Rick Doblin, Ph.D., Testimony to US Sentencing Commission Re: MDMA

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I. Introduction

For the last 35 years, from 1982 when I first learned about MDMA to 1986 when I founded the non-profit research and educational organization, the Multidisciplinary Association for Psychedelic Studies (MAPS), my life has been focused around understanding the therapeutic potential of MDMA and developing MDMA-assisted psychotherapy into an FDA-approved treatment available by prescription. In 2001, I testified before the USSC regarding MDMA, only to see the penalties increased based on risk estimates that seemed excessive at the time; subsequent research ultimately demonstrated a lower risk profile. I'm deeply grateful for this new opportunity sixteen years later to present this written and oral testimony to the USSC to aid in its deliberations reviewing the current sentencing guidelines.

II. The Creation & Criminalization of MDMA

a. Origin of MDMA

MDMA was discovered and patented by the German pharmaceutical company Merck in 1912. MDMA was manufactured as part of a series of chemical intermediates. Merck's goal was to create a new chemical pathway to avoid a competitor's patent in an effort to develop a medicine for uncontrolled bleeding. Merck first tested MDMA in animals in 1927 and found nothing of interest, and never tested MDMA in humans. MDMA is now off-patent.[1]

In 1953-54, MDMA was one of eight compounds studied in animals with funding from the US Army Chemical Center. This research was declassified in 1969 and published in 1972. In 1967, a biochemist formerly employed by Dow Chemical named Alexander Shulgin re-synthesized MDMA after being introduced to the substance at a conference. He provided initial reports of its pharmacology, with 80 mg to 160 mg required to produce desired subjective effects in humans.[2] MDMA was found to robustly influence human emotional status in a unique way without adversely affecting physiological functions or perception, such as visual perception or cognition.[3]

After being rediscovered, MDMA was used as an adjunct to psychotherapy. In 1977, Shulgin introduced a psychologist named Leo Zeff to MDMA. At the time, MDMA was a legal compound only known to a small group of psychopharmacologists. Zeff incorporated MDMA into his psychotherapy practice and ultimately shared MDMA widely with therapists across the country, introducing the substance to hundreds of therapists over the course of years.[4] As reported

[1] Ronald Freudenmann, *et al.*, *The origin of MDMA (ecstasy) revisited: the true story reconstructed from the original documents*, 101(9) Addiction 1241 (2006).
[2] Shulgin, Alexander & Anne, *Pihkal: A Chemical Love Story*, Transform Press (1991), 69. ISBN: 0-9630096-0-5.
[3] MDMA Investigator's Brochure, 8th Ed. (30 March 2016) ("IB") at 10 (citations removed) [Appendix A].
[4] *Id*.

by the National Institute on Drug Abuse (NIDA) website, some MDMA therapists at the time even called MDMA "penicillin for the soul" because it was perceived to enhance communication in patient sessions and reportedly allowed users to achieve insights about their problems.[5] Chemists and therapists distributing the legal compound hoped to make a meaningful contribution to people's psychological health. Dozens of known therapeutic uses of MDMA are recorded in the public domain so use patents are not available.

Based on my conversations in the early to mid-1980s with MDMA therapists and with chemists producing MDMA for therapists, I estimate about half a million doses of legal MDMA were distributed from the late 1970s to 1984 for use in therapeutic and personal growth settings, without attracting attention of the police. However, in the early 1980s, MDMA began to be marketed outside of therapeutic contexts by entrepreneurs who rebranded MDMA as "Ecstasy" in the club scenes in Dallas, Los Angeles and elsewhere. This campaign initiated recreational use.[6] It was apparent to those using MDMA in therapeutic contexts that the recreational use of MDMA was going to lead to the criminalization of MDMA for all uses, since at the time Nancy Reagan was simultaneously re-escalating the United States' "war on drugs." In 1984, Senator Lloyd Bentsen of Texas requested that the DEA schedule and criminalize MDMA, starting in motion the ending of MDMA's status as a legal substance.

b. History of Criminalization

The DEA first proposed to place MDMA in Schedule I in July of 1984.[7] In response, with the help of pro-bono legal services, I helped organize a group of psychiatrists and psychotherapists to request DEA Administrative Law Judge (ALJ) hearings seeking to maintain MDMA's legal medical use. These hearings were granted and began in early 1985. In the midst of the DEA hearings, which generated media attention that was generally positive about the effects of MDMA, DEA's Acting Administrator John Lawn placed MDMA on Schedule I using emergency scheduling powers, based on a perception of a "continuing and apparently increasing number [of people] being exposed to MDMA, its potential neurotoxicity and the lack of accepted medical use or established safety for use of MDMA."[8]

In 1986, the World Health Organization (WHO) of the United Nations followed the United States' criminalization process, placing MDMA in Schedule I. However, Dr. Paul Grof, the chairman of WHO's Expert Committee on Drug Dependence that reviewed the data on MDMA, voted against the recommendation for criminalization due to concerns that premature scheduling could negatively impact research into MDMA's risks and benefits. The only scientific evidence referenced by the Expert Committee as the basis of the scheduling recommendation was research on a related but different compound, MDA, administered to rats in frequent and high doses. The

[5] A Brief History of MDMA. NIDA. Found at: https://www.drugabuse.gov/publications/research-reports/mdma-ecstasy-abuse/brief-history-mdma.
[6] *Id.*
[7] 49 Fed. Reg. 30210-30212 (July 27, 1984).
[8] DEA Press Release on Emergency Scheduling. May 31, 1985. Found at: http://www.maps.org/research-archive/dea-mdma/pdf/0180.PDF.

