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Psychedelic Rehabilitation for Drug Policy and Trauma Survivors
Advancing Mental Health Care by Granting Access to MDMA-assisted Therapy for the
Treatment of Post-traumatic Stress Disorder

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Abstract

According to current international drug policy, psychedelic drugs share the same abuse and addictability potential as heroin. The presumption is that acknowledging any difference would not only pose a threat to the safety and health of society but would compromise established moral values. Legislators have created a campaign against psychedelics since their revival in the 1960s, fighting a war against an imagined evil. Refusing to allow space for possible therapeutic applications of psychedelic drugs prevents individuals from a better quality of life and therefore violates human rights.

MDMA-assisted therapy (\pm 3,4-Methylenedioxy-methamphetamine) has been used successfully for years by an underground network of psychotherapists to treat PTSD (Post-traumatic Stress Disorder). After its popularisation in the 1980s, it was given an emergency assignment as a schedule I substance and would arbitrarily remain classified in the most restrictive categorisation. Drug policy continues to make research with MDMA a slow and expensive endeavour. Those suffering from PTSD still cannot access MDMA-assisted therapy despite its on-going 25-year development as a new drug with the Food and Drug Administration (FDA). MDMA-assisted therapy is the single most effective, efficient, and humane treatment for PTSD and the possibly greatest innovation in psychiatric care with the past 100 years.

This thesis will address how MDMA was illegally categorised as a schedule I substance and how legislators ignored the recommendations of the administrative judge, scientific evidence, and the criteria for scheduling substances. The scheduling of MDMA was a classic example of legal paternalism which impedes on personal autonomy, self-determination, and human dignity. Individuals should be afforded the right and responsibility to make informed decisions about their treatment options with the aid of an overseeing physician. The law cannot adequately assess the needs of each individual, especially when making uneducated decisions according to 'moral' code. When addressing the ethical concerns of MDMA, this thesis will demonstrate that this treatment is in fact more humane and respects the entirety of human rights.

Foreword

The idea to write about access to MDMA-assisted therapy came from multiple inspirations: my personal and professional experience in the mental health field and my desire to help transform psychiatric care. When attending the Interdisciplinary Conference on Psychedelic Research in Amsterdam this past June, I was overwhelmed by an inspiring speech given by Dr. Ben Sessa. He conveyed all my frustrations with the failure of psychiatric care and the little progress it has made in the past 100 years. Our approach to mental health continually distances itself from humanity, becoming a game of trial and error with medications and treatment. People with a diagnosis enter into a revolving door of treatment centres, therapists, and medications often until old age. One of the reasons mental health is so stigmatised is because it is perceived as incurable—once diagnosed, forever branded. I believe that MDMA research has provided the first real glimpse of what psychedelic drugs can do for mental health care. Drug policy needs to provide a safe way for people to access safe, medical grade MDMA (or any other psychedelic substance) and be treated by a trained professional. In mental suffering there is desperation, which puts individuals at risk for self-treatment or seeking help from guerrilla clinics.

My other intention is to change the discourse around psychedelic drugs. When speaking to friends and classmates about their perceptions, I received many of the same responses—they all expressed fear of losing control. I stop to wonder why people don't fear losing control the first time they drink alcohol; if anything, this is the ultimate substance for breaking down inhibitions. Alcohol intoxication allows people to completely disconnect from their sense of self, aiding in poor perception and ability to make decisions. The distrust of psychedelics derives from the misconceptions and myths, depicting them as a catalyst for psychosis, delusions, and severe hallucinations (in reality alcohol abuse can produce this result¹). Users are repeatedly stigmatised as irresponsible, rebellious, unintelligible, and delusional. Due to the strict prohibition of psychedelics, many users remain 'in the closet' per

¹ Alcohol-Related Psychosis, <http://emedicine.medscape.com/article/289848-overview>.

se. They are hesitant to talk about their life-changing experiences out of fear that they will lose the respect of their peers. This makes it very difficult to change the damaging discourse around psychedelic drugs. It is my hope that with increasing research and eventual approval of psychedelic-integrated therapy that psychedelic drugs will be regarded with respect and appreciation.

I would like to thank my supervisor, Judit Sándor, for giving me full range in my research topic and encouraging me to investigate an issue I am passionate about. Also thanks are due to Orsolya Salát for helping me arrange the financing and opportunity to attend the conference in Amsterdam. I am extremely grateful to all the E.Ma staff and my fellow classmates for teaching me invaluable knowledge and inspiring me throughout this wonderful year. I will carry this experience with the warmest of memories and fondness in my heart!

I would like to dedicate this work to my sister, Madeline. I am lucky to have such a woman in my life who has taught me selfless love. After all the support she has given me through the writing of my thesis, I have no way of expressing the amount of gratitude I feel towards her.

