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Mending Invisible Wounds: The Efficacy and Legality of MDMA-Assisted Psychotherapy in United States' Veterans Suffering with Post-Traumatic Stress Disorder

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MENDING INVISIBLE WOUNDS: THE EFFICACY AND LEGALITY OF MDMA-ASSISTED PSYCHOTHERAPY IN UNITED STATES' VETERANS SUFFERING WITH POST-TRAUMATIC STRESS DISORDER

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I. INTRODUCTION

In 2001, the United States invaded Afghanistan.[1] Two years later, American armed forces were fully deployed in both Afghanistan and Iraq, and their presence persists to this day.[2] Amidst the loss of life exists a subtler tragedy: psychiatrists report that around 20% of service members suffer from post-traumatic stress disorder upon returning home from combat.[3] More distressingly, an average of 22 veterans commit suicide each day.[4]

Though anecdotal, the story of Andrew Brennan provides an extreme but powerful narrative of PTSD's suffocating grasp on returning veterans.[5] The State of Alabama recently refused to stay the execution of the 66-year-old Vietnam veteran who was imprisoned for shooting an Atlanta police officer in 1998.[6] At trial, Mr. Brennan's lawyers pointed out that he had been diagnosed with severe posttraumatic stress disorder as a result of his service in Vietnam.[7] On the night of the shooting, Mr. Brennan was "in the throes of an emotional flashback" when he pulled a rifle from his truck and began shooting at the officer.[8] At the time of the tragedy, Mr. Brennan had been prescribed anti-psychotic medication for a diagnosed bipolar disorder.[9] This approach—a reliance solely on prescription medication as a remedy for PTSD—proved unsuccessful here, as it has so many times before.[10]

Although many of organizations exist to support troops suffering with post-traumatic stress disorder,[11] a veteran's ability to receive effective emerging treatments from their healthcare provider is frustrated by outdated legislation.[12] Emerging

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[1] BARBARA SALAZAR TORREON, CONGRESSIONAL REPORT SERVICE, U.S. PERIODS OF WAR (2010).

[2] *Id*.

[3] *See* Lisa Richardson et al., *Prevalence Estimates of Combat-Related PTSD: A Critical Review*, 44 AUSTRALIAN AND NEW ZEALAND J. OF PSYCHIATRY 4 (2011).

[4] *See* JANET KEMP AND RONALD BOSSARTE, DEP'T OF VETERAN AFFAIRS, SUICIDE REPORT: 2012 (2013).

[5] *Panel Refuses to Stop Execution of Vietnam Vet With PTSD*, MIL. TIMES (January 13, 2015).

[6] *Id.*

[7] *Id*.

[8] *Id*.

[9] *Id*.

[10] *See, e.g. Disjunctive Risperidone Treatment for Antidepressant-Resistant Symptoms of Chronic Military Service–Related PTSD*, 306 J. of Am. Med. Ass'n 5 (2011).

[11] *Id.*

[12] *See* Justin Smith, *The Values and Control of MDMA*, 10 CONTEMP. JUSTICE REV. 297 (2007).

treatments and research seeking to combat PTSD are hindered by the Drug Enforcement Agency's ("DEA") interpretation, and subsequent reinterpretations, of the Controlled Substances Act.[13] Scheduling substances as "Schedule I" prohibits healthcare professionals from utilizing emerging remedies in PTSD treatment by erecting various administrative and bureaucratic barriers to research. [14] As a result, some substances with positive medical purposes are kept from those who must be afforded all possible remedies.[15]

Schedule I classification requires medical researchers to obtain FDA approval before experimentation, a burdensome hurdle in the way of furthering understanding of the substance.[16] Researchers are further required to record and secure all testing procedures in conformance with DEA guidelines, a process that further confines the scope of research.[17] Lastly, classifying drugs as Schedule I has historically created a stigma that makes research vastly more difficult, as volunteers become scarce and the incentive to investigate becomes associated with criminal behavior and a poor professional reputation. [18] The timing of the classification strikes a massive blow to the mental stability of returning troops; neurological and psychopharmacological research began providing its most insightful and promising research just as the federal government began crippling access to the substance. As a result, a massive pool of veterans, ranging from Vietnam to the current engagement, were stripped of a chance to alleviate the vicious symptoms of post-traumatic stress disorder.

The most compelling emerging treatment is commonly referred to as "MDMA-assisted psychotherapy," in which psychiatrists incorporate 3,4-methylenedioxy-methamphetamine into one-on-one or group therapy sessions with veterans suffering with PTSD.[19] Although psychiatrists studied the therapeutic benefits of MDMA-assisted psychotherapy throughout the 1970's and 1980's, research was suppressed by the DEA's classification of MDMA as a Schedule I substance in 1986.[20] In the last decade, however, there has been a resurgence of interest, funding, and medical

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[13] *Id*.

[14] *Id*.

[15] *See* Alan Zarembo, *Exploring Therapeutic Effects of MDMA on Post-Traumatic stress*, L.A. TIMES, (March 15, 2014), http://articles.latimes.com/2014/mar/15/local/la-me-mdma-20140316.

[16] Grinspoon v. Drug Enforcement Admin., 828 F.2d 881, 896 (1st Cir. 1987). "Dr. Grinspoon has correctly identified several ways in which the placement of MDMA in Schedule I will impede his research and the efforts of other researchers interested in exploring the possibility of clinical uses for MDMA." *Id*.

[17] *Id*.

[18] Renee Lewis, *DEA approves study using MDMA for anxiety in seriously ill patients*, Al Jazeera America (March 17, 2015), http://america.aljazeera.com/articles/2015/3/17/clinical-trial-approved-for-mdma-psychotherapy.html .

[19] MDMA-assisted therapy sessions demonstrated the greatest efficacy when conducted two-three times annually. *See* Michael Mithoefer ET AL., *Safety and Efficacy of±3, 4-methylenedioxymethamphetamine-Assisted Psychotherapy in Subjects with Cronic, Treatment-Resistant Posttraumatic Stress Disorder*, 25 J. OF PSYCHOPHARMACOLOGY 439 (2011).

[20] *See* NAT'L INSTITUTE OF HEALTH, WHAT WE KNOW AND DON'T KNOW ABOUT MDMA: A SCIENTIFIC REVIEW (2001).

research on the efficacy, safety, and necessity of MDMA-assisted therapy.[21] This comes as a result of the current state of veteran treatment effectiveness, which cannot suppress the growing prevalence of the disorder.[22]

Though Veteran Affairs has provided crucial life sustaining—and often lifesaving—treatments to returning soldiers, the substantial and ever-increasing rates of veteran suicides, drug addictions, and criminal behavior indicate a need for broader options in treatment.[23] One of the most profound discoveries uncovered through MDMA-assisted psychotherapy research is MDMA's facilitation of the alleviation of addictive behavior in subjects, and, as a result, an alleviation of addictions in general.[24] Addiction is one of the key symptoms of posttraumatic stress disorder, and drug abuse plays a large role in the other afflictions suffered by veterans, namely criminal activity and a high rate of suicide.[25] If there is any hope of treating this debilitating psychotic phenomenon—or at least containing its rapid growth and addressing its profound depth—alternative remedies as a means must not be ignored for a normative end.[26]

Accordingly, this article will argue that physicians must be able to treat PTSD victims through MDMA-assisted psychotherapy, an alternative remedy to PTSD treatment that has shown overwhelming promise in domestic and international medical research. In doing so, it will first discuss 21 U.S.C.A. § 812, which labels MDMA as a Schedule I substance and prohibits healthcare professionals from using MDMA-assisted psychotherapy to treat PTSD victims.[27] Next, the article will assert that the Drug Enforcement Agency ("DEA") erroneously categorized MDMA as a substance lacking an accepted medical use and lack of safety under medical supervision.[28] The article will set out studies, domestic and international, where clinical testing of MDMA-assisted therapy to treat PTSD have been met with

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[21] Treating PTSD with MDMA-Assisted Psychotherapy website: http://www.mdmaptsd.org/news.html.

[22] *See* Cukor ET AL., *Emerging treatments for PTSD*, 29 CLIN. PSYCHOLOGY REV. 715 (2009).

[23] Jack Gilbert, *Veterans are being given MDMA to help them forget about war*, Vice News (April 22, 2014, 1:00 PM) https://news.vice.com/article/veterans-are-being-given-mdma-to-help-them-forget-about-war.

[24] *See* Maia Szalavitz, *Ecstasy as Therapy: have some of its negative effects been overblown?*, Time (Feb. 18, 2011) http://healthland.time.com/2011/02/18/ecstasy-as-therapy-have-some-of-its-negative-effects-been-overblown/; *See also* Moreno-Lopez, et. al., *Neural Correlates of the Severity of Cocaine, Heroin, Alcohol, MDMA and Cannabis Use in Polysubstance Abusers: A Resting-PET Brain Metabolism Study*, PLOS One (June 29, 2012).

[25] *See* Tanielian & Jaycox, *Invisible Wounds of War: psychological and cognitive injuries, their consequences, and services to assist recover*, RAND Center for Military Policy Research (2008).

[26] *See* Brian Anderson, *The agony of ecstasy: the quiet mission to fight PTSD with MDMA*, Vice News (August 16, 2011) http://motherboard.vice.com/blog/the-agony-and-the-ecstasy-the-quiet-mission-to-fight-ptsd-with-psychedelic-drugs; *see also* John Richards, *Amphetamine derivatives*, 5 Nova Science 81 (2006).

[27] Controlled Substances Act, 21 U.S.C. § 812 (2009).