World Health Organization (WHO) noted that there was insufficient data to draw strong conclusions: "No data are available concerning [MDMA's] clinical abuse liability, nature and magnitude of associated public health or social problems."[9] The WHO Expert Committee on Drug Dependence, despite its chairman's objections, determined that there was inadequate research supporting MDMA's therapeutic use,[10] though it had been used therapeutically, outside of research, for over a decade. However, the Committee noted in its report that it was impressed by the non-clinical reports of MDMA and urged countries to pursue further research.[11]

In May 1986, after two years of hearings, DEA ALJ Francis Young recommended *against* placing MDMA on Schedule I. He disagreed with the DEA's claim that FDA approval of a drug was "binding on the medical profession which respect to what is, or is not, accepted medical… use."[12] Specifically, he acknowledged that the nonexistence of a New Drug Application (NDA) did not preclude the drug from having medical use.[13] The Opinion also acknowledged MDMA's past use in therapy, and recommended that MDMA be placed in Schedule III.

Despite the weight of the evidence undermining MDMA's placement in Schedule I, and the fact that the DEA had acted outside of its authority when it Emergency Scheduled MDMA, Lawn overruled ALJ Young and classified MDMA as Schedule I in October of 1986.[14]

In 1987, Dr. Lester Grinspoon, a psychiatrist on the faculty of Harvard Medical School, sued the DEA on the grounds that DEA had ignored MDMA's medical use, and the federal court agreed, finding Lawn's ruling "unpersuasive."[15] This decision vacated MDMA's schedule I status. A month later, DEA Administrator Lawn intervened *again* and reverted MDMA to its Schedule I placement, dismissing the expert testimony of psychiatrists discussing over 200 cases of MDMA-assisted psychotherapy because they were not published in medical journals.

It is notable that subsequent to the first emergency placement, the DEA arrested several individuals for MDMA distribution. The DEA claimed that its emergency scheduling authority was derived from the Comprehensive Crime Control Act (CCCA), which Congress passed in 1984. The CCCA granted the Attorney General powers to temporarily schedule drugs without following regular procedures when there was imminent risk to public health. However, the Attorney General

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[9] World Health Organization, *22nd report of the Expert Committee on Drug Dependence*, Technical Report Series (1985) at 25. Found at: http://apps.who.int/iris/bitstream/10665/39635/1/WHO_TRS_729.pdf.
[10] *Id.*
[11] *Id.* at 26 (Despite insufficient methodologically sound data to reliably comment on MDMA's purported therapeutic usefulness, the report stated that "There was...sufficient interest expressed to recommend that investigations be encouraged to follow up these preliminary findings. To that end, the Expert Committee urged countries to use the provisions of article 7 of the Convention on Psychotropic Substances to facilitate research on this interesting substance.")
[12] In the matter of MDMA Scheduling, Docket No. 84-48 (Dec. 2, 2014).
[13] Young stated: "If this is the criterion, 'accepted safety' for use by physicians is reduced to being determined by… a businessman's or corporation's determination of the economic feasibility of mass production. Congress has not given the slightest hint of an intention to rely here on such judgments. That would, however, be the bottom line result of the Agency's position in many cases.... It ignores the reality that commercial pharmaceutical manufacturers base their production decisions on economic considerations. If they are commercially manufacturing a product, they have, no doubt, concluded that the pharmaceutical can be safely used. But the converse is not necessarily true." *Id.*
[14] 51 Fed. Reg. 198, 36552 (October 14, 1986).
[15] *Grinspoon v. DEA*, 828 F.2d 881 (1st Cir., 1987).

had never formally sub-delegated these "emergency scheduling" powers to the DEA. In 1988, three individuals who had pled guilty to distribution of MDMA challenged the emergency scheduling procedure. Based in part on the discrepancies in amount of due process required for the two scheduling procedures, the US Court of Appeals for the Ninth Circuit ruled that DEA's emergency scheduling of MDMA was illegal, freeing the arrested individuals on procedural grounds.[9]

III. The MDMA Sentencing Guideline Lacks An Empirical Basis.

a. Two federal courts have found the 2001 MDMA Sentencing Guidelines to be excessive.

In 2011, at sentencing in two separate federal MDMA trafficking cases, Hon. William Pauley III from the Southern District of New York and Hon. Ricardo S. Martinez from the Western District of Washington, both chose to vary downward from the MDMA Guideline range. In collaboration with MAPS,[16] ACLU attorneys Jay Rorty and Scott Michelman argued that because the MDMA guideline was based on now-discredited science, it lacked an empirical basis and thus need not be adhered to.[17] The courts agreed, acknowledging the 2001 Sentencing Commission's reliance on exaggerated, scientifically unsound perceptions of MDMA's harmfulness.

When sentencing the defendant in *US v. McCarthy*, Judge Pauley adopted an MDMA-to-marijuana ratio of 200:1, higher than the pre-2001 ratio of 35:1 but lower than the present ratio of 500:1.[18] In his Opinion, Judge Pauley concluded that MDMA is not in fact more harmful than cocaine (as concluded by the Sentencing Commission in 2001), but also that it is not as harmful as marijuana.[19] Specifically, he noted that failing to recognize the totality of cocaine's effects, which "render it significantly more harmful than MDMA," led to an imbalanced analysis which did not include multiple factors that could have led to a lighter sentencing determination.[20] In addition, Judge Pauley concluded that the Commission's analysis of MDMA's actual negative impacts - which focused on neurotoxicity alone - was "selective and incomplete."[21]

In *US v. Phan*, the court was not considering imposing a sentence above 36 months, already lower than the 41- to 188-month range which was otherwise possible given the pre-2001 Guideline.[22] However, despite already planning on a downward deviation from the Guideline,

[16] MAPS/ACLU Sentencing Press Release [Appendix D]
[17] *US v. Phan* (W.D. WA 2011), Supplemental Sentencing Memorandum ("*Phan* memo") at 8 [Appendix B].
[18] *US v. McCarthy* (S.D. NY 2011), Memorandum and Order ("*McCarthy* order") at 8 [Appendix C].
[19] *Id*. at 8.
[20] *Id*. at 7.
[21] *Id.* at 5.
[22] *US v. Phan* (W.D. WA 2011), Sentencing Hearing Transcript at 4-5 ("If this court were to treat MDMA as equivalent to marijuana on a ratio of one-to-one, then the resulting level in this case would start at 20. With the appropriate adjustments as set out in the presentence report that's prepared by probation, the end result would be a level 22. This defendant falls in a criminal history category one. His resulting range would then be 41 to 51 months.

Judge Martinez nonetheless acknowledged the need to re-evaluate the guideline ranges in the face of new experience and knowledge.[23] Ultimately, Judge Martinez noted:

> The exact question of whether or not this court believes that there is a problem with the current MDMA guideline I think is before this court, and I believe the answer is, yes, there is. Based on everything that I have seen that was presented here, based on the arguments that were made in the Southern District of New York [*US v. McCarthy*], I think it's imperative that the Sentencing Guideline Commission address this issue, just like they did with disparity between crack and powder cocaine.[24]

b. As successfully argued by the ACLU, the present MDMA Sentencing Guideline is based on inaccurate science.

The sentencing memo submitted to the court in *US v. Phan* provides a thorough overview and rebuttal of the now-discredited science relied on to form the 2001 MDMA Guideline.[25] The memo notes that the Commission's scientific evidence exhibited a number of problems including inadequate controls, inappropriate doses, non-replicable studies, and most notably, research by a researcher who later retracted another study claiming that MDMA caused Parkinson's because the study mistakenly used *d-methamphetamine,* an entirely different compound than the purported MDMA.[26] The *Phan* memo states:

> Specifically, when considering the guidelines for MDMA, the Commission's 'empirical data' included case studies of individuals who were heavy users of other drugs; studies in which animals were administered doses that we now know are exponentially larger relative to their size than doses human beings ingest; a website that the Commission itself noted was not scientific; and the work of a

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If the court were instead to use the ratio of 35-to-one, because that was my understanding of the pre-2001 -- the ratio that was used prior to the 2001 amendments to the current MDMA guidelines, then the resulting guideline range for this defendant, Mr. Phan, would be level 34 and call for a range of 151 to 188 months.").

[23] *Id*. at 6-7. ("I think the fact that the Ninth Circuit has explained that district judges are at liberty to reject any guidelines on policy grounds, and the Ninth Circuit has also held that it would be error to attach a presumption of reasonableness to the guideline range, in view of all that, the court is not required to embrace any particular alternative ratio, and this court will not do so in this situation for a variety of reasons. One, I will not do it because it's not necessary in this case in order for the court to impose a sentence that is sufficient, but not more than necessary to accomplish the reasonable objectives of sentencing. But I do it for another reason that's even more important. The court agrees that there may very well be problems with the MDMA guidelines as currently constructed. As we learn more about the effects of certain drugs on humans, especially after years of experience with those drugs and especially as more designer drugs come into play, it obviously makes logical sense to go back and re-evaluate all the guideline ranges.")

[24] *Phan* memo at 7-8.

[25] *Id.* at 15.

[26] *Id.*

> researcher who subsequently retracted multiple MDMA studies because he was testing the wrong chemical compound.[27]

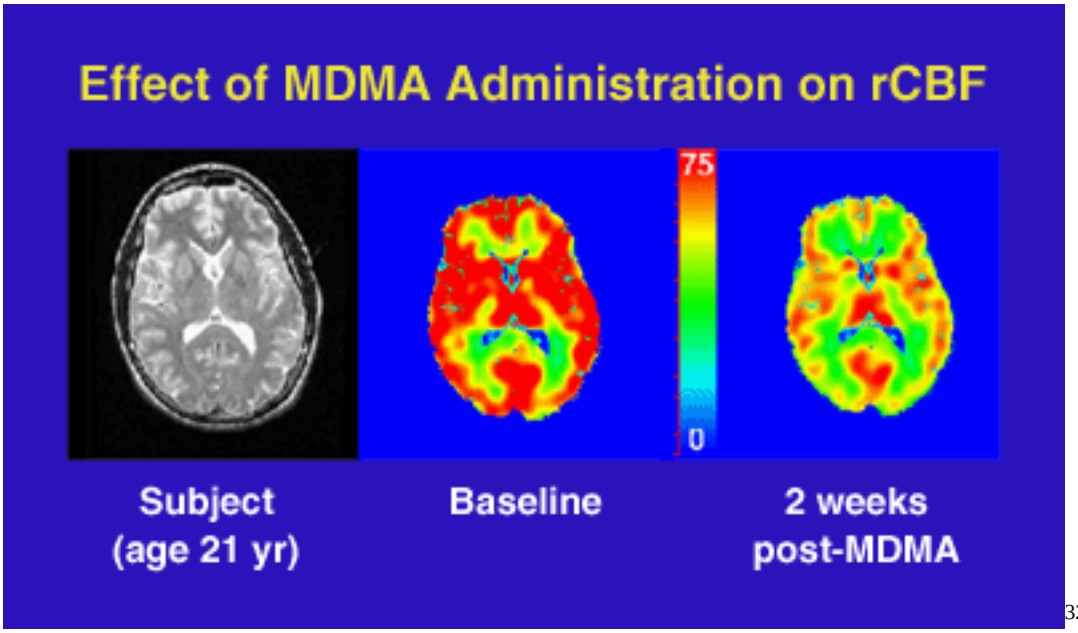
It is also notable that the *Phan* memo compared the discrepancy between fact and reality of MDMA's harmfulness to the discrepancy regarding the crack cocaine guideline at issue in *US v. Kimbrough.*[28] In other words, the Commission's formulation of the Guideline for MDMA sentences, similar to its original formulation for crack cocaine, is based on alarmist and now discredited studies.