List of Abbreviations

ADHA	Attention Deficit/Hyperactivity Disorder
ALJ	Administrative Law Judge
BNDD	Bureau of Narcotics and Dangerous Drugs
CBT	Cognitive Behaviour Therapy
CDAPCA	Comprehensive Drug Abuse Prevention and Control Act
CSA	Controlled Substance Act
CND	Commission on Narcotic Drugs
CNS	Central Nervous System
ECtHR	European Court of Human Rights
EMA	European Medicines Agency
DARE	Drug Abuse Resistance Education
DEA	Drug Enforcement Agency
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HHS	Health and Human Services
HPA	Hypothalamic-Pituitary-Adrenal Axis
ICESCR	International Covenant on Economic, Social, and Cultural Rights
INCB	International Narcotics Control Board
LP	Legal Paternalism
LSD	Lysergic Acid Diethylamide
MAPS	Multidisciplinary Association for Psychedelic Studies
MDA	3,4-methylenedioxy-amphetamine
MDMA	±3,4-Methylenedioxy-methamphetamine
MP	Moral Paternalism

MPBC	MAPS Public Benefit Corporation
PTSD	Post Traumatic Stress Disorder
RAVE	Reducing American's Vulnerability to Ecstasy
SSRI	Selective Serotonin Re-uptake Inhibitors
UDHR	Universal Declaration of Human Rights
UNODC	United Nations Office of Drugs and Crime
VA	Department of Veterans Affairs
WHO	World Health Organisation

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I. Introduction

Throughout the entire globe and even highly developed countries, access to mental health care remains a problem due to a lack of physical and financial resources. An even greater issue, which compromises human dignity is the ineffectiveness of those accessible treatments. It would be in the best interest of the state financially to provide access to the most effective treatment to fulfill their moral obligation. Research in the medical applications of psychedelic substances for mental health has shown exceptional promise in comparison to conventional methods. Despite the urgent need for progressive psychiatric care, the current restrictive drug policy makes treatment inaccessible. The failure of modern psychiatric care creates life-long sentences of suffering; many who pursue treatment traverse down a long road of medications, therapy, and clinics. Mental health care is reduced to sustaining individuals at a minimum functional level since ‘remission’ is an unlikely outcome. On the other hand, treatment options are exhausted to cure diseases like cancer. Society clearly perceives suffering differently when it comes to mental illness, viewing trauma survivors as damaged and fragile. Meanwhile, cancer survivors are depicted as enduring a more physically strenuous road to recovery and are revered as heroes. It appears there is a hierarchy of pain; where physical suffering is easier for society to confront. This perception of mental health is what hinders progress in psychiatric care and the development of effective medicines.

Pain is a difficult construct to measure, even on a scale of one to ten. Trauma survivors may spend years in therapy trying to reach a stable point in their lives, but not without experiencing immense and prolonged emotional suffering. Enduring medication changes, unwanted side effects, and financial burdens further add to the challenges of daily life. But there is hope—recently the psychedelic substance, MDMA (\pm 3,4-Methylenedioxy-methamphetamine), has become the forerunner in psychiatry to treat PTSD (post-traumatic stress disorder) due to its high clinical response rate in only a few sessions. Uniquely, it is used in conjunction with psychotherapy as a catalyst to process and decode traumatic memories. However, this psychedelic drug is most famously known for its illicit use rather

than its applications in the medical field. It caused a ‘moral panic’ amongst legislators and was assigned the most restrictive drug scheduling. As a result, researchers have faced numerous obstacles in conducting approved studies which would provide sound evidence for the medical use of MDMA. Where moral code takes precedent over humane treatment, trauma survivors remain without access to a promising alternative treatment and are unable to obtain relief.

The following will discuss the profound effects PTSD has on individuals’ lives, their families’ lives, and their economic and social standing. Next, the origins and history of MDMA will be covered to understand its current perception in society. Finally, it will conclude with the scheduling of MDMA as a Schedule I substance and its understanding according to policy makers. This will provide a basis for understanding why MDMA-assisted therapy is integral to developing and humanising psychiatric care.

I.I The Scale and Phenomenon of Post-Traumatic Stress Disorder

Fear is something all human beings experience. It is the most primal instinct which protects us from danger—equipped with an automatic response system, which contracts the muscles and increases the heart rate in anticipation until there is no longer a threat. For trauma survivors, instinct has gone haywire. A fear response is triggered by various stimuli and the state of fear feels impossible to escape. Frozen like a deer in the woods, a frenzy of panic beneath, the mind will choose dissociation or physical action. The perceived intensity of the threat is incongruent with reality, causing someone to react to triggers as if it were a life-threatening situation. