsweek* at 96, (1985), April 16. (“The government’s surprise at the therapists’ reaction was evidenced by a DEA pharmacist’s statement that they ‘had no idea psychiatrists were using it.’”).

report to the Administrator at the conclusion of the proceedings as to what he felt would be the most appropriate scheduling of MDMA.<sup>25</sup> The hearings were scheduled for the summer and fall of 1985.<sup>26</sup> From the perspective of the proponents of MDMA, the delegation of the MDMA scheduling matter to an ALJ had to be viewed as a positive as they would have a chance to present detailed evidence of its therapeutic benefits and medical usefulness and the scheduling of MDMA was postponed until the conclusion of the hearings.

Despite the positive prospects with regards to an administrative law hearing, those in the psychiatric community advocating MDMA suffered a setback as the DEA's claimed fears concerning the possible neurotoxic effects of ecstasy use resulted in an emergency scheduling of MDMA, on July 1, 1985, as the hearings were proceeding.<sup>27</sup> The DEA's authority for emergency scheduling was grounded in the Comprehensive Control Act of 1984, an amendment to the CSA, which provided the attorney general with authority, delegated to the DEA, to place any substance posing "an imminent hazard to public safety" into Schedule I while the final scheduling process was ongoing.<sup>28</sup> (Interestingly, the emergency scheduling was subsequently challenged and rejected since the Attorney General had not formally delegated authority to the Director of the DEA.)<sup>29</sup> The DEA's claimed justification for an emergency scheduling rested on a then-unpublished study associating high dosage administration of MDA (3,4-

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<sup>25</sup>See Cohen, *supra* note 12, at 4.

<sup>26</sup>See Beck and Rosenbaum, *supra* note 24, at 21.

<sup>27</sup>Grinspoon, 828 F.2d at 884 n.4.

<sup>28</sup>21 U.S.C. 811(h)(1) (1994).

<sup>29</sup>Kane, J. 1986 Memorandum and Opinion. Case No. 86-CR-153 In the United States District Court For The District of Colorado. Pees and McNeill, Defendants, October 1.

methylenedioxyamphetamine), a chemical compound highly similar to MDMA, in rats with damage to nerve terminals which use serotonin as a neurotransmitter.<sup>30</sup> While the DEA presented the MDA studies as their rationale behind the emergency scheduling, the ALJ presented various findings of fact drawing distinctions between the two chemical compounds<sup>31</sup>. It should also be noted that assuming the two compounds were indeed identical, which again they were not, relying on such animal studies is questionable at best, as evidenced by an article from a paper co-authored by a DEA witness questioning the efficacy of extrapolating to humans the results of animal testing.<sup>32</sup> Hence the more probable reason was the governments wish to immediately halt the rapidly expanding recreational use of the drug.<sup>33</sup> Whatever the true rationale behind the emergency scheduling, the effect was negative for ecstasy's psychiatric advocates and severely hindered the chance of any further research into the drug's therapeutic potential.<sup>34</sup>

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<sup>30</sup>See Beck and Rosenbaum, *supra* note 24, at 21 (citing to Ricuarte, G. et.al, "Hallucinogenic Amphetamine Selectivity Destroys Brain Serotonin Nerve Terminals," *Science* 229:986-988 (1985).

<sup>31</sup>In the Matter of MDMA Scheduling, Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law, and Decisions of Administrative Law Judge, No. 84-48 (1986) (visited Mar. 31, 2000) at 17-24, findings of fact 7-84 <<http://www.mninter.net/~publish/mdma.htm>>

<sup>32</sup>*Id.* at 21, finding of fact 48 ("The significance of animal discrimination test findings as to abuse potential in humans is far from certain. An Agency witness in this proceeding co-authored an article, published in 1984, which states that unless a particular compound has been tested in humans, one cannot be certain that structure-activity relationships will apply in the clinical situation, i.e., when used in humans. He cautioned that the most common error found in animal models is the identification of 'falsepositives'. That is, the animal models may indicate a compound to be active, whereas actual testing in humans reveals inactivity. The article also says that it is clear that no present animal models correlate with the qualitative differences between hallucinogens found in humans.")

<sup>33</sup>See *id.* at 23, finding of fact 61 ("In the Los Angeles area there was a noticeable increase in the street use of MDMA shortly before its becoming illegal on July 1, 1985. This coincided with the attention MDMA received in the news media at that time. There was also a significant increase in the manufacture of MDMA at that time.... It has been estimated that in all of 1976, 10,000 doses of MDMA were distributed in the United States for street use, as opposed to 30,000 doses per month in 1985.")

<sup>34</sup>*supra* note 7.

As the hearings continued the integral question still remained as to whether or not the temporary Schedule I placement of MDMA would become permanent. Of paramount importance during the hearings was the question of whether or not ecstasy had a “currently accepted medical use” in the United States.<sup>35</sup> For if MDMA advocates could display that ecstasy did indeed have a “currently accepted medical use”, they could avoid a permanent Schedule I placement of the drug which would be crippling to future research. Again for a Schedule I placement *all* of the following three criteria must be met: 1 – high potential for abuse; 2 – *no currently accepted medical use* in treatment in the United States; and 3 – lack of accepted medical use for safety under medical supervision.

Before the question of whether or not MDMA had a “currently accepted medical use” could be definitively answered, the issue of what constituted a “currently accepted medical use” had to be decided. The ALJ held this question to be a legal issue of statutory interpretation hence no findings of fact were necessary.<sup>36</sup> The DEA asserted that “accepted medical use” was simply determined by whether or not a drug had received FDA approval under Section 505 of the Federal Food, Drug and Cosmetic Act of 1938 (“FDCA”).<sup>37</sup> Declaring that such an interpretation would “greatly simplify the scheduling task of the DEA staff” Young rejected this assertion. The ALJ cited a litany of FDA statements regarding the question of the FDA’s authority in situations where physicians had used drugs for purposes the FDA has not approved.<sup>38</sup> The most telling of

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<sup>35</sup>21 U.S.C. §(b) (1994).

<sup>36</sup>MDMA Scheduling, *supra* note 30, at 4.

<sup>37</sup>21 U.S.C. § 355 (1994).

<sup>38</sup>MDMA Scheduling, *supra* note 30, at 5-7.

which was the following FDA statement in June 1983: “Although no final rule has been issued on this subject, the Agency has continued to apply the principle set forth in the preamble to the 1972 proposal. *In FDA’s Drug Bulletin of April 1982, the Agency sought to clarify and reiterate the position that the Act does not regulate the ‘practice of medicine’*.”<sup>39</sup>

Despite this long-standing position of the FDA, the position that they lacked the authority to regulate the “practice of medicine”, they introduced at the hearings a brief pointing to the following statement of the Commissioner of the FDA in 1982:

Thus, the lack of an approved New Drug Application for a drug substance leads FDA to find that a substance lacks “accepted medical use in treatment” for two reasons. First, if use of the drug is unlawful whenever interstate commerce is involved, medical use of the drug cannot be classified as accepted. Second, in the absence of the data necessary for approval of the NDA, the agency has no basis for concluding that medical use of the drug in treatment can be considered acceptable by medical standards.<sup>40</sup>

In response the Commissioner’s statement the ALJ stated:

The last quotation flies directly in the face of statutory interpretation by FDA, issued over a period of eleven years. *It represents a complete reversal of position with no stated basis whatsoever.* One can only conclude that, in the context of the battle over marijuana, FDA temporarily lost sight of its long-acknowledged lack of statutory authority to regulate the practice of medicine.<sup>41</sup>

The foregoing actions of the FDA and this statement by ALJ Young, lend much credence to Dr. Grinspoon’s contention that illicit drugs (ecstasy, marijuana) cause non-drug users (DEA, FDA) to behave irrationally.

Ultimately, despite the FDA’s attempted manipulations, the ALJ concluded

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<sup>39</sup>Id. at 6. (emphasis added).

<sup>40</sup>Id. at 7.

<sup>41</sup>Id. at 7 (emphasis added).

that “accepted medical use in the United States” is not determined by approvals of the FDA, but rather “by what is actually going on in the health care community.”<sup>42</sup>

With the issue concerning the proper statutory interpretation of “accepted medical use” apparently settled, the proponents of ecstasy as a therapeutic drug had the opportunity to present support for their position. Various physicians submitted affidavits at the hearings citing some of the following as therapeutic benefits of MDMA making it an invaluable therapeutic adjunct for a wide range of problems: 1 - enhances communication; 2 - increases empathy; 3 - fear reduction.<sup>43</sup>

The leading advocate of MDMA as an adjunct to psychotherapy was Dr. George Greer, a Board Certified psychiatrist in New Mexico. Dr. Greer had been working with MDMA for four and a half years and administered ecstasy to seventy-six patients.<sup>44</sup> His work with MDMA was reviewed by a committee of his peers.<sup>45</sup> Dr. Rick J. Strassman, an Assistant Professor of Psychiatry at the University of New Mexico School of medicine, was a member of Greer’s peer review committee and stated the following with regards to Dr. Greer’s work using ecstasy as a therapeutic adjunct:

I have reviewed his inclusionary and exclusionary criteria for entrance into the protocol, informed consent forms, protocol for the administration of 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 expe-

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<sup>42</sup>Id. at 11.

<sup>43</sup>Beck and Rosenbaum, *supra* note 24, at 22 (citation omitted).

<sup>44</sup>MDMA Scheduling, *supra* note 30, at 12.

<sup>45</sup>Id.

rienced significant benefit. *Therefore, within the standards of practice set forth by the physicians' community, MDMA has a currently accepted medical use in the hands of a qualified physician (e.g., Dr. Greer).*<sup>46</sup>

Another member of Dr. Greer's peer review group, Dr. Rodney A. Houghton, Chief Resident in the Department of Psychiatry at the University of New Mexico remarked:

In my expert opinion, as one who is familiar with the accepted standards of psychiatric practice in New Mexico, indeed, having established many of those standards for five rural communities and community programs throughout the state, *I believe Dr. Greer's use of MDMA is an accepted and safe medical practice.* I base this opinion not only on my own experience and what I believe to be acceptable, but also on my conversations with teachers and colleagues about his work.<sup>47</sup>

Dr. Will MacHendrie, a Board Certified psychiatrist in New Mexico and a member of the peer review group stated:

For the past two and one-half years, I have been on the Peer Review Committee for Dr. George Greer's use of MDMA. In that capacity, I have extensively reviewed his methodology and his results regarding therapeutic use of MDMA. *I feel that there is definitely a medically accepted use of this drug in treatment, and that there is acceptable safety for use under medical supervision.*<sup>48</sup>

Despite these overwhelmingly positive testimonials, a problem facing Dr. Greer and the advocates of MDMA as a therapeutic adjunct was the absence of "scientifically proven" studies and the difficulty in conducting such studies with regards to psychedelic drugs such as MDMA.<sup>49</sup> Aware of this obstacle, Dr. Greer expressed his opinion on the matter in the following way:

I would like to draw a distinction here between a scientifically proven effective

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<sup>46</sup>Id. at 12, 13. (emphasis added)

<sup>47</sup>Id. at 13. (emphasis added)

<sup>48</sup>Id. (emphasis added)

<sup>49</sup>Grinspoon and Bakalar, *supra* note 4, at 396 ("The most serious deficiencies in psychedelic drug studies were absence of controls and inadequate follow-up; in addition, psychedelic drug effects are so striking that it is difficult to design a double-blind study. No form of psychotherapy for neurotics has ever been able to justify itself under stringent controls, and psychedelic drug therapy is no exception.")

treatment and a medically acceptable treatment. Many treatments, especially in psychiatry, are accepted by many practitioners, but have not been proven to be effective to the satisfaction of all scientists in the field. The efficacy of psychotherapy itself, with its myriad techniques, has yet to be scientifically proven to be effective to the satisfaction of many psychiatrists and psychologists. Yet, it is considered to be medically accepted treatment. *It is my clinical judgment, and that of my peer review committee, that based on my clinical experience, the use of MDMA is a medically accepted part of the treatment approach I use.*<sup>50</sup>

Another of the primary issues for the advocates of MDMA was distinguishing the drug from MDA, the previously mentioned similar chemical compound, due to the fact that LD50 MDA neurotoxicity studies in rats were integral in the emergency scheduling of ecstasy. In an effort to achieve this goal Dr. Greer presented as evidence a personal letter he had received from Dr. Alexander Shulgin, a renowned researcher and the author of the first published study on the effects of MDMA<sup>51</sup>, providing in-depth detail regarding the differences that exist when comparing MDMA to MDA.<sup>52</sup> A review of the ALJ's findings of fact<sup>53</sup> concerning the relationship of MDMA and MDA, one of which states, "the uncontradicted evidence of the record is that there are qualitative differences in humans between MDA and MDMA"<sup>54</sup>, displays once again that the government

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<sup>50</sup>Cohen, supra note 12, at 28. (emphasis added)

<sup>51</sup>See Julie Holland, M.D., *Transcript of Lindesmith MDMA Seminar, 3/30/00 NYC*, at 1 (visited May 18, 2000) <<http://www.maps.org/research/mdma/holland0300.html>>

<sup>52</sup>Id. (citation omitted).

<sup>53</sup>MDMA Scheduling, supra note 30, at 22, finding of fact 56 ("There are observed differences in humans between the effects of MDA and MDMA. Studies other than the one reported by Shulgin in 1980 have shown MDA to have duration of action in humans of 12 to 15 hours, as compared to four to six hours for MDMA. MDA has been found to produce a mild cognitive impairment in humans at 75 mg. dosage level, while MDMA did not impair cognition even at 200mg. As MDA dosages increase from 75 to 200mg., the effects in humans become increasingly similar to the effects of LSD, including the presence of visions. As dosages of MDMA increase from 75 to 200mg., the intensity of the sense of well-being and inner flow of associations which characterize the experience increase only moderately while the ego functions remain intact, cognition is unimpaired and visions are notably absent. Large doses of MDA (200mg) produce significantly greater disorientation and an up-welling of visual images that are not characteristic of MDMA in similar dosage range.")

<sup>54</sup>Id. at 22, finding of fact 58.



acted irrationally by relying on non-human MDA studies as a claimed basis for the emergency scheduling of ecstasy.

Ultimately the prevalent feeling among MDMA proponents was that a Schedule III placement would solve the problem of uncontrolled recreational use ecstasy, while still allowing for medical treatment and scientific research in controlled environments where the probability of abuse would be minimal.<sup>55</sup>

The major obstacle facing MDMA advocates, that of scientifically unsound studies lacking in credibility, was embraced by those opposing the use of MDMA as a therapeutic adjunct. Various research experts testifying for the DEA criticized the anecdotal nature of the MDMA advocates' studies. These views were most encapsulated by Dr. Joel Kleinmann, a psychiatrist, testified that, "although these reports make interesting reading their lack of scientific design, methodology and controls makes them scientifically unsound."<sup>56</sup>

In addition to presenting the studies showing MDA's toxicity in non-human subjects<sup>57</sup> and questioning the scientific validity of MDMA advocates' studies, the government criticized MDMA proponents for failing to follow the proper

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<sup>55</sup>Cohen, *supra* note 12, at 30.

<sup>56</sup>Beck and Rosenbaum, *supra* note 24, at 23 (citing to Kleinman, J., Rebuttal Testimony on Behalf of Drug Enforcement Administration, United States Department of Justice, Drug Enforcement Administration Hearings, Docket No. 84-88 (1985).

<sup>57</sup>Cohen, *supra* note 12, at 32 (citation omitted) ("Dr. Lewis Seiden also testified on behalf of the government Dr. Seiden's affidavit included comparisons of MDMA to several other compounds, particularly MDA. Based on the effects that MDA had on rats following excessive administered doses, he hypothesized that MDMA would have similar, or perhaps, the same neurotoxic effects on other animal species and would pose potential hazards to humans as well.")

procedures<sup>58</sup> in experimenting and researching with a new drug.<sup>59</sup> Referring back to the history of MDMA, facilitates recognizing why this argument is unfair with regards to ecstasy. The issue is one of economic incentive as alluded to by the ALJ.<sup>60</sup> Since MDMA was already patented in 1914, putting it effectively into the public domain, any company could produce and market ecstasy under approved conditions. In order to obtain FDA approval for marketing, a pharmaceutical company would have to invest substantial capital in research. The incentives of such a course of action are minimal, as another company could simply market MDMA after FDA approval with minimal investigation and expenditure. The DEA's failure to at least recognize this "special" circumstance and subsequent claim that there is no "accepted medical use" due to a lack of FDA approval is once again a demonstration of its irrational behavior with respect to MDMA.

On May 22, 1986 the ALJ, having heard 33 witnesses and received 95 exhibits into evidence, recommended a Schedule III placement of the drug.<sup>61</sup> Again, for a Schedule I placement all three of the criteria have to be met. Francis Young's opinion concluded that not only had all three not been met, but that none of the three had been met. That MDMA did have a "currently accepted medical use

<sup>58</sup>21 C.F.R. § 312.34(a) (1999). (Drugs studied in clinical trials are called investigational new drugs ("IND"). Sponsors wishing to conduct a clinical trial to test a new drug must submit IND applications to the FDA.)

<sup>59</sup>Cohen, *supra* note 12, at 32 ("Dr. Seiden also explained that when studies are performed on drugs, they should be performed in a systematic and well-controlled manner, as is usually done under an Investigational Drug Permit.")

<sup>60</sup>MDMA Scheduling, *supra* note 30, at 7 ("The fact no one has sought approval does not necessarily mean that no one is using the drug and that such use is not accepted by the profession. There are very real economic factors effecting whether an New Drug Application is sought for a drug.")

<sup>61</sup>*Id.* at 28.

for treatment in the United State's, and "accepted use for safety under medical supervision", and that a "high potential for abuse" had not been established by the record.<sup>62</sup> MDMA advocates had won the battle. With a Schedule III placement they would easily be able to continue research and investigation concerning the therapeutic value of MDMA. Unfortunately for MDMA advocates who had won the battle, the "war on drugs" and more importantly the war concerning ecstasy was far from over.

Following a thorough review of the record the DEA Administrator refused to accept the recommendation of the ALJ and on November 13, 1986 issued a final ruling placing MDMA on Schedule I.<sup>63</sup> In reaching his decision, the Administrator found that MDMA met all three criteria of Schedule I. The Administrator disagreed with the ALJ with regards to the authority of the FDA to regulate the "practice of medicine". Specifically, the Administrator held that the phrase "currently accepted medical use" in treatment in the United States meant that the FDA has evaluated the substance for safety and approved it for interstate marketing in the United States."<sup>64</sup> Using this as the basis for "accepted medical use" the Administrator further reasoned that because no new drug application ("NDA") or Investigational New Drug Permit ("IND") had been approved by the FDA for interstate marketing of ecstasy that MDMA could not be lawfully marketed and did not have a "currently accepted medical use in treatment in the United States."<sup>65</sup> Hence, despite the multitude and weight of the evidence

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<sup>62</sup>Id. at 27.

<sup>63</sup>See Grinspoon, 828 F.2d at 884.

<sup>64</sup>See id.

<sup>65</sup>See id.

presented by the ALJ of the FDA's long-standing position not to regulate the "practice of medicine", the DEA as they did with the issue of medicinal marijuana, completely reversed course without a clearly stated rationale, resulting in MDMA's permanent placement into Schedule I.

On March 3, 1987, Lester Grinspoon, a Harvard Medical School professor and one of the staunchest supporters of MDMA as therapeutic adjunct, appealed the Administrator's final ruling placing ecstasy in Schedule I. Grinspoon's concern, the most prevalent concern of MDMA advocates was that a Schedule I control would effectively foreclose research on the therapeutic uses of MDMA.<sup>66</sup> Most relevantly, Grinspoon's challenge was that the Administrator had applied the wrong legal standards for "currently accepted medical use in the United States".<sup>67</sup>

The Fifth Circuit's review of the Administrator's interpretation of "accepted medical use" was done following the guidelines set out by the Supreme Court in *Chevron*.<sup>68</sup> The two-step *Chevron* analysis entails the following:

1 - Whether Congress had directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress; 2 - If... the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based upon a permissible construction of the statute.<sup>69</sup>

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<sup>66</sup>Id. at 882.

<sup>67</sup>Id.

<sup>68</sup>*Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

<sup>69</sup>Grinspoon, 828 F.2d at 885.

Employing a Chevron analysis with regards to “accepted medical use”, the Court held that, while it was undisputed that Congress had not directly spoken to the proper interpretation of this criteria for Schedule I placement, the Court was not compelled to proceed to the deferential second step of the Chevron analysis.<sup>70</sup> The Court supported this proposition by citing to the following footnote in the Chevron opinion: “If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is law and must be given effect.”<sup>71</sup>

After conducting a detailed review of the statutory language and structure regarding Schedule I the Court found it “unlikely that substituting the lack of FDA interstate marketing approval for the statutory requirements that a substance lack both an ‘accepted medical use’ and ‘accepted safety for use... under supervision’ is consistent with the intent of Congress in enacting the CSA.”<sup>72</sup>

Of particular interest when reviewing the Court’s detailed analysis of the arguments pertaining to the statutory language and structure of the CSA is the Fifth Circuit’s specific attention to the issue of MDMA advocates failure to obtain an IND or NDA. Stating that the language and structure of the CSA and FDCA are helpful in determining whether the Administrator’s interpretation is reflective of congressional intent, the Court presented the following argument:

The CSA clearly provides that a substance may not be placed in Schedule I

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<sup>70</sup>Id.

<sup>71</sup>Id at 884 (citation omitted).

<sup>72</sup>Id. at 888.

unless it lacks both a ‘currently accepted medical use in treatment in the United States’ and ‘accepted safety for use...under medical supervision.’ The FDCA on the other hand, provides that a substance may fail to obtain FDA interstate marketing approval for any of seven specific reasons.<sup>73</sup> Although approval may be withheld because the substance lacks both ‘safety’,<sup>74</sup> and ‘efficacy’ for a particular use,<sup>75</sup> it is equally possible for a substance to be disapproved for interstate marketing because it lacks only one of these attributes, or because the application fails to contain relevant patent information,<sup>76</sup> or even because the labeling proposed for the drug ‘is false or misleading in any particular.’<sup>77 78</sup>

Reasoning that the FDCA does not even allude to the term “medical use” and pointing out the “plain” possibility that a substance with an “accepted medical use may fail to obtain interstate marketing approval, the court found, as did ALJ Young, that the absence of FDA approval is not a foundation for determining that a substance has no “accepted medical use.”<sup>79</sup>

Further refuting the DEA’s assertion that FDA approval was required for a drug to have an “accepted medical use” the Fifth Circuit pointed out that unlike the CSA scheduling restrictions, the FDCA interstate marketing provisions do not apply to drugs manufactured and marketed wholly intrastate.<sup>80</sup> Once again echoing ALJ Young, the Court asserted that an already patented drug such as MDMA lacks the potential to be exploited commercially, and that such exploitation “is irrelevant to one who, like (Dr.) Grinspoon, seeks only to do research.”<sup>81</sup>

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<sup>73</sup>21 U.S.C. § 355(d)(1)-(7).

<sup>74</sup>21 U.S.C. § 355(d)(2).

<sup>75</sup>21 U.S.C. § 355(d)(5).

<sup>76</sup>21 U.S.C. § 355(d)(6).

<sup>77</sup>21 U.S.C. § 355(d)(7).

<sup>78</sup>Grinspoon, 828 F.2d at 887.

<sup>79</sup>Id.

<sup>80</sup>Id.

<sup>81</sup>Id.

The lack of commercial incentive and the language of the CSA and FDA resulted in a “tentative” conclusion by the Fifth Circuit that an absence of FDA approval does not preclude the possibility of a substance having an “accepted medical use.”<sup>82</sup>

The Fifth Circuit continued its Chevron analysis by reviewing legislative history and subsequent legislation to determine whether or not they supported their “tentative” conclusion. The Court strongly rejected both of the Administrator’s arguments purporting to support his construction of the statutory language and was extremely scathing in so doing. The Administrator presented the following passage from the 1968 House Committee Report<sup>83</sup>: “Under Reorganization Plan No. 1 of 1968 a Bureau of Narcotics and Dangerous Drugs has been established in the Department of Justice to regulate all these drugs... to prevent diversion from legitimate channels. Safety and efficacy will continue to be regulated under the Federal Food, Drug, and Cosmetic Act by HHS.”<sup>84</sup> The Administrator continued that the above led to the proposition that, “Congress clearly intended that the ‘safety and efficacy’ of narcotic and dangerous drugs (e.g., whether such drugs are acceptable for medical use and safe for such use) be determined by HHS under the FDCA.”<sup>85</sup> The Fifth Circuit objected to the Administrator’s conclusion, stating that his parenthetical comment - “equating a finding of ‘safety and efficacy’ by the FDA with a finding of ‘accepted medical use’ and ‘accepted safety for use under medical supervision’ - (was) *totally un-*

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<sup>82</sup>Id.

<sup>83</sup>H.R.Rep. No. 1444, 91<sup>st</sup> Cong., 2d Sess. (1970).

<sup>84</sup>Grinspoon, 828 F.2d 888 (citation omitted).

<sup>85</sup>Id. (citation omitted).

*supported* by the House Committee.”<sup>86</sup> The Court continued “*we are loath to accept such a disingenuous argument.*”<sup>87</sup> Ultimately the Fifth Circuit’s rebuke of the Administrator’s stated position, particularly the “*totally unsupported*” language, sounds quite similar to ALJ Young questioning the FDA’s reversal of an eleven-year stance against their authority to regulate medicine in the face of medical marijuana, and his “*no stated basis whatsoever*” language. Once again, the government’s irrational behavior in the face of an illicit drug had been clearly exposed.

Having refuted the Administrator’s legislative history arguments in support of his construction of the statutory language, the Fifth Circuit looked next to the Administrator’s arguments concerning subsequent legislation, and found these arguments to “*weaken, not strengthen*, the position espoused by the Administrator in (the) litigation.”<sup>88</sup>

The Administrator’s first argument pointed to the 1984 “emergency scheduling” amendment to the CSA. He claimed that since the provision did not allow for expedited scheduling in cases where the FDA has permitted the substance to be marketed in interstate commerce it followed that this standard, rather than the typical Schedule I criteria, should be relied on in all cases.<sup>89</sup> However, the court rejected this position stating this simplistic criteria was needed in cases where it would be “necessary to avoid an imminent hazard to public safety,”<sup>90</sup>

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<sup>86</sup>Id. (emphasis added)

<sup>87</sup>Id. (emphasis added)

<sup>88</sup>Id. at 889. (emphasis added)

<sup>89</sup>Id.

<sup>90</sup>21 U.S.C. § 811(h)(1) (1994).



as opposed to the case of MDMA, and the “general run of cases”, where the use of such “shorthand methods” would not be appropriate.<sup>91</sup>

The second argument referred to a 1986 amendment to the CSA, the Controlled Substances Analogue Act.<sup>92</sup> Similar to his first argument the Administrator claimed that since excluded from the scope of the amendments controls was any substance for which there is an approved IND or NDA, that Congress intended this lack of FDA approval standard should be relied on in all cases.<sup>93</sup> However, once again the Fifth Circuit distinguished the unique nature of cases involving analogues intended for human consumption from nonanalogues and held this “shorthand method” to be contrary to Congressional intent in general cases.<sup>94</sup>

The final argument asserted by the Administrator concerned Congress, in 1984, placing a drug with an “accepted medical use” in Schedule I. The Administrator pointed to language in a House Committee Report<sup>95</sup> stating that the DEA “does not have the authority to impose Schedule I controls on a drug which has been approved by FDA for medical use.”<sup>96</sup> The Administrator advanced the position that the above displayed Congress’ approval of the notion that a substance could not have an “accepted medical use” unless the FDA has

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<sup>91</sup>Grinspoon, 828 F.2d at 882.

<sup>92</sup>21 U.S.C. §§ 802(32)(A), 813 (this amendment defines a “controlled substance analogue” as a substance having a chemical structure and effect on the central nervous system substantially similar to that of a Schedule I or II controlled drug).

<sup>93</sup>Grinspoon, 828 F.2d at 889.

<sup>94</sup>Id.

<sup>95</sup>H.R. Rep. No. 534, 98<sup>th</sup> Cong., 2d. Sess. 4 (1984).

<sup>96</sup>Grinspoon, 828 F.2d at 890.

already approved it for interstate marketing.<sup>97</sup> The Court, using basic logic, easily rejected this argument stating that although FDA approval is sufficient to prove a substance has an “accepted medical use”, it simply does not follow that the absence of FDA approval is evidence that a substance has no “accepted medical use.”<sup>98</sup>

Ultimately, as recognized by the Fifth Circuit, general legal principles of equity and process would be greatly minimized if one were to accept the construction of the CSA put forth by the Administrator. To simply conclude that a substance has no “accepted medical use” on the basis of the substance not having obtained approval for marketing would also be wholly unfair. From a policy standpoint, administrative hearings such as the MDMA hearings and the opportunity they present for medical professionals to establish an “accepted medical use” for a drug would become obsolete. Recognizing this the Fifth Circuit stated, “(administrative hearings) would be reduced to an empty formality and, for participants like Dr. Grinspoon, would amount to an exercise in futility”.<sup>99</sup> Supporting this reasoning, the Court revisited the Administrator’s arguments concerning the “emergency scheduling” and “controlled substance analogue” provisions of the CSA pointing out that neither requires a hearing prior to regulatory action and that both serve as “stop-gap measures to be employed pending a final scheduling determination by the DEA, following a full evidentiary hearing, for the substance in question.”<sup>100</sup> The case of ecstasy was

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<sup>97</sup>Id.

<sup>98</sup>Id.

<sup>99</sup>Id.

<sup>100</sup>Id.

not one requiring a “stop-gap” approach, and to forego any presentation from medical practitioners as to whether or not MDMA has an “accepted medical use”, would not only be irrational, but would violate basic principles of process and fairness. As the Court noted, “Our review of the legislative sources below also convinces us that *the Administrator’s interpretation is unreasonable and would be invalid even under the (deferential) second prong of the Chevron test.*”<sup>101</sup>

Ultimately, the Fifth Circuit vacated the Administrator’s determination that ecstasy should be placed in Schedule I and remanded the issue of whether or not MDMA had an “accepted medical use” for further consideration, with the instructions that the absence of FDA interstate marketing approval did not provide sufficient evidence to support the conclusion that MDMA did not have an “accepted medical use.”<sup>102</sup>

With the determination that a lack of FDA interstate marketing approval did not preclude a substance from having an “accepted medical use” the question remained open as to what standard should be used in determining whether or not MDMA had an “accepted medical use.” Dr. Grinspoon advanced a position similar to the position of ALJ Young, that the standard should be based upon the opinions of the medical community.<sup>103</sup> Dr. Grinspoon presented, the testimony of two representatives of the Bureau of Narcotics and Dangerous Drugs (“BNDD”), the DEA’s predecessor, to support his claim. The statements,

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<sup>101</sup>Id at 885 n. 6. (emphasis added)

<sup>102</sup>Id. at 891.

<sup>103</sup>Id.

which were also presented by ALJ Young in support of his position concerning the standard for “accepted medical use”, were made during consideration of the Comprehensive Drug Abuse Prevention and Control Act of 1970. Michael R. Sonnenreich, at the time Deputy Chief Counsel of the BNDD, testified that drugs in Schedule I would “*have no medical use as determined by the medical community*”.<sup>104</sup> Similarly, John Ingersoll, Director of the BNDD, testified Schedule I drugs would be those *that “the medical profession has already determined to have no legitimate use in the United States.”*<sup>105</sup> However, despite the overwhelming clarity of these statements, the Fifth Circuit while acknowledging that they “(tended) to support Dr. Grinspoon’s position”, rejected this standard and quoted Supreme Court legal precedent that “statements made to committees of Congress... are without weight in the interpretation of a statute.”<sup>106</sup> Ultimately the Court noted the implicit delegation of Congress to the Administrator to interpret “accepted medical use” under the CSA and the case was remanded for further consideration with no standard in place and instructions that the Administrator could not rely on an absence of FDA approval to support the conclusion that MDMA did not have an “accepted medical use”.<sup>107</sup>

The Fifth Circuit’s decision vacating and remanding the Schedule I placement of MDMA resulted in, effective December 22, 1987<sup>108</sup>, the deletion of ecstasy from Schedule I pending the Administrator’s reconsideration of the record

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<sup>104</sup>Id. (citation omitted). (emphasis added)

<sup>105</sup>Id. at 892(citation omitted). (emphasis added)

<sup>106</sup>Id. (citation omitted).

<sup>107</sup>Id.

<sup>108</sup>See Fed. Reg. 2225-02 (1988).

from the earlier scheduling proceedings and issuance of another final rule.<sup>109</sup> This positive development for MDMA advocates was extremely fleeting. Relying solely on the existing hearing record, “specifically concluding that it was complete and had provided all interested parties an opportunity to present evidence and brief the issues”, the Administrator issued a final rule permanently placing MDMA on Schedule I effective March 23, 1988.<sup>110</sup>

The failure of the Administrator to hold additional hearings was challenged in first the Fifth<sup>111</sup> and then the Eleventh Circuit<sup>112</sup> and was upheld due the “completeness of the existing record and the absence of a specific directive in Grinspoon to schedule additional hearings.”<sup>113</sup>

An analysis of the findings of fact presented by ALJ Young, his recommendation based on those findings that MDMA be placed not even in Schedule II, but Schedule III of the CSA, the Fifth Circuit and ALJ’s scathing language regarding particular arguments advanced by the DEA, results in much skepticism at the blind acceptance of the Administrator’s final placement of MDMA in Schedule I absent a statement or analysis of the standard employed in the determination of whether or not ecstasy had an “accepted medical use.”

### **III. MDMA: RESEARCH IN THE POST-SCHEDULING YEARS**

The 1988 final placement of MDMA in Schedule I of the CSA was a devas-

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<sup>109</sup>United States v. Franz, 87 F.3d 440, 445 (11<sup>th</sup> Cir. 1996).

<sup>110</sup>Id.

<sup>111</sup>United States v. Piaget, 915 F.2d 138 (5<sup>th</sup> Cir. 1990).

<sup>112</sup>Franz, 87 F.3d at 445.

<sup>113</sup>Id.

tating blow for those advocating MDMA's use as a therapeutic adjunct. The Schedule I categorization eliminated a physician's ability to prescribe MDMA for medical use and severely limited the possibilities for future research. In order for research on Schedule I substance stringent guidelines have to be followed. Applications from researchers for a DEA Schedule I license, must be preceded by FDA approval of an IND. Applications must detail the nature and the motive behind the proposed research, the security measures that would be taken to protect human subjects, as well as the substances used in conducting such a research inquiry, DEA Schedule I applications will be placed on hold pending FDA review and approval of an IND.<sup>114</sup> Upon receiving the application the DEA forwards a copy of the application to the FDA for the purpose of conducting a medical evaluation before a final decision is made in conjunction by the two agencies.<sup>115</sup> In practice, this simply constitutes the DEA checking with the FDA to see if an IND has already been approved. If the application process is adhered to and the research is approved, the results of the research are reported to both the FDA and DEA for review. With the eight-factor test (Table 2) initially relied on in the emergency scheduling of ecstasy having been rejected by the D.C. Circuit<sup>116</sup>, the DEA now uses a five-factor test (Table 3) to determine whether or not a drug is in "currently accepted medical use".<sup>117</sup>

Table 3: The DEA'S "New" Five Part Test

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<sup>114</sup>See Dogwill, *supra* note 2, at 248 (citation omitted).

<sup>115</sup>*Id.*

<sup>116</sup>*Alliance for Cannabis Therapeutics et al v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991).

<sup>117</sup>*Alliance for Cannabis Therapeutics et al v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

(1)	The drug's chemistry must be known and reproducible.
(2)	There must be adequate safety studies.
(3)	There must be adequate and well-controlled studies proving efficacy.
(4)	The drug must be accepted by qualified experts.
(5)	The scientific evidence must be widely available.

After applying the results of the research to the five-factor test, the authority to reschedule lays solely at the discretion of the DEA Administrator. The DEA can independently apply the five-factor test and reschedule through that route, but if the FDA independently approves an NDA, the DEA must reschedule the substance.<sup>118</sup> Since the five-factor test can effectively eliminate anything short of FDA approval, researchers are forced in practice to go through the FDA. Hence the future possibility, for MDMA advocates, of a rescheduling of MDMA out of Schedule I was/is primarily in the hands the government, a government that had acted irrationally in the past and most probably would continue to in the future. In short, the future of MDMA as a therapeutic adjunct appeared quite bleak.

From the foregoing rigid process, and through the various administrative decisions and legal proceedings beginning in 1984, it became abundantly clear to medical professionals endorsing the therapeutic benefits of MDMA that only through FDA approved research would ecstasy ever again be legally prescribed for medical use. Aware of these obstacles, in 1986 Rick Doblin, one of the primary coordinators of the pro-MDMA contingent, founded a non-profit organization, the Multidisciplinary Association for Psychedelic Studies ("MAPS"),

<sup>118</sup>See id.

and opened a Drug Master File for MDMA with the hopes of proving MDMA's therapeutic benefits through FDA approved protocols.<sup>119</sup> Opening a Drug Master File is part of one of the required steps for any drug before it can be legitimately researched in the United States.<sup>120</sup> The file contained data gathered from FDA required pre-clinical animal toxicity studies and between 1986 and 1988 five different applications for permission to conduct research with MDMA were submitted to the FDA's Neuropharmacologic Drug Products Division.<sup>121</sup> Aware of the DEA's previous criticism's concerning the lack of scientifically sound double-blind studies by MDMA advocates, three of the proposals were for double-blind controlled trials and submitted from researchers from the esteemed medical schools of Harvard, UC San Francisco and U. of New Mexico.<sup>122</sup> The two other proposals, were submitted by individual physicians for single case studies, one for a terminal cancer patient who had been treated successfully for pain prior to MDMA's criminalization and the other for a patient with unipolar depression for whom all other available treatments had been unsuccessful.<sup>123</sup> In rejecting all five studies the FDA pointed to the hypothetical risk of functional consequences of the potential neurotoxicity of ecstasy. The MDMA advocates, all too familiar with "irrational" actions of the FDA and DEA during the previous administrative and legal proceedings concerning MDMA, believed that the risk/benefit rationale presented by the FDA was disingenuous and that the

<sup>119</sup>Rick Doblin, *The Struggle to Conduct Research Into the Therapeutic Use of MDMA*, at 2 (visited Mar. 31, 2000) <<http://www.maps.org/research/mdma/index.html>>

<sup>120</sup>Id at 3

<sup>121</sup>Id at 2.

<sup>122</sup>Id.

<sup>123</sup>Id.



true reason for the rejection of the studies was an “underlying culture prejudice against medical research with drugs that were criminalized and on one or more FDA officials’ personal opposition to human research with psychedelics.”<sup>124</sup> Advocates pointed out that concerns regarding the neurotoxicity of MDMA were unproven as studies failed to link MDMA with behavioral and functional consequences and further, that a similar hysteria was generated in the 1960’s when it was claimed that LSD damaged chromosomes, similarly deterring research, and later it was proved that the LSD “damage” had no clinically significant effect.<sup>125</sup> Hence, once again, the FDA, without a solid rationale to support its actions stunted any efforts to further research on the possible therapeutic benefits of MDMA.

A review of the post-scheduling research concerning the potential neurotoxicity of MDMA lends support to the advocates’ of ecstasy assertions that the government has acted irrationally with regards to the drug. Because of MDMA’s illegal status and the FDA’s refusal to approve research proposals such as the five above, it has been virtually impossible to study ecstasy’s effects upon human behavior using the traditional double-blind placebo-controlled methodology.<sup>126</sup> Another issue is that the subjective effects of MDMA make it virtually impossible to conduct an effective double-blind study since most subjects and researchers can distinguish between MDMA and placebo. Hence the majority of the relevant information concerning the psychobiological effects

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<sup>124</sup>Id.

<sup>125</sup>Id.

<sup>126</sup>A.C. Parrott and J. Lasky, “Ecstasy (MDMA) effects on mood cognition: before, during and after a Saturday night dance”, *Psychopharmacology* (1998) 139:262.

of MDMA comes from either studies done on recreational users of the drug describing their ecstasy experiences<sup>127</sup> or animal studies which have provided much of the information concerning the neurotoxicity of MDMA in rats and monkeys.<sup>128</sup> Studies on recreational users of ecstasy have generally resulted in the finding of the following positive and negative effects of ecstasy use: (+) - elation, energeticness, agreeableness, and closeness to others; (-) - neurochemical depletion, lethargy, depression, memory impairments, and irritability.<sup>129</sup> Animal studies have shown that MDMA can lead to serotonergic neurodegeneration, in the hippocampus, which is important in memory functioning and other brain areas, which lead to the suggestion that the memory impairments in humans may reflect serotonergic neurodegeneration.<sup>130</sup> The FDA's reliance on studies such as these to thwart the further investigation into the possible therapeutic benefits of MDMA is completely unfounded in a multitude of ways. The studies concerning recreational ecstasy users are severely limited as a general matter for two reasons. The first is that the subjects of these studies are recreational users of the drug, as opposed to users of the drug in controlled clinical settings, and in the majority of the studies contain subjects who are first, polydrug users and/or second, have admittedly used MDMA a minimum of twenty times and frequently over one hundred times or more. The initial problem with the conclusion that the possibility of neurotoxic effects in these recreational users would result in the same for those in clinical settings is that these people have abused

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<sup>127</sup>Id. (citations omitted).

<sup>128</sup>Id. (citations omitted).

<sup>129</sup>Id. at 262 (citations omitted).

<sup>130</sup>Id. (citations omitted).

the drug, and in some cases abused other drugs, and taken ecstasy in extremely significantly higher doses than one would in a clinical setting. In short, there is absolutely no control over drug administration as there would be in a clinical setting.<sup>131</sup> The second and more telling problem is that along with a lack of confirmation of the dosage of ecstasy there is no objective confirmation of the purity of the ecstasy the subjects have taken.<sup>132</sup> Tablets illegally sold as ecstasy contain MDA, MDEA (3,4-methylenedioxy-ethylamphetamine), or mixtures of a range of other compounds (e.g. caffeine, ephedrine, selegiline, amphetamine, ketamine, LSD).<sup>133</sup> Hence, in many cases, the recreational “ecstasy” users may not even have ingested MDMA. As for the animal studies any assumptions made about humans regarding such studies are tenuous at best.<sup>134</sup> Especially in the present case where doses administered to the animals are far greater than the doses that would ever be administered to a human in a clinically controlled setting. In short, by relying on animal studies and data from abusers of ecstasy, who may not have even ingested pure MDMA, the government has clearly failed to provide an adequate basis for making the claim that MDMA administered in a controlled clinical setting would have neurotoxic effects that are of any clinical significance.

For a more technical understanding of the irrationality of the government relying on MDMA studies on recreational drug users to support their “fear” of

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<sup>131</sup>Michael John Morgan, “Memory Deficits Associated with Recreational Use of Ecstasy (MDMA)”, *Psychopharmacology* (1999) 141:35.

<sup>132</sup>Id.

<sup>133</sup>Id. (citing to Saunders, N. “Ecstasy and the Dance Culture” (1995); Wolff K. et. al. Contents of “ecstasy”, *Lancet* 356 : 1100-1101 (1995).

<sup>134</sup>See supra note 31.

the possibility of neurotoxic effects in clinically controlled settings the following excerpt from a summary of the recent (8/30/99 - 9/1/99) MAPS international scientific conference is illustrative:

### **The most important new data about MDMA neurotoxicity was**

presented by Dr. Franz Vollenweider, University of Zuerich.... Dr. Vollenweider's team and Dr. Ricuarte's's team at Johns Hopkins are the only groups in the world using PET scans to measure serotonin uptake sites. However, there is a crucial difference between the methodology of the two groups. Dr. Vollenweider studies the effects of actual administration of pure MDMA to MDMA-naive subjects. Dr. Ricuarte does not administer MDMA but studies people with extensive use of Ecstasy, which is sometimes MDMA and sometimes not, frequently taken in rave environments.... Dr. Vollenweider's study directly relates to determining the risk to research subjects in studies examining the therapeutic use of MDMA, where one or several doses will be administered to MDMA-naive patients. Dr. Ricuarte's studies in polydrug users who have taken MDMA 75 to thousands of times are valuable because this sort of study is most likely to show reductions in serotonin nerve terminals, since subjects have such a high exposure to MDMA. However, this study is of less relevance to understanding the risks of exposure to a few doses of MDMA in a clinical research context.<sup>135</sup>

Also presented by Rick Doblin at the MAPS conference were the recent findings of Dr. Lew Seiden, the same Lew Seiden who offered testimony in support of the DEA's reliance on animal studies in the original scheduling of MDMA<sup>136</sup>. Doblin summarized:

Lew Seiden, Ph.D., University of Chicago, presented data from animal research that showed conclusively that serotonin reductions are related to core body temperature, with higher ambient temperatures producing hypothermia which makes one vulnerable to serotonin reductions. This research calls into question risk assessments for clinical research subjects based on data from ravers who take MDMA in high-ambient temperatures, exercise vigorously, and

<sup>135</sup>Rick Doblin, *Clinical Research with MDMA and MDE A MAPS' Conference: Dead Sea Israel*, at 5-6 (visited Mar. 31, 2000) <<http://www.maps.org/news-letters/v09n4/09402dob.html>>.

<sup>136</sup>See supra note 56.

sometimes do not consume sufficient fluids. In contrast, clinical research contexts involve the administration of MDMA in temperature-controlled settings, to people who are resting in bed and supplied with fluids. This data about the importance of ambient temperatures requires a revision of the understanding of the mechanisms of MDMA-related neurotoxicity.

In addition after a presentation of Dr. Vollenweider's and Dr. Seiden's findings, as well as the findings of other medical professionals, which were correctly focused on the safety of the administration of MDMA in clinically controlled settings, the summary of the findings concluded as follows:

At present, the only evidence in humans for functional consequences from regular exposure rates to MDMA is from data that are not clinically significant and are not conclusively proven to be due to MDMA. The minimal findings in these studies of Ecstasy users is reassuring. In summary, there are no data showing that one or few doses of MDMA in a clinical research context bear substantial risks for long-term harms from possible neurotoxicity.

#### **IV. MDMA-ASSISTED THERAPY - PROMISING ANECDOTES**

Despite the positive results of the MAPS conference, the strength of the methodological arguments, and of the findings regarding neurotoxicity, MDMA advocates are still lacking "scientifically valid" evidence of any therapeutic benefits of MDMA. Prior, to presenting the prospects for FDA approval regarding such studies, I will present some primary anecdotal evidence which ecstasy advocates find so extremely promising. Evidence that has motivated MDMA advocates such as those in MAPS to independently fund their research for 15 years in an attempt to conduct FDA-approved clinical trials and have MDMA removed from Schedule I.

The following is an excerpt from an account of a woman therapist in the Midwest who gave her husband, Dick, a dose of MDMA to relieve his pain when

he was terminally ill with cancer:

What makes non-narcotic help so appealing is that the patient is conscious and communicating with those he loves. This is so important for both patient and loved ones. Dick had a beautiful death of acceptance and serenity. He died with the loving support of me and his son. It made a bond between us that sustained me through the heavy months that followed. Now that four years have passed, the pain is less, but my gratitude for giving Dick his MDMA is as strong and sharp as ever.<sup>137</sup>

An excerpt from the account of the daughter of a 92 year old man, George, to whom a dose of ecstasy was administered to relieve the emotional and physical pain following a stroke and imminent death:

There is no way I can say how grateful am for MDMA for opening up a way to help George with his emotional and physical pain. It was the first time this stiff necked, fearful old man had let go. Nobody had ever before seen that hidden, beautiful, lovely soul.<sup>138</sup>

Excerpts from the personal account from a thirty-three year old woman who had serious problems with depression for 12 years and took a dose of MDMA as a catalyst for healing her fears and depression:

<sup>137</sup>Rick Doblin, *An Account from a woman therapist in the Midwest who gave her husband MDMA to relieve his pain when he was terminally ill with cancer*, (visited Mar. 31, 2000) <<http://www.maps.org/research/mdma/cancerpain.html>>.

<sup>138</sup>Rick Doblin, *Alleviation of Emotional Pain in an Elderly Man*, (visited Mar. 31, 2000) <<http://www.maps.org/research/mdma/pain1.html>>

I am thirty three years old. I have had serious problems with depression since I graduated from college in 1983. I have been hospitalized twice and have been on various psychoactive medications between the years 1986 and 1995.... I have been through four psychiatrists and two psychologists in addition to several therapists and doctors in the hospitals. My symptoms have ranged from clinical depression to high anxiety to having delusions....

I believe what happens is the MDMA lessens or eliminates your experience of fear, thus you are able to delve into areas that you might normally not go into. When you're in these area, you can stay longer. You are not afraid of your own feelings and thoughts and you are not afraid to express them. You are not afraid of other peoples ideas or suggestions. Its been said so many times in so many different ways but it is still profound: Fear is man's greatest foe (and perhaps his only real foe.)

We talked late into the night. By 4 or 5AM, my friend was beginning to fall asleep and I was feeling like I might be able to sleep. That was the end of the actual drug experience. The after-effects are still being experienced. A week and a half after the MDMA episode I saw my therapist. I did not tell him that I had taken an illegal drug. I knew he would strongly disapprove. About 20 minutes into the session, he seemed a little disconcerted. He said something about how he had been gone for two weeks and instead of me getting worse while he was away, which would have been normal for me, I seemed better. He said that there was some new quality about me that he couldn't quite put his finger on, but I seemed stronger. It was hard for me not to share with him. I

only commented that I had evolved.

[Describing the long-term effects]

My therapist told me two weeks ago that I don't seem to be very open with him anymore and maybe that was a sign that I didn't need him and that I am strong enough to go "solo" (for the first time in 11 years). I am still open with my boyfriend and my close friends. I feel less alone than I've ever felt in my life.

Excerpts from a series of letters to MAPS of the daughter of a 59 year-old man who died of terminal pancreatic cancer. Prior to his death the daughter and father experienced two MDMA sessions:

I was able to have two successful MDMA sessions with him which allowed for some major breakthroughs and permitted him to enjoy a few precious hours of pain-free "quality time" with his family.... In looking back, I find that the two MDMA sessions we had were two of the most joyous memories during his final weeks of existence.

[Describing the session]

At that point in his illness, he was having trouble walking by himself, even to the bathroom, but he asked that I help him outside so he could look at his beloved garden for the last time....

Long after I would have expected the effects to wear off, Dad was bounding out of bed on his own to walk slowly back and forth to the bathroom, and was making jokes and making us laugh well into the night....

Our two sessions will undoubtedly stick out in my memory as time passes and I can begin to mellow the memories of agony and cherish the ones of quality time spent together. I wish you continued success in getting the status of MDMA changed through research, to allow for others to participate in such beautiful experiences.<sup>139</sup>

Excerpts of a letter to MAPS from the twenty-eight year old fiancée, Sue, of a twenty-five year old terminal cancer patient, Shane, relating the effects of their two MDMA sessions prior to his passing:

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<sup>139</sup>From the Newsletter of the Multidisciplinary Association for Psychedelic Studies, *MDMA: a catalyst for healing my fears and depression*, (visited Mar. 31, 2000) <<http://www.maps.org/news-letters/v06n1/06114per.html>>.