In 2004 I published a rebuttal to a number of arguments and studies used to justify MDMA's continued criminalization, including studies used to the 2001 guidelines.[29] For example, then-NIDA Director Alan Leshner's 2001 Senate Subcommittee on Government Affairs testimony was incredibly misleading; Leshner led the Senators to believe that MDMA caused permanent changes in cerebral blood flow, but in fact, the changes were both temporary and of no clinical consequence. As I explain in my 2004 rebuttal in more detail:

> Testimony that then-NIDA Director Alan Leshner gave on July 30, 2001 to the Senate Subcommittee on Government Affairs, illustrated with a large poster purporting to show that MDMA negatively affects (reduces) cerebral blood flow, was clearly misleading. The poster [below, 31] showed a healthy-looking brain with what was represented as normal cerebral blood flow, with this image labeled "Baseline." For comparison purposes, the poster also contained a second brain scan image of the same subject with reduced cerebral blood flow. This image was labeled "Two weeks post-MDMA." What Leshner didn't tell the Senators is that the scans were drawn from a study that showed no difference between Ecstasy users (N=21) and controls (N=21) in cerebral blood flow (Chang et al. 2000).[30]
>
> The images Leshner used in his Senate testimony came from one of the subset (N=10) of the Ecstasy users in the larger study who participated in Dr. Grob's Phase I MDMA safety study. These ten subjects were scanned at baseline, like the other eleven Ecstasy-using subjects in Dr. Chang's research. They were then scanned again after receiving two doses of MDMA administered in the context of Dr. Grob's study, at time points ranging from two weeks to 2-3 months after the last dose of MDMA. Subjects scanned two weeks after MDMA showed a temporary reduction in cerebral blood

[27] *Id.*
[28] *Id.* at 8-10.
[29] Doblin, Rick, *Exaggerating MDMA's risks to justify a prohibitionist policy*, MAPS Research Archive (January 16, 2004) ("Doblin 2004"). Found at: http://www.maps.org/research-archive/mdma/rd011604.html.
[30] Chang, et. al., *Effect of ecstasy 3,4-methylenedioxymethamphetamine / MDMA on cerebral blood flow: a co-registered x SPECT and MRI study*, Psychiatry Research: Neuroimaging Section 98 (2000), 15-28.

flow while subjects scanned from 2-3 months after MDMA showed a return to baseline. The impression Leshner left the Senators was that MDMA caused permanent changes in cerebral blood flow when the changes were both temporary and of no clinical consequence.[31]

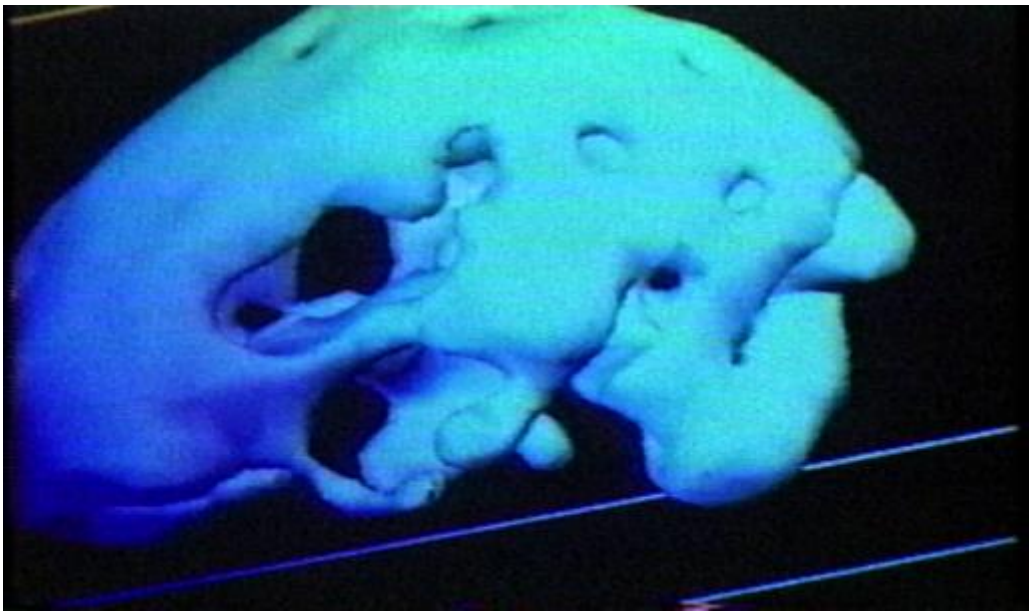


[32]

Ironically, Leshner didn't realize that in order to participate in the Phase 1 study and receive MDMA, FDA required subjects to have already had substantial exposure to MDMA. On average, the subjects in Dr. Chang's study had an exposure to MDMA of 211 times. Thus, the healthy-looking brain that Leshner showed to the Senators to contrast with the image of the same brain two weeks post-MDMA was actually the brain of a heavy MDMA user at baseline! If he had fully understood the science underlying the images he showed to the Senator, Leshner should have reported that the baseline image dramatically illustrated that MDMA caused no persisting long-term differences in cerebral blood flow as compared to the non-MDMA using controls. Instead, he used the image to convey an impression of the dangers of MDMA at odds with what the study actually demonstrated.

[31] Leshner, Alan, Hearing Before the Senate Subcommittee on Governmental Affairs - "Ecstasy Abuse and Control" Statement for the Record (July 30, 2001). Found at: http://www.drugabuse.gov/Testimony/7-30-01Testimony.html.

[32] Image originally found at: https://archives.drugabuse.gov/Testimony/7-30-01Testimony.html.



My rebuttal also addressed the misleading and alarmist myth that MDMA causes "holes" in user's brains. I wrote:

> Frightening and disturbing images of the brain of an MDMA user that showed explicit holes in the brain [above] that were claimed to have been caused by MDMA have been shown on an MTV special documentary about Ecstasy, as well as on an Oprah Winfrey show. These images were graphically manipulated to represent areas of lower cerebral blood flow as holes and are completely fraudulent. According to a March 2001 educational program about drugs aimed at young people that NIDA helped create, Alan Leshner stated, "We've heard people talk about Ecstasy causing holes in the brain and of course that's a bit of an exaggeration, but there is a core truth to it."[33]

The *Phan* memo provides another example of similarly problematic science: a leading MDMA neurotoxicity researcher, with federal funding from NIDA, published numerous retractions after admitting to mistakenly researching methamphetamine, not MDMA. The *Phan* memo explains:

> The Commission also relied on several studies that were not able to be replicated, or scientists whose work was fraught with methodological problems. For instance, Dr. George Ricaurte, cited and relied upon as '[a] leading researcher in MDMA toxicity studies' in the Commission's 2001 report to Congress, had to

[33] Doblin 2004.

> retract multiple studies after it was discovered that they had not been done with MDMA, but with mislabeled vials of methamphetamine. After this error came to light, in 2003 the journal Science retracted a Ricaurte study purporting to show that a single dose of MDMA could cause brain injury. The mislabeled vials corrupted several of Ricaurte's other studies, as well, and he was forced to withdraw four other papers. Even scientists Ricaurte named in defense of his work were quoted in the New York Times as saying that "some of his best-known work has nonetheless been 'sloppy' or 'not as methodologically rigorous as you might want."[34]

From 1989-2002, Drs. Ricaurte and McCann received federal grants totaling over $14.6 million dollars for MDMA and MDMA-related research.[35]

At my USSC testimony in March 2001, I opposed increasing penalties for MDMA for two primary reasons. The first was that enhanced penalties would increase difficulties in obtaining FDA and DEA permissions to conduct legitimate scientific research into the risks and benefits of the therapeutic use of MDMA as an adjunct to psychotherapy. The second, which is particularly relevant to this testimony, is that MDMA's risks have been greatly exaggerated, particularly the risk of serious functional or behavioral consequences from MDMA neurotoxicity.

USSC's sharp increase in mandatory minimum sentences for MDMA crimes in 2001, from a 35:1 to a 500:1 marijuana-to-MDMA ratio, reflects the hysteria, not the science, much like the circumstances responsible for MDMA's criminalization in the first place. Today, even more data is available to rebut the exaggerated claims of the past.

c. Most commonly cited MDMA neurotoxicity studies are misleading.

Animal studies that demonstrated MDMA to be neurotoxic were using extremely high doses of MDMA, not at all comparable to doses commonly used in humans. These studies administered multiple doses 50 to 100 times higher than doses used in human clinical trials, if appropriate allometric scaling is used between species. Serotonergic toxicity has not been found with doses close to the range used in clinical and recreational use.[35] However, as the MAPS Investigator's Brochure, a literature review of over 600 relevant MDMA studies, writes:

> Repeated very high doses of MDMA in animals reduce total serotonin levels in the brain, impair transport of serotonin, and cause psychobehavioral changes such as increased anxiety...However, the majority of these studies employed large doses of MDMA that overestimated human-equivalent doses, with findings now clearly indicating that doses used in nearly all rat and most primate studies

[34] *Phan* memo at 18 (citations omitted).
[35] Jerome, Ilsa, Ph.D., *NIDA and NCRR Funding for Ricaurte and McCann 1989-2003*, MAPS (2004). Found at: http://www.maps.org/research-archive/mdma/ricaurtefunding.pdf.

> are inappropriately high for comparison to use in clinical settings and are more pertinent toxicological effects of MDMA.[36]

In addition, the "timebomb" theory of MDMA neurotoxicity was premised on the belief that MDMA neurotoxicity was indeed harmful; but not because of MDMA's acute or short-term effects, but rather for effects that some predicted would only show up later in life, perhaps 25 years from when the MDMA was actually being used. However, more than 25 years have passed since those claims were made and we can see now that those fears have not been actualized.

III. MDMA's Robust Prosocial Capacity and Low Risk Profile

a. MDMA's Risk Profile

Analysis and research compiled in MAPS Investigator's Brochure suggests that MDMA's physiological effects are mild when consumed at common recreational and therapeutic doses, and "likely to be well tolerated by healthy individuals."[36] These physiological impacts rarely reach "elevations that exceed those seen after moderate exercise."[37] Negative effects include "lack of appetite, insomnia, dizziness, tight jaw or bruxism, difficulty concentrating, headache, impaired gait or balance, muscle tension, ruminations, feeling cold, and thirst," as well as a mild immunosuppressant effect.[38]

However, MDMA combined with aerobic dancing, a hot crowded environment and not drinking enough water, can become a lethal mix, sometimes resulting in heatstroke. A standard dose of MDMA raises body temperature about one degree, and also inhibits the body's natural thermoregulation, increasing likelihood of heatstroke. Heatstrokes can be easily avoided with the implementation of basic harm reduction measures like access to free water or "cool down rooms." Very rarely, Ecstasy users drink too much water and die from hyponatremia, preventable by substituting drinks with electrolites like Gatorade or fruit juices instead of water.

Black-market MDMA possesses a higher risk profile than responsibly-dosed, pure MDMA. The risks of consuming illicit MDMA include: taking MDMA in an unsafe physical or psychological setting, insufficient knowledge about MDMA, insufficient access to basic harm reduction measures, ingesting a more dangerous substance that is sold as (but is not actually) MDMA, and risks associated with contact with law enforcement. *These risks, however, are all the result of MDMA's criminalization, not MDMA itself.*

MAPS has developed an expertize in minimizing the harms of problematic use of psychedelic substances. MAPS sponsors a program called the Zendo Project, which supports

[36] IB (*supra* note 3) at 9.
[37] *Id.*
[38] *Id.*

medical and emergency teams at large festivals and events across the United States and the world by working with people having difficult psychedelic experiences, commonly known as "bad trips." Instead of being arrested by police or tranquilized by medical staff unfamiliar with psychedelic experiences, the Zendo Project provides a supportive space and peer-counselors specially trained to de-escalate challenging psychedelic experiences, and ultimately transform them into valuable healing and growing opportunities. The Zendo Project has supported almost 2,000 people[39] through difficult psychedelic experiences. Notably, MDMA produces far fewer difficult psychological experiences than substances such as LSD, despite MDMA being more popular. At Burning Man, a festival that hosts 70,000 attendees for a week in the Nevada desert, approximately 6% of Zendo's drug-related intakes in 2016 were related to MDMA.

MDMA is not and has never been the dangerous drug it was once made out to be. Emergency room statistics from 2011 - the most recent publicly available data - show that MDMA-related emergency department visits only amounted to only 1.8% of drug or alcohol-related visits that year.[40] A majority of these visits were inspired by acute psychological distress, and most cases were resolved after supportive care.[41] Further, between 2013 and 2016, the rate of MDMA use in young people has decreased.[42] The social harm from MDMA use is small, and although its use does come with certain risks, they can be significantly mitigated or eliminated with education, harm reduction, and decriminalization.

b. MDMA literature reviews highlight MDMA's prosocial capacities.

In July 2016, the peer-reviewed scientific journal Cell published a commentary about current research into the use of MDMA as a probe for social behaviors and as an adjunct to psychotherapy. The article, authored by neuroscientists Boris Heifets, M.D., Ph.D., and Robert Malenka, M.D., Ph.D., of Stanford University, summarizes current knowledge about MDMA's mechanism of action, highlighting its ability to catalyze prosocial, empathogenic effects. The authors of the Cell article write:

> Here, we argue for the importance of using all the available tools of modern basic and clinical neuroscience research to maps MDMA's mechanism of action in the brain.
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> [...]
>
> While such pragmatic clinical studies will certainly be important, we are equally excited about the utility of MDMA as a unique and relatively simple manipulation that can be used to probe the neural

[39] Since 2012, the Zendo Project has assisted 1,986 guests and trained approximately 1,166 volunteers, and trained hundreds more in the principles of psychedelic peer counseling.
[40] Drug Abuse Warning Network, *2011: National Estimates of Drug-Related Emergency Department Visits*. HHS (2011). Found at: http://archive.samhsa.gov/data/2k13/DAWN2k11ED/DAWN2k11ED.htm.
[41] IB (*supra* note 3) at 32.
[42] *Monitoring the Future Study: Trends in Prevalence of Various Drugs*. NIDA (2013-2016). Found at: https://www.drugabuse.gov/trends-statistics/monitoring-future/monitoring-future-study-trends-in-prevalence-various-drugs

> basis of prosocial behaviors in a wide range of species.
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> [...]
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> As a probe of brain function, [MDMA] is a remarkably simple but powerful tool that can be used to advance our understanding of the neural basis of empathy, social reward, and related prosocial behaviors. Such understanding can only benefit individuals and the human interactions in which they engage. The world's populations need more compassion and empathy for one another. The study of MDMA provides one small but potentially important step toward reaching that goal.[43]

MAPS has also compiled and published a comprehensive Investigator's Brochure, which is a summary and analysis of the world's relevant, peer-reviewed literature about MDMA. MAPS published the Eighth Edition of the IB in March 2016.[44] The Investigator's Brochure includes a number of notable findings, a short excerpt of which is quoted below:

> The combined neurobiological effects of MDMA can increase compassion for self and others, reduce defenses and fear of emotional injury, and make unpleasant memories less disturbing while enhancing communication and capacity for introspection. These factors taken together can provide the opportunity for a corrective emotional experience in the context of psychotherapy. Many of the therapeutic effects of MDMA-assisted psychotherapy are evident within a short period of treatment, often after the initial session.
>
> Increased feelings of interpersonal closeness, changes in social perception and reduced anxiety may make MDMA a suitable pharmacological adjunct to enhance psychotherapy for anxiety disorders, such as PTSD and social anxiety in autistic adults. MDMA may provide a much needed option in the treatment of PTSD and anxiety associated with other conditions. Published results from MAPS study (MP-1) showed clinically and statistically significant improvements in PTSD severity in 20 per protocol subjects. Findings from the long-term follow-up of MP-1 suggest that therapeutic benefits were sustained for an average of 41 months post-treatment. The sponsor's second Phase 2 pilot study conducted in Switzerland (MP-2) demonstrated clinically significant improvements in PTSD symptoms, with results in the 125 mg MDMA dose group numerically but not statistically superior to the

[43] Heifets, Boris, M.D., Ph.D., and Malenka, Robert, M.D., Ph.D., *MDMA as a Probe and Treatment for Social Behaviors*, Cell (July 14, 2016) ("Heifets"). Found at: http://www.cell.com/cell/fulltext/S0092-8674(16)30853-4.
[44] IB (*supra* note 3).

> 25 mg MDMA dose group. Long-term follow-up data 12 months later suggest that therapeutic benefits continued to increase in this subject population. There were no drug-related Serious Adverse Events (SAEs) or safety concerns in either study.
>
> Data from MAPS studies and published literature show that MDMA produces sympathomimetic effects that...are likely to be well tolerated by healthy individuals. Most people do not experience elevations that exceed those seen after moderate exercise….Common reactions reported in the literature and clinical trials from MDMA are transient and diminish as drug effects wane during the session and over the next one to 7 days…. Due to [the limited duration of listed effects,] these sub-acute reactions are not likely to have clinical significance.
>
> As of 01 October 2015, with 1180 individuals exposed to MDMA in controlled research settings (which includes 122 in MAPS-sponsored studies), there have been no unexpected drug-related SAEs to date, and expected SAEs have been rare and non-life threatening.[45]

In sum, there is evidence that MDMA can result in increased compassion, decreased anxiety, and a change in perception that combines effectively with psychotherapy to produce fertile grounds for personal healing and development. Results from MAPS-sponsored research with MDMA-assisted psychotherapy for PTSD is particularly encouraging. At this time, MAPS has completed Phase 2 investigations of MDMA-assisted psychotherapy for PTSD, we are now preparing to begin Phase 3.

c. MAPS has sponsored and published FDA-approved studies demonstrating the healing capacity of MDMA-assisted psychotherapy in clinical settings.

Since 2001, MAPS has sponsored nine FDA-approved drug development studies evaluating the efficacy of MDMA-assisted psychotherapy for psychiatric disorders including PTSD, anxiety associated with a life threatening illness, and social anxiety in autistic adults, at research sites across the United States and around the world. MAPS' FDA-approved clinical trials have demonstrated that MDMA, in conjunction with psychotherapy, has promising therapeutic capabilities. In November 2016, the Food and Drug Administration approved a large-scale, Phase 3 trial of MDMA-assisted psychotherapy for chronic PTSD, the final phase of research required for full FDA-approval for MDMA-assisted psychotherapy. If Phase 3 follows Phase 2's success, the trial would trigger MDMA's rescheduling, as MDMA would no longer qualify for Schedule I with "no accepted medical use."

[45] IB (*supra* note 3) at 9.

FDA's green light for Phase 3 MDMA/PTSD studies was based on the results of a meta-analysis from Phase 2 MDMA/PTSD pilot studies in 107 subjects: in all participants' evaluated so far for the 12-month follow up after experiencing MDMA-assisted psychotherapy for PTSD (N=86), 67% of participants no longer met PTSD diagnostic criteria. For comparison: the only medications currently FDA-approved to treat PTSD, Zoloft and Paxil, are approximately 50% effective at reducing symptoms of PTSD, but not eliminating them. In one small MDMA-assisted psychotherapy pilot study in Charleston, South Carolina, 83% of participants no longer qualified for PTSD,[45] and three-quarters of participants sustained their PTSD-free results three and a half years later.[46]

A MAPS pilot study evaluating MDMA-assisted psychotherapy for the treatment of social anxiety in autistic adults has produced promising results that support a large effect size in treating social anxiety symptoms, with data being prepared for a scientific paper to be submitted for publication. Results are not available for our study of MDMA-assisted psychotherapy for anxiety associated with life-threatening diagnoses, but the study is ongoing and a review of the safety data has revealed that MDMA is well-tolerated in this population.

MDMA-assisted psychotherapy works by allowing the participant to address the root cause of his or her trauma in a safe and supportive environment, and re-process that trauma without the debilitating associations of fear and anxiety. MDMA reduces fear activation in the amygdala, which allows participants to revisit past trauma, and develop compassion for themselves.

One study participant, a military veteran named CJ Hardin, explained to the New York Times in November 2016: "[MDMA] changed my life...It allowed me to see my trauma without fear or hesitation and finally process things and move forward…[Before] I just felt hopeless and in the dark...But the MDMA sessions showed me a light I could move toward. Now I'm out of the darkness and the world is all around me."[46]

Another study participant named Julie Nelson, who survived sexual assault, recounts to Elle magazine in March 2017: "[MDMA] was like stepping off a burning tightrope...I always felt shredded internally, and this was the first time I felt whole and soft, and that the world wasn't trying to eat me."[47]

d. Highlights of Non-MAPS MDMA Research

As more MDMA research is published, more institutions continue to show interest in pursuing this promising line of research. MAPS is collaborating with a number of VA therapists across the country and is funding several research pilot projects combining MDMA with existing psychotherapeutic approaches to PTSD including Cognitive Behavioral Conjoint Therapy and Prolonged Exposure. In the U.K. a MAPS-trained psychiatrist is starting a study evaluating MDMA-assisted psychotherapy in the treatment of alcohol use disorder. Yale University's Department of Psychiatry will be starting a study increasing exploration of MDMA's mechanism

[46] Philipps, David. *F.D.A. Agrees to New Trials for Ecstasy as Relief for PTSD Patients*, New York Times (November 29th, 2016). Found at: https://www.nytimes.com/2016/11/29/us/ptsd-mdma-ecstasy.html?_r=0.
[47] Kamp, Louisa, *Could a Club Drug Be The Secret to Curing PTSD?* Elle Magazine (March 1, 2017). Found at: http://www.elle.com/culture/a43266/mdma-ecstasy-molly-ptsd-treatment/.

of action, with a focus on fMRI neuroimaging research in people with PTSD after they have taken MDMA. NIDA has provided grants to the University of Chicago Psychiatry and Behavioral Neurosciences Department to conduct studies of MDMA and emotional processing. Two such studies, which draw conclusions about MDMA's prosocial capacities, are summarized here:

One study, entitled "MDMA decreases the effects of simulated social rejection," concluded:

> Our finding that MDMA decreases perceptions of rejection in simulated social situations extends previous results indicating that MDMA reduces perception of social threat in faces. Together these findings suggest a cognitive mechanism by which MDMA might produce pro-social behavior and feelings and how the drug might function as an adjunct to psychotherapy. These phenomena merit further study in non-simulated social environments.[48]

A second study entitled "MDMA alters emotional processing and facilitates social interaction" concluded:

> MDMA alters basic emotional processes by slowing identification of negative emotions and increasing responses to positive emotions in others. Further, it positively affects behavior and perceptions during actual social interaction. These effects may contribute to the efficacy of MDMA in psychotherapy, but appear less closely related to its abuse potential.[49]

e. Non-clinical MDMA use can produce self-healing.

While non-clinical use of Ecstasy can be problematic for some people, and in rare instances even fatal when consumed in certain temperature-elevated settings without harm reduction services , there are also thousands of people who have experienced healing benefits from MDMA even when taken outside of clinical settings. There are numerous anecdotal accounts of self-medication and self-healing posted on the internet. Multiple short documentaries have been produced detailing the experiences of veterans who cured their own PTSD with MDMA.[50] MAPS has heard hundreds of anecdotes of personal accounts from people who have used MDMA to heal from a number of other mental and physical health disorders, ranging from eating disorders to alcoholism; dozens of these accounts have been published on the MAPS website.[51] One such anecdote, written by a woman who used MDMA with her husband to heal from her sexual trauma,

[48] Frye, C.G., M.C. Wardle, G.J. Norman, H. de Wit (2014) MDMA decreases the effects of simulated social rejection. *Pharmacology, Biochemistry and Behavior*, 117, 1-6. PMC3910346
[49] Wardle, M.C., H. de Wit (2014) MDMA alters emotional processing and facilitates social interaction. *Psychopharmacology*. PMC4194242
[50] *See* Ecstatic States, found at: https://vimeo.com/94074343. *See also* Psychedelic Soldiers, found at: https://www.youtube.com/watch?v=hGVaiC0SwsQ.
[51] *Accounts of MDMA's Healing Effects,* MAPS. Found at: http://www.maps.org/research/mdma/104-research/mdma/other-mdma-resources/5401-accounts-of-mdma%E2%80%99s-healing-effects.

is excerpted here:

> My first experience [with MDMA] was marriage-saving and life-changing, allowing me to acquire an emotional bond with my husband through empathy, compassion, and understanding that I had never before experienced, and a "discovery of body", which (after years of sexual dysfunction in our marriage, i.e. painful intercourse only endured with tears streaming out of my eyes and following through out of duty alone, never knowing if I had ever experienced an orgasm,) was beyond words as I experienced sex "how it was meant to be" for the first time ever. I achieved a different perspective on life and a sense of harmony with the universe and that I was wanted and somehow needed on the planet, just enough to give me back the will to live. Little did I know that this was the first step that had to take place in the uncovering of the layers that were built up around at least one sexual trauma in my past; walls so thick that I convinced even myself that the trauma never existed.
>
> […]
>
> This MDMA substance was able to provide the necessary detachment from the physical pain that I needed in order to get in touch with what physically happened, it opened me up to the compassion that I needed to feel towards myself and gave me the courage to accept my own responsibility and why it happened, it provided the confidence I needed to be able to have faith in my own ability to honestly communicate this event to my husband after having lied to him about it for all those years, it gave me faith in his ability to understand and have compassion towards me while at the same time it gave me compassion and understanding towards him for the hurt that he felt from the lies and misrepresentation, and it drove me with a resolve I needed to pursue getting better and to seek out the proper help that I needed to deal more effectively with these issues. This MDMA substance gave me a passion for and a drive toward seeking out the truth about myself and about this event, whereas other prescription anti-depressant and anti-anxiety type drugs that I had taken in the past had killed the memories and "made me happy" in a denial-type, temporary fashion.[52]

[52] Anonymous. *MDMA for PTSD for Violent Sexual Abuse*. Found at: http://www.maps.org/research-archive/mdma/june022704.html. (Note that this was anonymously reported for fear of incrimination).

IV. Conclusion

In sum, the totality of evidence we have available, which is significantly more than there was when the USSC came to its first conclusion - that one gram of MDMA should carry with it the same penalties as 500 grams of cannabis – strongly indicates that the sentencing guidelines are extremely disproportionate and in fact unrelated to MDMA's actual risks. The MDMA Sentencing Guideline should reflect MDMA's actual risk profile, rather than the exaggerated and inaccurate risk profile that it has been presented with in the past.

V. Appendices

APPENDIX A: MDMA Investigator's Brochure, 8th Ed. (30 March 2016) ("IB")

APPENDIX B: *US v. Phan* (W.D. WA 2011), Supplemental Sentencing Memorandum ("*Phan* memo")

APPENDIX C: *US v. McCarthy* (S.D. NY 2011), Memorandum and Order ("*McCarthy* order")

APPENDIX D: MAPS/ACLU Sentencing Press Release

APPENDIX E: Media Highlights