[28] *Id*.

overwhelmingly positive results. Finally, the article will argue that MDMA's accepted medical use, low physical and psychological dependence, and known safety under medical supervision support its classification as a Schedule III under the CSA, and that the 1986 classification of MDMA as a Schedule I narcotic was, and continues to be, an arbitrary and capricious agency interpretation of an otherwise viable piece of congressional legislation.

II. BACKGROUND

A. Brief History of MDMA: Origins, Therapeutic Uses, and Cultural Impact.

In 1914, the German pharmaceutical company Merck & Co. patented the substance 3, 4-methylenedioxymethamphetamine, commonly known as MDMA.[29] The origins of its synthesis are unclear: some assert that the purpose behind Merck's patent was to create an anorectic or diet suppressant, while others suggest that Merck utilized MDMA as a precursor to hydrastinine, a haemostatic drug.[30] Some evidence suggests that both American and German researchers resynthesized MDMA in the 1950s while seeking to create stimulants for Air Force pilots, however this fact is also contested.[31]

The first officially documented experiments involving MDMA in the United States occurred in a U.S. military-sponsored animal study in 1953.[32] The results of the study remained classified until 1972.[33] In this study, researchers investigated the lethal dosage levels ("LDs" or "LD/50s") of mescaline and seven analogs in five separate species of mammals: mice, rats, dogs, guinea pigs, and monkeys.[34] The core purpose of the study was to identify a lethal dosage of the substances in mammals.[35] For obvious ethical reasons, however, the lethal dosage levels in humans could only be inferred.[36]

In 1965, Alexander Shulgin, a chemist working at Dow Pharmaceutical Company, resynthesized MDMA.[37] Shulgin then published the first study testing MDMA's

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[29] *See* A.C. Parrott, *Human Pharmacology of Ecstasy: A Review of 15 Years of Empirical Research*, 16 HUMAN PSYCHOPHARMACOLOGY: CLINICAL AND EXPERIMENTAL 557 (2001).

[30] Bernschneider-Reif, et al., *The origin of MDMA ("Ecstasy") – separating the facts from the myth* (2006).

[31] *Id*.

[32] *Id*.

[33] *See* Hardman et al., *Relationship of the structure of mescaline and seven analogs to toxicity and behavior in five species of laboratory animals*, 25 Toxicology and Applied Pharmacology 299 (1972).

[34] *See* Alexander Shulgin, *History of MDMA*, *in* ECSTASY: CLINICAL, PHARMACOLOGICAL AND NEUROLOGICAL EFFECTS OF THE DRUG MDMA 1, 1-20 (1990).

[35] Hardman, *supra* note 33.

[36] *Id*.

[37] *See* Shulgin, *supra* note 34.

psychotropic effects in human subjects.[38] This study compared the effects of MDMA, 3,4-Methylenedioxyamphetamine ("MDA"), and 2-(5-Methoxy-1H-indol-3-yl)ethanamine ("mexamine") on human subjects.[39] Shulgin's study concluded that MDMA had a higher threshold than MDA,[40] and further that the substance "appear[ed] to evoke an easily controlled altered state of consciousness with emotional and sensual overtones. It can be compared…to psilocybin, devoid of the hallucinatory component, or to low levels of MDA." [41] Additionally, Shulgin acknowledged a need for further acute studies of psychotropics in human subjects, specifically in regards to MDMA's potential effect on mental illness.[42]

Two years later, researchers investigated MDMA's pharmacological properties in humans.[43] In 1978, Dr. George Greer published a clinical study whereby experimenters administered MDMA in humans.[44] Greer administered low level of MDMA to 29 patients in a medical setting.[45] The test sought to curtail "drug abuse problems, facilitate communication and intimacy between people involved in emotion relationships, and…as an adjunct to insight-oriented psychotherapy."[46] The test produced some undesirable side effects, none of which were serious and none that lasted longer than a week.[47] These included increased blood pressure and heart rate over the span of two hours.[48] Desirable side effects included alleviation of symptoms in subjects with DSM-III psychological disorders, "relieving low self-esteem and increasing self-acceptance and self-confidence," and relief of physical ailments such as back pain.[49]

Around the same time, researchers throughout the United States began administering MDMA in the therapeutic setting, recording its physical and psychological effects on human patients suffering with psychological disorders.[50] Undesirable physical effects, identical to those identified in Dr. Greer's 1976 study,

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[38] *See* Alexander Shulgin & Nichols, D.E., *Characterization of Three New Psychomimetics*, 74 PSYCHOPHARMACOLOGY OF HALLUCINOGENS 83 (1978).

[39] *See* Shulgin, *supra* note 34. MDA came into the view of medical researchers for its potential in treating various symptoms of Parkinson's disease. *Id*.

[40] *Id*.

[41] *Id.*

[42] *See* Shulgin, *supra* note 38.

[43] *See* Shulgin, *supra* note 38.

[44] *See e.g.*, George Greer, *MDMA: A New Psychotropic Compound and Its Effects in Humans* (1983).

[45] *Id*.

[46] *See* Shulgin, *supra* note 38.

[47] *See* Greer, *supra* note 44.

[48] *Id*.

[49] *Id*.

[50] *See* Philip Wolfson, *Meeting at the Edge with Adam: a Man for All Seasons*, 18 J. OF PSYCHOACTIVE DRUGS 329 (1986).

were uniformly reported.[51] These included elevated heart rate and blood pressure, as well as the suppression of appetite.[52] No instances of death, injury, or long-term neurological deficiency were reported.[53]

Subjectively, volunteers identified strong improvements in "self-understanding," spiritual and personal growth, a lessening of an otherwise powerful desire to abuse drugs or alcohol, and a renewed drive to address personal issues.[54] Other accounts indicate an increased desire and capacity to suppress drug abuse, heightened sensations of self-worth, and a transcendent sense of calm that persisted well beyond the conclusion of the experiments.[55] MDMA's significant psychological effects on patients suffering with depression, drug or alcohol abuse, and sexual dysfunction prompted a worldwide interest in the medical benefits of MDMA in the early 1970's[56]

Following early research, the general consensus in the medical community was that "MDMA is reasonably safe, produces positive mood changes in users, does not cause negative problems if used sparingly and episodically, and is without evidence of abuse."[57] That being said, the scientific data through the 1970's and early 80's had yet to conclusively show that MDMA use did not produce long-term neurotoxicity.[58] Nonetheless, as one study concluded, "MDMA, at the doses tested, has remarkably consistent and predictable psychological effects that are transient and free of clinically-apparent major toxicity."[59]

As its medical and social popularity increased throughout the 1970's and early 1980's, the Health and Human Services Department urged the continuation and expansion of MDMA research.[60] In spite of this, the FDA refrained from permitting any Investigational New Drug ("IND") license to medical researchers seeking to research MDMA, thus hindering the potential for expanded clinical research in humans.[61] With the medical community's desire for greater MDMA research came

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[51] *See* Harold Kalant, *Pharmacology and Toxicology of "Ecstasy" and Related Drugs*, 165 CANADIAN MED. J. 917, 925 (2001); *see also* Sotiria Bexis & James Docherty, *Effects of MDMA, MDA and MDEA on Blood Pressure, Heart Rate, Locomotor Activity and Body Temperature in the Rat Involve α-Adrenoceptors,* 147 J. OF PHARMACOLOGY, 926 (2006).

[52] *See* Shulgin, *supra* note 38.

[53] *Id.*

[54] George Greer & Requa Tolbert, *Subjective Reports of the Effects of MDMA in a Clinical Setting*, 18 J. OF PSYCHOACTIVE DRUGS 319 (1986).

[55] Marsha Rosenbaum & Rick Doblin, *Why MDMA Should Not Have Been Made Illegal*, *in* THE DRUG LEGALIZATION DEBATE (James A. Inciardi ed., 1991).

[56] *See* Shulgin, *supra* note 38.

[57] Joseph Downing, *The psychological and physiological effects of MDMA on Normal Volunteers* (1986).

[58] *Id*.

[59] *Id*.

[60] *See id.*

[61] *Id.*

public controversy and subsequent Congressional legislation, acting in conjunction to bring "clinical studies with MDMA…to a complete halt."[62]

B. Public Opposition, the Controlled Substances Act, and the Grinspoon Case

As scientific knowledge of MDMA's benefits began to grow, so too did its reputation as a dangerous "mind-altering psychedelic."[63] In 1981, the countercultural publication Wet ran a story promoting the use of MDMA.[64] The publication caused great controversy, and initiated a steeply divided debate on the medical benefits, harms, and legality of MDMA.[65]

By 1983, MDMA had grown popular in the American south.[66] In Texas, for example, several night clubs and bars were known to distribute MDMA to patrons.[67] The popularity of the substance among young club-goers attracted the attention of cocaine dealers, who began organizing complex and far-reaching sale structures of MDMA. As a result, "distribution grew and recreational, as opposed to the more therapeutically oriented use, increased dramatically. [68]

A few months later, open sales in Texas prompted legislators to push scheduling of MDMA. Shortly thereafter, the DEA filed its Notice of Proposed Rulemaking to the Federal Register, "announcing its intention to place MDMA in Schedule I."[69] As legislators and federal officials began their march toward full-force illegalization, medical professionals mobilized in resistance to this possibility. A "small but dedicated group of medical professionals maintained that MDMA was too valuable in therapy" to merely dismiss it.[70] Other medical researchers, however, along with the U.S Department of Justice, raised concerns of abuse and potential neurotoxicity in humans.[71]

As MDMA gained medical and cultural popularity in the 1970's and throughout the early 1980's, researchers quickly began to focus on what it perceived to be "potential neurotoxic qualities."[72] The Food and Drug Administration (FDA)

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[62] *Id.*

[63] *See* Shulgin, *supra* note 38.

[64] *See generally Ecstasy: Everything Looks Wonderful When You're Young and On Drugs*, WET MAGAZINE, p. 76 (1981).

[65] *See* Shulgin, *supra* note 38.

[66] *How the Starck Club Changed Dallas*, D Magazine (2013).

[67] Rosenbaum, *supra* note 55.

[68] *Id*.

[69] Marshal Rosenbaum and Rick Doblin, *Why MDMA Should Not Have Been Made Illegal*, THE PSYCHEDELIC LIBRARY, http://www.psychedelic-library.org/rosenbaum.htm (last visited March 24, 2016).

See Shulgin, *supra* note 34.

[71] *See id.*; *see also* E. O'Hearn et al., *Methylenedioxyamphetamine and Methylenedioxymethamphetamine Cause Selective Ablation of Serotonergic Axon Terminals in Forebrain*, THE J. OF NEUROSCIENCE, 2788, 2800 (1988).

[72] *Id.*

"temporarily scheduled" the drug as a dangerous narcotic in 1985, refusing to approve it for interstate marketing approval.[73]

In its 1987 Notice of Proposed Rulemaking, the DEA asserted that MDMA "lacked any legitimate medical uses, significantly threatened the health of users, and had a high potential for abuse."[74] In response, medical professionals with experience in conducting MDMA-assisted therapy throughout the United States fiercely opposed the "unjustified" agency determination.[75] These doctors asserted that MDMA was a "tremendous aid" to alleviating the symptoms of several devastating psychiatric conditions, and sought to support that assertion data.[76]

In spite of strong opposition from the medical community, DEA director John Lawn held an emergency scheduling hearing, where he announced that MDMA was an "immanent hazard to public safety," and placed it under Schedule I.[77] In response, Dr. Lester Grinspoon, a professor of Psychiatry at Harvard University, brought suit against the DEA administrator.[78] Dr. Grinspoon won his case before the Second Circuit Court of Appeals because, as the Second Circuit stated, "FDA approval is not determinative of a lack of acceptable medical use."[79] Thus, the scheduling was remanded to the DEA director for reconsideration.[80] Three months later, however, the DEA reissued its ruling, and once again classified MDMA as a schedule I narcotic with no accepted medical use.[81]

On March 23, 1988 the DEA placed MDMA into Schedule I under the Controlled Substances Act ("CSA") The CSA, which Congress passed in 1970, set out to accomplish three main goals: (1) to prevent drug abuse and dependence; (2) provide treatment and rehabilitation for drug abusers and dependents; and (3) strengthen law enforcement in the context of drug abuse.[82] The CSA created five classifications for

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[73] *See* Greer & Tolbert, *supra* note 44.

[74] 21 U.S.C. § 812 (2009).

[75] *See* 53 FR 5156-01 (1988). Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act, 53 Fed. Reg. 5156 (February 22, 1988)(to be codified at 21 CFR pt 1308).

[76] *Id.*

[77] The New York Times, *U.S. Will Ban 'Ecstasy,' A Hallucinogenic Drug*, http://www.nytimes.com/1985/06/01/us/us-will-ban-ecstasy-a-hallucinogenic-drug.html (last visited March 24, 2016).

[78] Grinspoon v. Drug Enf't Admin., 828 F.2d 881, 882 (1st Cir. 1987).

[79] *Id.*

[80] Richard Glen Boire, *The Politics of Medicine: the Schedluing of MDMA*, CENTER FOR COGNITIVE LIBERTY & ETHICS, http://www.cognitiveliberty.org/dll/mdma_scheduling_history.htm (last visited March 24, 2016).

[81] *Id.*

[82] Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236 (1970).

> Sec. 101. The Congress makes the following findings and declarations:

varying substances based on the drug's potential for abuse, dependence, and accepted medical uses.[83] In a final scheduling hearing, Director Lawn concluded that pursuant to the purposes of the CSA, and due to a lack of an accepted medical use and lack of known safety under medical supervision, MDMA would hereinafter be classified as a Schedule I.[84]

C. Veteran PTSD, Current Treatments, and MDMA-Assisted Psychotherapy[85]

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(1) Many of the drugs included within this title have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people. *Id*.

[83] United States Drug Enforcement Administration (DEA), *Drug Scheduling*, http://www.dea.gov/druginfo/ds.shtml (last visited March 24, 2016) .; Schedule I substances are those considered to have a high potential for abuse, no accepted medical use, and a lack of accepted safe use under medical supervision. *Id*.

[84] Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act, *supra* note 76.; Remand, 53 Fed.Reg. 5156 (1988).

a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) 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 safety for use of the drug or other substance under medical supervision.

(2) 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.

[85] The DEA has recently permitted a study of MDMA for patients suffering with anxiety due to life threatening illnesses. "The height of the drug war in 1985, the agency classified MDMA in Schedule I under the Controlled Substances Act. The federal government considers Schedule I drugs to be among the "most dangerous," with no known medical benefits and the potential for "severe psychological or physical dependence." That decision overruled a previous recommendation by the DEA's chief administrative law judge that the drug be placed in

This scheduling placed severe restrictions on MDMA research. For example, for several decades the FDA refused to permit experimentation because of a "concern for the health of volunteers."[86] Further, therapists and physicians abandoned clinical use and research of MDMA in fear of losing their license and damaging their reputations.[87] Thus, a substance with a substantial record of therapeutic benefits was abandoned as a result of the DEA's ruling.

Today, post-traumatic stress disorder is a highly prevalent psychological disorder in veterans of war.[88] The symptoms of PTSD are numerous and severe. These include vivid flashbacks, hallucinations, insomnia, nightmares, hyperarousal, negative changes in beliefs or mood, and other drastic behavioral changes.[89] These symptoms can be crippling to veterans seeking to assimilate to civilian life.[90]

For example, Tim Amoroso is a 24-year-old ex-Army Ranger who fought in Afghanistan.[91] Upon returning home to New Hampshire, Tim battled with "memories of looking for body parts" as a result of experiencing a suicide bomb attack on his platoon.[92] Like hundreds of thousands of returning vets, Tim turned to the VA in an attempt to eradicate these vicious memories.[93]

The VA prescribed Tim with antidepressants and antianxiety medications, neither of which brought meaningful relief.[94] The lack of efficacy of these medications led Tim to seek alternative remedies to treat his PTSD.[95] One summer, Tim purchased MDMA and ingested it under the supervision of a friend.[96] According to Tim, the positive effect of the MDMA outweighed anything he had experienced on

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Schedule III, which would have allowed doctors to continue using it in therapy." *See* Wing, infra note 170.

[86] Constance Scharff, Ph.D., *Does MDMA Have Psychotherapeutic Potential,* http://www.constancescharff.com/?p=248 (last visited March 24, 2016).

[87] Marsha Rosenbaum and Rick Doblin, *supra* note 55.

[88] Veterans and PTSD, *Veterans statistics: PTSD, Depression, TBI, Suicide*, http://www.veteransandptsd.com/index.html (last visited March 24, 2016)

[89] U.S. Department of Veterans Affairs, *PTSD: National Center for PTSD*, http://www.ptsd.va.gov/public/PTSD-overview/basics/symptoms_of_ptsd.asp (last visited March 24, 2016).

[90] *Id.*

[91] Alan Zarembo, *Exploring Therapeutic Effects of MDMA on Post-Traumatic Stress Disorder*, L.A. TIMES, (March 15, 2014), http://articles.latimes.com/2014/mar/15/local/la-me-mdma-20140316.

[92] *See id.*

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Id.*

antidepressants.[97] "I feel like I found meaning again," said Tim. "My life wasn't as bad as I thought it was."[98]

Since 2001, over 1.5 million American soldiers like Tim have been deployed to Afghanistan or Iraq.[99] Upon returning from deployment, Veteran Affairs estimates that 20-30% of soldiers suffer from post-traumatic stress disorder, major depressive disorder, traumatic brain injury, or some combination of the three.[100] Until recently, the hidden nature of these wounds has hindered research and subsequent understanding of this mental disorder.[101]

All Operation Iraqi Freedom ("OIF") and Operation Enduring Freedom ("OEF") veterans are eligible to receive aid from the VA.[102] That being said, young veterans face several challenges in accessing quality mental treatment from the VA.[103] For example, the VA operates on a fixed budget, and cannot be expected to keep pace with the rapid amount of OIF/OED and Vietnam veterans seeking treatment.[104] Further, VA services may give higher priority to physically-disabled veterans. Also, many veterans do not live close to a VA facility.[105]

Additionally, current PTSD treatments have not been met with meaningful success.[106] The VA offers four different services for PTSD treatment: one-on-one mental health assessment and testing, medications, individual and family psychotherapy, and group therapy.[107] Regardless of the available treatments, the average PTSD victim still qualifies for the disease four months after treatment.[108] Psychiatrists, physicians, and medical researchers question the efficacy of Prozac,

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[97] *Id*.

[98] *Id.*

[99] RAND Center for Military Health Policy Research, *Invisible Wounds: Mental Health and Cognitive Care Needs of America's Returning Veterans* (2008), http://www.rand.org/content/dam/rand/pubs/research_briefs/2008/RAND_RB9336.pdf .

[100] *Id.*

[101] *Id.*

[102] U.S. Department of Veterans Affairs, *Returning Service Members (OEF/OIF/OND)*, http://www.oefoif.va.gov/healthcare.asp (last visited March 25, 2016).

[103] RAND Center for Military Health Policy Research, *supra* note 99, at 4.

[104] *Id.*

[105] *Id.*

[106] *Id.*

[107] U.S. Department of Veteran Affairs, *PTSD Treatment Programs in the U.S. Department of Veteran Affairs*, http://www.ptsd.va.gov/public/treatment/therapy-med/va-ptsd-treatment-programs.asp (last visited March 25, 2016).

[108] C. Bartley Frueh & Sally Satel, *Veterans Affairs Needs to Get a Clue About PTSD Treatment*, TIME (June 27, 2014), http://time.com/2933356/ptsd-awareness-day-veterans-affairs-treatment/ .

Paxil, and Zoloft in treating PTSD symptoms.[109] Furthermore, research suggests that antidepressants are often no more effective than a placebo in treating veterans who suffer with PTSD.[110] Ineffective treatments and the common practice of self-medication undoubtedly aggravate the fragile mental state of veterans with the disorder.[111] In an effort to address this growing problem, the FDA recently approved a study of MDMA-assisted psychotherapy in treating veterans, police officers, and firefighters who suffer with PTSD.[112] Since MDMA remains in Schedule I, however, psychiatrists may not conduct MDMA-assisted therapy sessions on an as-needed basis, and access for veterans is limited to these types of seldom-approved volunteer studies.[113]

III. ACCEPTED MEDICAL USE OF MDMA TO TREAT POST-TRAUMATIC STRESS DISORDER IN VETERANS

A. Accepted Medical Use Defined

Schedule I substances are those that the DEA determines lack an accepted medical use, have a high potential for abuse, and cannot be used safely under medical supervision.[114] The CSA does not define "accepted medical use" in the definition section of the act.[115] Thus, its meaning has been the subject of much debate since the act's promulgation.[116]

There are two main inquiries the DEA will undertake in determining whether a substance has an accepted medical use. First, the DEA considers five distinct factors

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[109] Zoloft, for example, has been found to be effective in female patients, but not in male. Michael A. Hertzberg, M.D., et al., *Lack of Efficacy for Fluoxetine in PTSD: A Placebo Controlled Trial in Combat Veterans,* 12 ANNALS OF CLINICAL PSYCHIATRY 101 (2000).

[110] Jay C. Fournier, M.A., et al., *Antidepressant Drug effects and Depression Severity: A Patient-Level Meta-Analysis*, 303 JOURNAL OF AM. MED. ASS'N 47 (2009).

[111] *See* Alexander McFarlane, *Epidemiological Evidence About the Relationship Between PTSD and Alcohol Abuse*, 23 ADDICTIVE BEHAVIORS 813 (1998); *see also* Paige Ouimette, et al., *Course and Treatment of Patients with Both Substance Use and Posttraumatic Stress Disorders*, 23 ADDICTIVE BEHAVIORS 785 (1998).

[112] Michael C. Mithoefer, et al., *The safety and efficacy of ±3,4-methylenedioxymethamphetamine-assisted psychotherapy in subjects with chronic, treatment-resistant posttraumatic stress disorder: the first randomized controlled pilot study*, 25 J. OF PSYCHOPHARMACOLOGY 439 (2010). Drug Policy Alliance, *Healing a Broken System: Veterans and the War on Drugs* (November 2012), http://www.drugpolicy.org/sites/default/files/DPA_Healing%20a%20Broken%20System_Veterans%20and%20the%20War%20on%20Drugs_November%202012_Final_0.pdf .

[113] *Id*.

[114] 21 U.S.C. § 812 (2009).

[115] Marijuana Scheduling Petition, 57 Fed. Reg.10,499, 10,504 (March 26, 1992). (stating regrettably, the Controlled Substances Act does not speak directly to what is meant by 'currently accepted medical use).

[116] *Id.*, at 10,503.

of the substance. Second, the DEA considers whether the substance has FDA approval.[117]

The DEA will consider the following five factors to determine whether a substance has an accepted medical use in the United States: (1) the substance's chemistry is known and reproducible; (2) there are adequate safety studies; (3) there are adequate and well controlled studies determining efficacy; (4) the drug is accepted by qualified experts; and (5) the scientific evidence is widely available. [118] The DEA will conclude that a substance has an accepted medical use if all five of these factors are met.[119]

B. DEA Findings and Rationale in Scheduling MDMA

In order to determine the DEA's rationale for placing MDMA in Schedule I, an analysis of its 1988 final ruling is required. In that ruling, Director Lawn extrapolated upon each of the five enumerated factors, ultimately concluding that MDMA deserved Schedule I classification.[120]

First, the administrator noted that MDMA lacked FDA approval. Director Lawn relied upon the fact that a single FDA pharmacologist, "experienced in evaluating the safety and efficacy of drugs," found that current research provided "no data or evidence to support a claim that MDMA is effective as a therapeutic agent."[121] Nonetheless, Director Lawn correctly indicated that fact that a drug is not lawfully approved for marketing is a "factor to be considered in determining whether a substance lacks accepted safety for use under medical supervision, but is not conclusive."[122]

He further noted that MDMA had not been subject to sufficient animal testing to support trials in humans, stating that the "published literature contains no references

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[117] Denial of Petition To Initiate Proceedings To Reschedule Marijuana, 76 Fed. Reg. 40,552, 40,559 (July 8, 2011)(to be codified at 21 CFR pt. 2).

[118] *See* 76 Fed. Reg. 40552 (2011); *See id*. For the DEA to find that a substance has a currently accepted medical use under the CSA, all five factors must be met. 76 Fed. Reg. 40552 (2011); *All. for Cannabis Therapeutics v. Drug Enf't Admin.,* 15 F.3d 1131, 1134 (1994). "The current test dates back to a 1992 order denying NORML's 1973 rescheduling petition. In announcing the test, DEA Administrator Robert C. Bonner explained that it was derived from the Food, Drug and Cosmetic Act. Bonner "[t]he pattern of initial scheduling of drugs in the Controlled Substances Act, viewed in light of the prior legal status of these drugs under the FDCA, convinces me that Congress equated the term 'currently accepted medical use in treatment in the United States' as used in the Controlled Substances Act with the core FDCA standards for acceptance of drugs for medical use." Denial of Petition to Initiate Proceedings To Reschedule Marijuana, *supra* note 118. Importantly, however, Bonner cautioned that "not … every FDCA requirement … is pertinent to scheduling determinations under the Controlled Substances Act," so it appears to be possible for a drug that does not have FDA approval to be found to have a currently accepted medical use under the DEA's test. Marijuana Scheduling Petition, *supra* note 116, at 10,506." *Id.*

[119] Marijuana Scheduling Petition, *supra* note 115, at 40,552.

[120] Schedules of Controlled Substances; Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act, *supra* note 76, at 5156.

[121] *See* 53 FR 5156-01 (1988). *Id.*, at 5157.

[122] *Id.*, at 5158.

to the clinical use of MDMA nor animal studies to indicate such clinical use."[123] Without clinical studies, the Director asserted that all information regarding long term neurotoxicity in humans is mere speculation, and thus that there was no way of knowing whether it was safe.[124] Director Lawn explained the safety concern as follows:

> Studies in animals [show] that MDMA produces long term serotonergic nerve terminal degeneration. Such effects would not necessarily be observed immediately in individuals who had taken the drug. The long term safety of MDMA has not been established through reproductive or carcinogenic studies. Since MDMA has not been shown to be effective for treating a specific condition, it is impossible to make a risk/benefit analysis of the drug. Two psychiatrists who testified on behalf of the agency in the proceedings indicated that they would not administer MDMA to humans until and unless further studies had been conducted to establish its safety and lack of neurotoxicity.[125]

Additionally, the Director observed that no data presented at the hearing had the potential for peer review, and that the evidence available was "purely anecdotal."[126] He noted that the evidence in the record before the DEA merely demonstrated that a few psychiatrists had administered MDMA to approximately 200 subjects.[127] "These physicians were not conducting scientific studies with MDMA, they were administering the drug as if it was an approved product which had been scientifically tested."[128] Thus, he concluded that the evidence presented was anecdotal accounts and not "scientific" so as to demonstrate an accepted medical use.[129]

Further, he asserted that MDMA lacked any "therapeutic use," citing a "panel of international experts" who allegedly arrived at the same conclusion.[130] Thus, the director concluded that the published scientific and medical literature as of 1988, coupled with information from the files of the Food and Drug Administration (i.e. a lack of interstate marketing approval), "did not establish or support claims of

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[123] *Id*. The director concluded that "[t]he published literature contains no references to the clinical use of MDMA nor animal studies to indicate such a clinical use. Recognized texts, reference books and pharmacopeia contain no references to the therapeutic use of MDMA. The two unpublished studies supporting the therapeutic use of MDMA which were presented during the hearings, do not contain any data which can be assessed by scientific review to draw a conclusion that MDMA has a therapeutic use. Indeed, the psychiatrists who conducted the studies admit that the information which they obtained was anecdotal, and that the studies were not scientifically controlled." *Id*.

[124] *Id*.

[125] *Id*.

[126] *Id*.

[127] *Id*.

[128] *Id*.

[129] *Id*.

[130] Lastly, Mr. Lawn noted that the lack of FDA interstate marketing approval "clearly demonstrates" an absence of an accepted medical use for MDMA. *Id.*

therapeutic use of MDMA, as an adjunct to psychotherapy, in treatment in the United States."[131] Accordingly, Director Lawn concluded that MDMA had no accepted medical use and deserved Schedule I status.[132]

Today, pure MDMA has been proved to be "sufficiently safe" when ingested a minimal number of time over a long period.[133] MDMA-assisted psychotherapy follows this trajectory, as MDMA ingestion occurs once during a three-month period.[134] Additionally, further animal testing has provided a foundation for MDMA testing in humans.[135] Recent studies have been successfully completed in the medical setting, demonstrating a plausibly degree of certainty toward the safety of the tests.[136] Evidence is not purely anecdotal; the sample sizes in modern experiments range from 12-60 human test subjects, and the scope of MDMA research spans the globe.[137] Finally, Director Lawn fails to indicate the rationale of the "panel of international experts," or what, if any, evidentiary basis they provided for their conclusion.[138] On the contrary, the evidence today demonstrates a greater international interest in curing PTSD through MDMA-assisted psychotherapy than our national interest.

C. MDMA's Accepted Medical Use in the Context of Medically Assisted Psychotherapy

First, MDMA's chemistry is known and reproducible today.[139] According to the DEA, a substance's chemistry is known and reproducible when it can be reproduced into dosages which can be standardized.[140] This standard is elucidated by several hearings regarding the accepted medical use of marijuana.[141] For example, in concluding that the chemistry of marijuana is not known or reproducible, the DEA reasoned that "over 400 different chemicals have been identified in the plant," and that

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[131] *Id*.

[132] *Id*.

[133] Students for Sensible Drug Policy, *SSDP Psychedelic Legalization Toolkit*, http://ssdp.org/campaigns/ssdp-psychedelic-legalization-toolkit/ (last visited March 25, 2016).

[134] MAPS, *Treating PTSD with MDMA-Assisted Psychotherapy*, http://www.mdmaptsd.org/patients.html (last visited March 25, 2016).

[135] National Institute on Drug Abuse, *The Neurobiology of Ecstasy*, https://www.drugabuse.gov/publications/teaching-packets/neurobiology-ecstasy (last visited March 25, 2016).

[136] *See* MAPS – MDMA-Assisted Psychotherapy, http://www.maps.org/research/mdma.

[137] *Id*.

[138] *See* 53 FR 5156-01 (1988).

[139] Harold Kalant, *Pharmacology and Toxicology of "Ecstasy" (MDMA) and Related Drugs*, 165 CANADIAN MED. ASS'N J. 917, 925 (2001); James Rochester, *Ecstasy (3,4 Methylenedioxymethamphetamine): History, Neurochemistry, and Toxicology*, 12 AM. BOARD FAM PRAC. 137, 137 (1999).

[140] Marijuana Scheduling Petition; Denial of Petition; Remand, 57 Fed. Reg. 10499, 10504 (Mar. 26, 1992).

[141] *Id.*

"proportions of concentrations differ from plant to plant, depending on growing conditions, age of the plant, harvesting and storage factors."[142]

Unlike marijuana, the chemical structure and function of MDMA does not depend on external conditions, nor is it composed of a significant amount of varying chemicals.[143] These four chemicals combine to synthesize MDMA in its pure form.[144] Ecstasy, the illicit street drug which utilizes PMK to produce a psychoactive effect, includes a much higher amount of chemicals and adulterous additives.[145] Accordingly, the chemical structure of pure MDMA is well known, and is easily reproducible in a clinical setting and in comparison with marijuana or other Schedule I substances.[146]

Second, medical researchers around the world have conducted a significant amount of studies regarding MDMA's safety.[147] As stated by the DEA in 1992, "there must be adequate studies, by all methods reasonably applicable, to show the pharmacological and toxicological effects of the drug" in order to know its safety.[148] These include animal studies and clinical tests with large number of humans.[149] The studies "need not be well controlled, but must be adequate."[150]

A profusion of studies testing the effects of MDMA on animal subjects has occurred since the 1950's.[151] In 1986, researches at the Medical College of Virginia tested the self-administration of MDMA in rhesus monkeys.[152] In 2001, Johns Hopkins University tested the cognitive performance of MDMA-treated rhesus

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[142] *Id*. at 10507

[143] MDMA, specifically 3,4-Methylenedioxy-N-Methylamphetamine, is the sole psychoactive agent in the chemical, and contains no other chemicals that produce the psychoactive effect. There are four "principle precursors" used in the manufacture of MDMA: safrole, isosafrole, piperonal, and 3,4-methylenedioxyphenyl-2-propanone ("PMK"). Alexander Shulgin, *The Background and Chemistry of MDMA*, 18 J. OF PSYCHOACTIVE DRUGS 291, 291 (1986).

[144] *Id*.

[145] *Id*.

[146] *Id*.

[147] *Id*.

[148] Grinspoon, 828 F.2d at 881.

[149] *Id*. at 894-95.

[150] Edison Pharmaceuticals Co. v. FDA, 600 F.2d 831, 840 (D.C. Cir. 1979).

[151] The first known test occurred in 1953 at the University of Michigan. The United States Military conducted tests on a variety of species in an attempt to determine neurotoxicity animals in a variety of animals. Lethal dosages of MDMA were find at high concentration in rats, mice, and monkeys. *See Shulgin, supra* note 34

[152] Patrick Beardsley, et al., *Self-Administration of Methylenedioxymethamphetamine (MDMA) by Rhesus Monkeys*, 18 DRUG AND ALCOHOL DEPENDENCE 149, 149 (1986).

monkeys.[153] A study of primate PET-scans before and after administration of a neurotoxic level of MDMA revealed its effect on serotonin in the primate brain.[154]

The lethal dosage level of MDMA has not been determined in humans. Nonetheless, researchers have conducted many clinical tests on a significant number of human subjects.[155] In 1978, clinical psychiatrist Alexander Shulgin administered MDMA to fellow therapists in an uncontrolled study of the subjective effects of MDMA.[156] Shulgin noted the physiological effects on heart rate and body temperature, as well as its mood elevated and spiritual qualities.[157] No toxic qualities in humans were identified or recorded.[158]

In 1994, the National Institute of Health conducted a study on the neurotoxicity of MDMA in the human brain.[159] The NIH study measured the neurotoxic effects of MDMA against physical characteristics of subjects, such as weight, height, sex, and personality traits.[160] The test concluded that MDMA users had "lower scores on personality measures of impulsivity," and that MDMA may have an effect on suppressing aggressive personality states.[161]

In July of 2000, the University of Psychiatry in Zurich published a study of the psychological and physiological effects of MDMA on humans who had been pretreated with haloperidol, a substance used in treating schizophrenia and other psychiatric mood disorders.[162] The study, which included 14 healthy subjects, concluded that MDMA produced an "affective state of well-being, with increased extroversion and socialability."[163] The study noted the physiological effect of MDMA on healthy individuals, listing an increase in blood pressure and heart rate, as

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[153] Michael Taffe, et al., *Cognitive Performance of MDMA-Treated Rhesus Monkeys: Sensitivity to Serotonergic Challenge*, 27 NEUROPSYCHOPHARMACOLOGY 993, 995-996 (2001).

[154] Sudhakar Selvaraj, et al., *Brain Serotonin Transporter Binding in Former Users of MDMA ("ecstasy")*, 194 BRIT. J. OF PSYCHIATRY 355, 355 (2009).

[155] Charles Grob, *MDMA Research: Preliminary Investigations with Human Subjects*, 9 INT'L J. OF DRUG POL'Y 119, 121 (1998).

[156] *Id*.

[157] NAT. INST. OF HEALTH, ECSTASY: WHAT WE KNOW AND DON'T KNOW ABOUT MDMA 5 (2001).

[158] *Id*. at 25-26.

[159] Una McCann, et al., *Serotonin Neurotoxicity After (±) 3, 4-methylenedioxymethamphetamine (MDMA; "Ecstasy"): a Controlled Study in Humans*, 10 NEUROPSYCHOPHARMACOLOGY 129, 129 (1994).

[160] Liesbeth Reneman, et al., *Effects of Dose, Sex, and Long-term Abstention From Use on Toxic Effects of MDMA (ecstasy) on Brain Serotonin Neurons*." 358 THE LANCET 1864, 1864 (2001).

[161] *Id*.

[162] Peter Oehen, et al., *A Randomized, Controlled Pilot Study of MDMA (±3,4-Methylenedioxymethamphetamine)-Assisted Psychotherapy for Treatment of Resistant, Chronic Post-Traumatic Stress Disorder (PTSD)*, 27 J. PSYCHOPHARMACOLOGY 40, 40 (2013).

[163] *Id*. at 41-42.

well as a heightened body temperature.[164] The main complaints from subjects were fatigue, lack of appetite, and thirst, among others.[165]

These studies comprise an adequate foundation through which the safety or danger of MDMA can be known. A great deal of information regarding the dangers and benefits of MDMA has been unveiled over the last several decades, especially in contrast to the medical information available to the scientific community in 1988. Human clinical testing has demonstrated knowledge of the known risks and benefits of MDMA.[166] These tests demonstrate an adequate safety level that supports an accepted medical use in the United States.

Third, studies demonstrate the efficacy of MDMA-assisted psychotherapy in treating soldiers suffering from post-traumatic stress disorder.[167] A recent double-blind study conducted by the Medical University of South Carolina found a 30% reduction in the Clinically-Administered PTSD Scale ("CAPS") as compared with those subjects receiving a placebo.[168] Psychiatric researchers in Zurich conducted a similar study on MDMA-assisted psychotherapy in veterans suffering with PTSD.[169] This double-blind study indicated a lessening of PTSD victim CAPS scores after two months of MDMA-assisted psychotherapy sessions.[170] Additionally, the efficacy of MDMA-assisted PTSD treatment was further analyzed in a 2007 evidence-based meta-analysis of the treatment.[171] A randomized triple-blind comparative study of MDMA use in conjunction with therapy in firefighters and police officers suffering with PTSD has been approved by the FDA and is scheduled to occur in 2016.[172]

The DEA conclusion that MDMA has "no therapeutic use in the United States" is no longer scientifically supported.[173] In the specific context of the PTSD pandemic in our nation's veterans, MDMA-assisted therapy is an effective means to combat otherwise untreatable symptoms.[174]

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[164] *Id*. at 47.