I recently lost my fiancée, Shane to cancer after a long battle. It has been trying on those who were close to him. It has also been a very fulfilling event, due in part to MDMA sessions we went through to seek to accept his death and relieve the emotional pain and hardships we encountered as the result of his terminal illness.

Taking MDMA together was the best decision we could have ever made in regards to the cancer. We discussed this many times before his death last week. Shane's very long obituary concluded with a request at the end; in his memory, in lieu of flowers, we asked people to support the MDMA research going on for people facing cancer....

There is such a need for recognition of this wonderful research and its potential to change the lives of those facing terminal illness. The spectacular people fighting the cause need the help of all of us out there to bring it to a positive light.... Nobody knows if someday they could be facing all that we did. Hopefully they never will, but in the event they do, it should be feasible that they have this readily available to them, unlike how we had to "break the law" to help our anguish....

It was an unbelievable night that I wish every government official could view. Every person who is skeptical of the legalization of MDMA to help people with cancer pain needs to view the miraculous events that began to unfold....

This video of our session shows what we deem a miracle. In the first two hours, Shane is clearly physically uncomfortable. That diminishes as time passes until suddenly he is pain-free. I'm not talking the mental/emotional pain that we knew would be gone; physically he had zero pain.... He even "hammed it up" for the camera as he virtually jogged towards the kitchen, leaning into the lens of the camcorder telling the world that he didn't hurt. No amount of morphine had been able to accomplish this and he had been living for a long time hurting to a harsh degree....

MDMA allowed us to do that night what our oncologist hadn't been able to do. To kill the disease entirely... if only for a night....

Cancer took my soul-mate from me physically for the remainder of my life. Cancer robbed us mentally and emotionally. We were able to fight back and "kill" the cancer not only for the last night we took MDMA together, but for the next five week's that followed before Shane's passing last week....

What I do believe fully and have seen and lived first hand is that while MDMA will not cure cancer, it can cure the emotional pain that accompanies it if used correctly. This entire fight makes me cry more than Shane's passing. I am appalled that it is not available to those who need it....

In the same token everyone facing terminal cancer should have the feelings of acceptance brought on by MDMA made available to them when it is so desperately needed....<sup>140</sup>

## **V. CONCLUSIONS AND THE FUTURE OF THERAPEUTIC**

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<sup>140</sup>From the Bulletin of the Multidisciplinary Association for Psychedelic Studies, *A series of letters on MDMA and cancer*, (visited Mar. 31, 2000)

<http://www.maps.org/news-letters/v09n4/09431sue.html>.

## MDMA

A critical element in our national drug control policy is the federal drug approval process. This established process for approving medications is based on the rigorous applications of *science, not ideology*. Thus, in America, every potential medication must meet rigorous criteria before it can be sold to the public or prescribed by doctors. This process protects Americans from dangerous drugs, unproven substances and ineffective treatments. It has helped provide America with medical care that is the envy of the rest of the world. This process must be preserved. Exempting any potential medication from this scientific scrutiny undermines the proven system and does a grave disservice to the public, as it will have neither a tested, rational basis on which to conclude the benefits of a drug outweigh its risk nor the assurance that the product is accompanied by sufficient information to permit its accurate prescription.<sup>141</sup>

The role of the government in the Schedule I placement of MDMA and the subsequent limitations on physicians advocating its therapeutic cannot be overstated. Through the emergency scheduling, through the rejection of the ALJ's recommendation, through the acceptance and reliance on questionable studies in relation to the precise issue, through a series of unsubstantiated and irrational legal and administrative decisions and statements, and through a reliance on a "war on drugs" ideology that fails to distinguish between therapeutic legalization/use and recreational legalization/use, the federal government, primarily via the FDA and DEA, have done a "grave disservice to the (American) public" with regard to therapeutic use MDMA.

An overwhelming amount of evidence presented, especially the anecdotal evidence, suggests that there are some real therapeutic benefits to MDMA.

Riveting anecdotal reports such as these make clear the incredible importance

<sup>141</sup>Dogwill, *supra* note 2, at 289, 290 (citing to Letter from Barry McCaffrey, Drug Policy Advisor, to Eleanor Holmes Norton (U.S. Representative), Andrew Brimmer (Financial Control Board Chairman), Lieutenant General Julius Becton (Board of Education Chief Executive Officer, Marion Barry (Mayor of Washington D.C.), and Linda Cropp (Acting Chair of Washington D.C. City Council) (July 22, 1997) <<http://www.ncjrs.org/pr72297.html>>. (emphases added).

of initiating clinical trials into the therapeutic use of MDMA.<sup>142</sup> And finally through the tremendous work of MDMA advocates such as Rick Doblin and the people of MAPS, it appears as if the government is finally living up to its “established process” of relying on “science, and not ideology.” Specifically, after years of pre-clinical studies and FDA stalling<sup>143</sup>, in a teleconference on June 24, 1999, MDMA advocates, Rick Doblin and terminally ill cancer patients received wonderful news.<sup>144</sup> The incredible cloud that had been hovering over therapeutic MDMA for over 15 years began to shift and rays of sunshine began to poke through. During the teleconference with FDA officials, the MDMA advocates were told that they no longer had to conduct the rigid and enormously expensive pre-clinical trials that had been an obstacle for so long, that they would be permitted to initiate a pilot study<sup>145</sup> using MDMA in human cancer patients and finally have a fair and scientific chance to prove the safety and efficacy of MDMA. Additionally, in Spain, the world’s first controlled scientific study of the therapeutic use MDMA will begin, in August 2000. The study,

<sup>142</sup>From the Newsletter of the Multidisciplinary Association for Psychedelic Studies, *Speaking with silence: MDMA in a couple dealing with cancer*, (visited Mar. 31, 2000) <<http://www.maps.org/news-letters/v07n4/07405sue.html>>.

<sup>143</sup>Rick Doblin, *The Struggle to Conduct Research into the Therapeutic Use of MDMA*, at 2 (visited Mar. 31, 2000) <<http://www.maps.org/research/mdma/index/html>> (“In 1992, FDA reviewed a MAPS-supported protocol submitted by Dr. Charles Grob... for a study of the use of MDMA is the treatment of pain, anxiety and depression in cancer patients... FDA (gave) final approval for the Phase I safety study on November 5, 1992. The safety study was completed in 1995... Dr. Grob submitted the first draft of the protocol for the study of cancer patients in 1997. Negotiations with FDA moved very slowly, due to initial FDA decisions to put MDMA psychotherapy research on the slow track to nowhere.”)

<sup>144</sup>Rick Doblin, *MDMA Research Permitted After Years of Effort*, at 1 (visited Mar. 18, 2000) <<http://www.maps.org/research/mdma/0699mdma.html>>

<sup>145</sup>Id. (“We will be permitted to initiate a pilot study in cancer patients focusing on a clearly defined clinical end-point... If and when we get information about therapeutic effect size without producing serious adverse side effects, we will be permitted to initiate a large scale clinical trial designed to be one of the two ‘adequate and well controlled’ trial necessary before FDA would approve a drug for marketing.”).

funded by MAPS, will evaluate the effects of MDMA in women suffering from post-traumatic stress disorder as a result of sexual assault.

Science, not ideology. Hope, not futility. Sunshine, not cloudiness. Rationality. After a 15 year uphill struggle MDMA advocates, with the assistance of the FDA, are finally getting the opportunity to prove and hopefully share the ecstasy that is MDMA assisted psychotherapy with those unfortunate individuals so desperately in need.