[165] *Id*. at 48.

[166] Jerrold S Meyer, *3,4-methylenedioxymethamphetamine (MDMA): current perspectives* SUBST ABUSE REHABILITATION 83–99.(2013).

[167] *U.S. Will Ban 'Ecstasy,' A Hallucinogenic Drug*, N.Y. TIMES (June 1, 1985), http://www.nytimes.com/1985/06/01/us/us-will-ban-ecstasy-a-hallucinogenic-drug.html.

[168] *Id*.

[169] *See supra* note 112.

[170] *Id*.

[171] A. C. Parrott, *The Psychotherapeutic Potential of MDMA (3, 4-methylenedioxymethamphetamine): An Evidence-Based Review*, 191 PSYCHOPHARMACOLOGY 181, 181 (2007).

[172] *See generally* MULTIDISCIPLINARY ASSOCIATION FOR PSYCHEDELIC SUBSTANCES (June 29, 2010).

[173] George Greer, Rebuttal Testimony of George Greer, M.D. in DEA Hearing on Scheduling of MDMA Under the Controlled Substances Act (last visited May 1, 2016); Grinspoon, 828 F.2d at 891.

[174] *See supra* note 85.

Fourth, the safety and efficacy of MDMA is supported by a community of reliable medical experts.[175] Studies conducted by medical professionals in Zurich have determined the safety of MDMA-assisted psychotherapy in a clinical setting.[176] Psychiatric researchers in the United States have concluded that MDMA-assisted therapy can be conducted safely and with effective results in PTSD victims.[177] The FDA has approved a triple-blind study of MDMA-assisted psychotherapy in the United States, the first of its kind since before it was illegalized in 1986.[178] Further, experiments in Israel and Jordan also provide support for the safety and efficacy of MDMA-assisted therapy.[179]

Fifth, the evidence supporting MDMA's positive effect on post-traumatic stress disorder is widely available to researchers and the public. In determining whether a drug is widely available to experts, courts analyze if there is "widely available scientific literature about the drug,[180] "whether it is widely taught in medical schools[181]," and "whether it is widely discussed by experts."[182]

At the time of the original scheduling in 1988, DEA director John Lawn correctly noted a lack of published literature referencing the clinical use of MDMA.[183] Lawn pointed to two "unpublished studies supporting therapeutic use of MDMA."[184] Further, Lawn indicated that recognized texts did not indicate the use of MDMA as a substance with therapeutic purposes.[185]

Today, MDMA has fixed itself at the center of academic and medical discussion. Harvard Medical School plans to study the therapeutic effects of psychedelic substances on terminally ill patients.[186] The FDA approved Harvard University's McLean Hospital's request to reinvigorate research programs incorporating

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[175] *Id.*

[176] *See supra* note 112.

[177] *See supra* note 134.

[178] *Supra* note 121.

[179] Rick Doblin, *Clinical Plan for MDMA (Ecstasy) in the Treatment of Posttraumatic Stress Disorder(PTSD): Partnering with the FDA*, 12 J. PSYCHOACTIVE DRUGS 5, 5 (2002).

[180] Premo Pharm. Lab., Inc. v. United States, 629 F.2d 795, 795 (2nd Cir. 1980).

[181] Lemmon Pharm/ Co. v. Richardson, 319 F. Sup. 375, 378 (E.D. Pa. 1970).

[182] *United States v. Bentex Ulcerine, 469 F. 2d 875, 879-880 (5th Cir. 1972).*

[183] Scheduling of 3,4-Methylenedioxymethamphetamine (MDMA) Into Schedule I of the Controlled Substances Act; Remand, 53 Fed. Reg. 5156-01 (Feb. 22, 1988). "The published literature contains no references to the clinical use of MDMA nor animal studies to indicate such a clinical use. Recognized texts, reference books and pharmacopeia contain no references to the therapeutic use of MDMA. The two unpublished studies supporting the therapeutic use of MDMA which were presented during the hearings, do not contain any data which can be assessed by scientific review to draw a conclusion that MDMA has a therapeutic use." *Id.*

[184] *Id.*

[185] *Id.*

[186] Risheng Xu, *HMS Will Give Ecstasy to Terminally-Ill Cancer Patients*, HARVARD CRIMSON (Jan. 5, 2005), http://www.thecrimson.com/article/2005/1/5/hms-will-give-ecstasy-to-terminal.

psychedelic medicine.[187] Further, the prestigious scientific publication "Scientific American" has called for the United States to implement MDMA into therapy.[188] The article correctly indicates that MDMA "had its origin in medical pharmacopeia."[189] The ever-expanding pool of clinical studies and academic discussions , and the surge in MDMA-assisted psychotherapy studies for PTSD treatment, all indicate a changing landscape where the effects of MDMA-assisted therapy are widely available to psychiatrists and researchers in the medical field.[190] Accordingly, in applying these five factors to the current scientific understand of MDMA, Schedule I classification must be reconsidered for a schedule that permits healthcare professionals to adequately address the debilitating symptoms of MDMA.

IV. APPLYING THE CHEVRON STANDARD TO DRUG ENFORCEMENT AGENCY SCHEDULING

DEA regulatory action regarding the Schedule I classification can be viewed under the Chevron "arbitrary and capricious" framework.[191] "The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress."[192] If the statute creating a program is ambiguous, that ambiguity is viewed as an express delegation of legislative discretion to an agency.[193] Thus, "regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute."[194]

Having established the ambiguity of the Controlled Substances Act as written by Congress, the issue of whether MDMA is erroneously scheduled must be viewed under the "arbitrary, capricious, or manifestly contrary to the statute" framework set out by the United States Supreme Court in Chevron.[195] This is not exactly an issue of first impression; the First Circuit dealt with the merits of this exact issue in 1987, in

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[187] John Horgan, *Psychedelic Medicine: Mind Bending, Health Giving*, NEW SCIENTIST (Feb. 23, 2005), http://www.newscientist.com/article/mg18524881.400-psychedelic-medicine-mind-bending-health-giving.html.

[188] Roni Jacobson, *Turn On, Tune in, Get Better: Psychedelic Drugs Hold Medical Promise*, SCI. AM. (Sept. 1, 2014), http://www.scientificamerican.com/article/turn-on-tune-in-get-better-psychedelic-drugs-hold-medical-promise.

[189] *Id.*

[190] *Id.*

[191] Grinspoon, 828 F.2d 884; Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 844 (U.S. 1984), Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 56 (U.S. 1983).

[192] Chevron, 467 U.S. at 843 (quoting Morton v. Ruiz, 415 U.S. 199, 231 (1974)).

[193] Chevron, 467 U.S. at 843.

[194] *Id.* at 844.

[195] *Id*.

the case of Grinspoon v. Drug Enforcement Administration.[196] The court in Grinspoon analyzed whether the DEA administrator's conclusion that MDMA had a high potential for abuse and lacked any accepted medical use was arbitrary and capricious.[197] The court answered both questions in the negative.[198] Nonetheless, the First Circuit's conclusion faces seemingly insurmountable challenges when viewed in relation to the progress of recent MDMA research.[199]

A. The First Circuit Correctly Concludes that Director Lawn's Findings Were Not Arbitrary and Capricious

Immediately following the DEA's ruling, psychiatrist and Harvard Medical Professor Lester Grinspoon petitioned the First Circuit to review Director Lawn's classification.[200] Dr. Grinspoon asserted four arguments in support of overturning the DEA ruling. First, Dr. Grinspoon argued that the director misapplied the "accepted medical uses" standard and thus erroneously found MDMA to be one of the substances under § 812 that lack an accepted use.[201] The final three reasons were premised on the notion that the scheduling was arbitrary and capricious and therefore must be vacated.[202]

Though the First Circuit agreed with Dr. Grinspoon on the first issue, and thus reversed the judgment and ordered the DEA to reconsider its ruling, Dr. Grinspoon was unsuccessful in arguing that the DEA interpretation arbitrarily and capriciously interpreted the CSA.[203] The First Circuit concluded that Congress had provided the DEA with sole power to determine the relative potential for abuse of a substance, so long as it provided substantial evidence in that regard.[204] Finding that Congress delegated that authority, and that the conclusion was based on substantial evidence, the Court refrained from finding the DEA ruling invalid on "arbitrary and capricious" grounds.[205] The Court stated the following:

> While we acknowledge that the Administrator's final rule is silent with respect to the legal standard required for a finding of "high" potential for abuse, we do not find the Administrator's action to be arbitrary and capricious. The fourth standard contained in the segment of the Committee Report quoted above makes it quite clear that the Administrator can permissibly reach a conclusion regarding a substance's level of potential for abuse by comparing the substance to drugs already scheduled under the

196 Grinspoon, 828 F.2d at 883.

197 *Id*.

198 *Id*.

199 *Id*.

200 *Id*.

201 *Id.* at 884.

202 *Id.* at 892.

203 *Id*.

204 *Id*.

205 *Id*.

> CSA. Here the Administrator has done just that, offering several findings concerning the evidence of close structural and pharmacological similarity between MDMA and other substances, such as MDA,12 which already *894 have been found to have a high potential for abuse and have been placed in Schedule I or II.[206]

Additionally, the Court acknowledged the legislative history of the Controlled Substances Act.[207] The House Committee Report provided that the Administrator can find a potential for abuse if the following apply:

> (1) There is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; or
>
> (2) There is significant diversion of the drug or drugs containing such a substance from legitimate drug channels; or
>
> (3) Individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or
>
> (4) The drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.[208]

Here, the court found that the director adhered to the Congressional intent of the CSA as it pertains to a high potential for abuse.[209] The court stated that the Administrator "offered several findings concerning the evidence of a close structural pharmacological similarity between MDMA and MDA, which have already been found to have a high potential for abuse and have been placed in Schedule I.[210] Further, the Administrator provided "animal studies, human behavioral studies, and a survey of MDMA users which suggest[ed] that MDMA is related in its effects to Schedule I substances such as LSD, cocaine, mescaline, and MDA."[211] The court concluded that the Administrators approach in analyzing the potential for abuse

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[206] 51 Fed.Reg. 36,555–57 (1986).

[207] *Grinspoon* 828 F.2d, 983at 885.

[208] *Id.*

[209] *Id.*

[210] *Id.*

[211] *Id.*

conformed to the intent of Congress, and thus did not render the decision arbitrary and capricious under the Chevron framework.[212]

Nonetheless, as demonstrated many studies cited in this article and Dr. Grinspoon's arguments before the First Circuit, the question remains as to "whether the evidence collected by the administrator is sufficient to justify his conclusion that MDMA has a high potential for abuse."[213]

B. The First Circuit Incorrectly Concludes that the Director's Conclusions were Sufficient under the "Substantial Evidence" Standard

There is no doubt that the CSA's legislative history demonstrates Congressional intent in delegating the "high potential for abuse" determination to the administrator.[214] That being said, the crucial analysis is whether that conclusion can withstand the notoriously low "substantial evidence" standard. In Am. Textile Mfrs. Inst. v. Donovan, the Supreme Court held that substantial evidence is that which "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion"[215] "[E]ven if reasonable minds could also go the other way, we must uphold the [agency] if its ultimate finding is supported by substantial evidence in the record as a whole."[216]

In his original 1986 ruling, Director Lawn cited various scientific studies to support his conclusion that MDMA had a high potential for abuse.[217] At that time, Dr. Grinspoon a professor of psychiatry at Harvard University and a medical researcher, presented his and other professionals studies on the efficacy of MDMA as

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[212] *Id.*

[213] *Id.*

[214] *Id*. "From this, the Administrator draws 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]." Respondent's Brief at 17–18 (emphasis deleted). The Administrator's conclusion is objectionable, however, because 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"—is totally unsupported by the quoted passage from the House Committee Report. Nowhere does Congress equate "safety and efficacy" under the FDCA with the second and third Schedule I criteria contained in section 812(b)(1). This, indeed, is the point at issue in this litigation, and we are loath to accept such a disingenuous argument." *Id*.

[215] Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 522 (U.S. 1981).

[216] *Id*. (*citing* NLRB v. J.K. electronics, Inc. v. Donovan, 452 U.S. 490 (1981).

[217] "(1) MDMA is the N-methyl analogue of MDA and retains the psychomimetic properties of MDA; (2) MDMA produces pharmacological effects in common with both central nervous system ("CNS") stimulants like amphetamine and hallucinogens like MDA in animals; (3) MDMA and MDA produce the same spectrum of pharmacological effects in mice, dogs, and monkeys when observed during toxicity studies; (4) MDMA, like MDA, amphetamine, and methamphetamine, produces neurotoxic effects when administered to animals; (5) MDMA and MDA may both produce the same neurotoxic effects to serotonergic nerves in humans; (6) in drug discrimination tests, rats trained to recognize amphetamine also recognized MDA and MDMA, and rats trained to recognize MDA also recognized MDMA; (7) based on recent tests involving human subjects, MDMA can be described as maintaining the same potency as MDA, but exhibiting subtle differences in the qualitative nature of the intoxication." Grinspoon, *supra* note 207at 895.

an adjunct to therapy.[218] Nonetheless, the Court upheld the agency determination that MDMA had a high potential for abuse, noting that an "appellate court must not second-guess the particular way the agency chooses to weigh the conflicting evidence or resolve the dispute."[219]

In the event that an agency points to "scientifically respectable evidence" that a petitioner can "continually dispute with rival, and…equally respectable evidence," the court will not question the means by which the agency chooses resolve the dispute.[220] Under this framework, substantial evidence must be "scientifically respectable" and, when a conflict between evidence exists, an agency must resolve that dispute.[221]

Director Lawn relied upon evidence in the record that is no longer "scientifically respectable" as it pertains to our current understanding of the neurotherapuetic effects of MDMA, especially when viewing within the context of post-traumatic stress disorder.[222] For example, current MDMA research concludes that MDMA lacks the addictive qualities present in other Schedule I substances like cocaine and heroin.[223]

Further, current research shows that MDMA does not cause lead to neurotoxicity when taken recreationally. One of the largest studies on MDMA, researchers from the UK concluded that "MDMA use may not result in long-term damage to serotonin neurons when used recreationally in humans."[224] Nor is such a finding subject to conflict, as the studies cited by the Director measure the effect of MDMA when issued at a threshold level.[225] This neurotoxic effect is substantially less than those frequently identified in heroin and cocaine use.[226] MDMA only produces neurotoxic effects when distributed at its threshold level in nonhuman animals; human studies

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[218] *Id.*

[219] *Id.*

[220] Asarco, Inc. v. OSHA, 746 F.2d 483 (9th Cir. 1984). Where the agency presents scientifically respectable evidence which the petitioner can *continually dispute with rival, and we will assume, equally respectable evidence*, the court must not second-guess the particular way the agency chooses to weigh the conflicting evidence or resolve the dispute. *Id.* (emphasis added).

[221] *Id*.

[222] *See generally* Multidisciplinary Association for Psychedelic Studies, http://www.maps.org/research/mdma .

[223] Johansen & Krebs, *Psychedelics not linked to mental health problems or suicidal behavior: a population study*, J. of Psychopharmacology.

[224] Selvaraj, et. al., *Brain serotonin transporter binding in former users of MDMA*, 194 Brit. J. of Psychiatry 355-359 (2009).

[225] *See* 53 FR 5156-01; *see also* Selvaraj *supra* note 224.

[226] *Oliveira* ,et. al., *Neurotoxicity of heroin-cocaine combinations in rat cortical neurons*, 276 J. of Toxicology 11 (2010). "The data show that drug combinations potentiate cortical neurotoxicity and that the mode of co-exposure changes cellular death pathways activated by the drugs, strongly suggesting that chemical interactions occurring in Her:Coc, such as adduct formation, shift cell death mechanisms towards necrosis. Since impairment of the prefrontal cortex is involved in the loss of impulse control observed in drug addicts, the data presented here may contribute to explain the increase in treatment failure observed in speedball abusers." *Id*.

have not produced any of evidence of neurotoxic damage or neurodegeneration following therapeutic use.[227]

When looking at the Director Lawn's rationale in 1986, it becomes apparent that the medical purposes for which Dr. Grinspoon argued were not met with substantially conflicting evidence, as the only studies present in the Committee Report contain studies administering MDMA to animals at threshold, or maximum LD/50 levels, and not over an extended period of time. Furthermore, a host of scientific data exists differentiating MDMA's potential from abuse from other Schedule I substances, with some studies concluding that MDMA has no potential for abuse whatsoever. Regardless of a small potential for abuse, it is not high, as required by the CSA, nor is it at all comparable to substances with which it currently shares Schedule I status. Nonetheless, DEA scheduling updates and completed lists are reviewed and restated bi-annually.[228] With the growing body of data demonstrating MDMA's positive effect on PTSD victims, coupled with the ineffective treatments currently available to veterans suffering with the disease, there is substantial evidence to support a second challenge to the rule, and a reversal or reconsideration of Director Lawn's 1986 classification.

V. MDMA IN SCHEDULE III

A. Meeting the Schedule III Criteria

Schedule III substances are those that the DEA concludes have an accepted medical use in the United States, a lower potential for abuse than those substances in Schedule I and II, and low physical dependence or high psychological dependence.[229] Doctors may prescribe Schedule III substances to patients, but the sale or ingestion without a prescription is illegal.[230] Based on the analysis above, MDMA is most reasonably categorized as a Schedule III substance under the Controlled Substances Act.[231]

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[227] *Id*.

[228] Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II, 21 C.F.R. 1308, *available at* https://www.federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedulehttps://www.federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule .

[229] 21 U.S.C. §829 (2016).

> (b) Schedule III and IV substances
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> Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance in schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed without a written or oral prescription in conformity with section 503(b) of that Act. Such prescriptions may not be filled or refilled more than six months after the date thereof or be refilled more than five times after the date of the prescription unless renewed by the practitioner. 21 U.S.C. §829 (2016).

[230] 21 U.S.C §812 (2016).

[231] *See* Marsha Rosenbaum & Rick Doblin, *A Short History of MDMA Use*, (1991).

Under § 812 of the CSA, the "known facts as to MDMA must be compared with the known facts as to human abuse of other substances."[232] Consider cocaine, for example. Cocaine causes a far greater amount of problems in the United States as a result of its addictive qualities.[233] Cocaine produces a high tolerance in users, produces pleasurable sensations in the brain that incite repetitive use and inevitable addiction, and is used in a much more consistent way than MDMA.[234] Regardless of these marked differences in abuse prevalence, MDMA and cocaine share Schedule I classification due to a lack of accepted medical use and high potential for abuse.[235]

Aside from MDMA's social and habitual distinction from cocaine, researchers have examined MDMA's potential for abuse in animal studies on rhesus monkeys.[236] Medical researchers have tested many Schedule I, II, and III substances on rhesus monkeys to determine a potential for abuse by looking at primate rates of self-administration.[237] These tests measure the rate at which monkeys, generally rhesus monkeys, ingest a particular substance after an initial dosage.[238] Studies of MDMA indicate that rhesus monkeys self-administer the drug less than other Schedule I substances, such as cocaine or heroin.[239]

Only a small amount of studies have examined MDMA dependence in humans.[240] Those studies indicate that ecstasy produces withdrawal symptoms in heavy users.[241] Nonetheless, "craving for ecstasy was low overall," and social factors, not physiological responses, incited urges to take MDMA.[242] Thus, "physiological basis of an ecstasy dependence syndrome might be relatively weaker in comparison to drugs with clear and marked dependence potential" such as cocaine or other Schedule I opioids.[243]

Scientists at the University of Toronto uncovered the acute and long-term effects of MDMA in average users.[244] Acute effects ranged from renewed energy, a sense of fulfillment, increased sexual arousal, and an overwhelming sense of euphoria, to

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[232] D.E.A., *In the Matter of MDMA Scheduling*, no 84-48 (1986).

[233] *Id*.

[234] *Id.*

[235] 21 U.S.C. §812 (2016).

[236] Zarembo *supra* note 91.

[237] *Id.*

[238] *Id*.

[239] *See* Louisa, Degenhardt ET AL., *Is Ecstasy a Drug of Dependence*? 107 DRUG AND ALCOHOL DEPENDENCE 1, 1-10 (2010).

[240] *Id.*

[241] *Id.*

[242] *See* James Hopper ET AL., Incidence and Patterns of Polydrug Use and Craving for Ecstasy in Regular Ecstasy Users, 85 DRUG AND ALCOHOL DEPENDENCE 221, 235 (2006).

[243] Shulgin *supra* note 38.

[244] *Id.*

increases in body temperature, heart rate, and a sense of a mental and physical "crash".[245]

Studies of long-term MDMA users shows a prevalence of "serotonin neurotoxicity."[246] The substantial release of serotonin produced by MDMA intake causes damage to serotonin metabolites in the cerebrospinal fluid.[247] A long-term MDMA user releases less serotonin during "neuronal," or regular activity in brain activity, has "abnormally low levels of serotonin," a smaller amount of serotonin transporter molecules, and altered pattern of blood flow to the brain."[248]

These physical and psychological effects, though significant, do not comport to the physical and psychological effects of other Schedule I substances.[249] For example, MDA (3,4-Methylenedioxyamphetamine), a structural relative of MDMA, produces cognitive impairment at low dosage levels and causes hallucinations and disorientation.[250] Physical effects of drugs such as methamphetamine, heroin, and cocaine far outweigh those produced by MDMA.[251] These drugs are far more addictive and cause irreparable harm to the human nervous system.[252]

Several Schedule III substances share similar qualities with MDMA in the context of physical dependence. For example, Benzphetamine is an amphetamine that metabolizes into a methamphetamine upon digestion.[253] Benzphetamine suppresses appetite in order to reduce caloric intake in obese patients.[254]

Due to its low potential for abuse and low physical dependence, MDMA reasonably conforms to the substance characteristics set out in Schedule III. MDMA possesses a significantly smaller potential for abuse in primate and human subjects than other Schedule I substances.[255] Further, it does not cause a strong physical or psychological dependence in humans.[256] The physiological effects are relatively minimum, and the fluctuation of serotonin levels emulate many Schedule III substances. Accordingly, research today urges Schedule III classification.

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[245] *Id.*

[246] *See* George Ricaurte ET AL., *(±) 3, 4-Methylenedioxymethamphetamine ('Ecstasy')-induced Serotonin Neurotoxicity: Studies in Animals*, 42 NEUROPSYCHOBIOLOGY 5-10 (2000).

[247] *Id.*

[248] *Id.*

[249] *See generally* JULIE HOLLAND, A COMPREHENSIVE LOOK AT THE RISKS AND BENEFITS OF MDMA (Inner Traditions/Bear & Co. ed. 2001).

[250] *See* Shuglin *supra, 38*.

[251] *See* Reneman *supra, 160*.

[252] *Id.*

[253] F. Musshoff, *Illegal or Legitimate Use? Precursor Compounds to Amphetamine and Methamphetamine*, 32 DRUG METABOLISM REVIEWS 15-44 (2000).

[254] When abused, however, Benzphetamine may cause severe hallucinations. Similarly, Clortermine and Phendimetrazine are appetite suppressors that act on serotonin levels in the brain. Methamphetamine comprises the structure of both of these substances, as well as MDMA. *See Id.*

[255] *See generally,* Holland *supra* note 249.

[256] *Id.*

B. Impact of Schedule III Classification of MDMA Treatment in Veterans Suffering with PTSD

Reclassifying MDMA as a Schedule III substance would provide veterans with an opportunity to experience the benefits of MDMA-assisted psychotherapy.[257] Such a notion is slowly becoming reality, as the Multidisciplinary Association for Psychedelic Substances recently completed a Phase 2 Pilot Study of MDMA in therapy settings.[258] The end goal of this study is to acquire approval of MDMA as a prescription substance by 2021.[259] This goal is unattainable in the United States so long as MDMA remains classified as a substance lacking any accepted medical use.[260]

In the United States, the FDA has only approved of two pharmacological treatments for victims of PTSD: Zoloft and Paxil.[261] Zoloft and Paxil act to increase the amount of serotonin in the brain, utilizing the exact same mechanism as MDMA.[262] MDMA affects serotonin levels "acutely for 4-8 hours," whereas Zoloft and Paxil chronically affect serotonin levels and must be taken daily.[263] Thus, medication not only becomes more burdensome on the patient but more financially impactful on tight-budgeted organizations like the VA.[264]

If MDMA becomes a Schedule III narcotic in the near future, a plethora of "bureaucratic delays" could be avoided. Research on MDMA's effect on PTSD would not be restricted by the necessity of FDA approval; mandatory registration with the DEA would no longer hinder the once swift and fluid process of research; medical researchers would not be deterred from furthering their studies because of stringent DEA reporting guidelines; an inappropriate and unfounded national stigma could be corrected, and the long road to addressing PTSD could shorten significantly.

VI. CONCLUSION

The justifications for rescheduling MDMA as a Schedule III substance are plentiful, and as the decade—and the war against posttraumatic stress—continues, those reasons will continue to present themselves in an irrefutable light. The understanding of MDMA's medically accepted use has grown substantially since its Schedule I classification in 1986.[265] Though the stigma against MDMA exists en masse, its efficacy of a treatment in the limited context of posttraumatic stress disorder

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[257] 21 U.S.C. §829 (2016).

[258] *See* Scheduling *supra*, note 183.

[259] *Id.*

[260] Rosenbaum & Doblin *supra* note 55.

[261] *Id.*

[262] *Id.*

[263] *Id.*

[264] *See* Rosenbaum & Doblin *supra* note 55.

[265] *See generally*, Mithoefer *supra* note 112.

is piercing societal perception. It is this treatment—an alternative approach to halting an ever-expanding disorder—that solely justifies a DEA interpretation of the "medically accepted use" standard. To give MDMA Schedule III status would not interrupt the Congressional purpose behind the CSA, and would funnel treatment to a much-needed group of afflicted individuals.

More prevalent than MDMA's effect on posttraumatic stress disorder is its power over addiction. Its importance to returning veterans becomes ever the more crucial, as addiction is one of the strongest, most consistent, and must exacerbating of the symptoms of PTSD. Again, when viewing MDMA within the context of surrounding Schedule I narcotics, there is a vast discrepancy in rates of addiction.[266] Further, the psychedelic—scientifically referred to as hallucinogenic—substances are in that rare class of Schedule I drugs that have shown positive results insofar as they alleviate addiction. Thus, a sort of tragic irony exists here, whereby substances deemed as having a "high potential for abuse" in fact function to curb the abuse of other, more dangerous Schedule I narcotics.

Physiologically, MDMA acts as a stimulant, increasing heart rate and blood pressure.[267] Accompanying these physical symptoms is a subjective, but uniform sense of euphoria, love, and compassion, effects that countless of veterans have reported following MDMA-assisted therapy.[268] This is a fundamental change in perspective that has the opportunity to be incited without forcing veterans to seek illegal means to that end.[269] The efficacy of MDMA-assisted therapy in treating PTSD has brought MDMA into the international healthcare discussion. The justifications for keeping it out of the hands of healthcare professionals and patients far outweigh the physiological and psychological effects of the substance on humans. Thus, access to MDMA must be provided to veterans if PTSD is to be meaningfully treated in the near future.

In the last decade, scientific progress has elucidated the power of a stigmatized and illegalized substance with regard to its effective use in therapy. It is important to note that the Controlled Substances Act is open for rescheduling hearings on an annual basis.[270] As a result, the DEA will be presented with the opportunity to conform its legislation to the scientific understand regarding MDMA and its use in psychotherapy, and will have the opportunity to do so without frustrating congressional purpose. A rescheduling of the substance to Schedule III, as opposed to Schedule I, would provide physicians with the ability to administer MDMA in dispersed therapy sessions over a wide range of time, a technique with proven benefits unseen in the current antidepressant atmosphere. Making this change will allow outdated drug legislation to catch up with scientific progress, and in doing so, make a meaningful and necessary step toward addressing PTSD in American veterans.

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[266] *See* Fed. Reg. *supra* note 206.

[267] *See* NLRB *supra* note 216.

[268] Shulgin *supra* note 38.

[270] 21 U.S.C. §812(a) (2016).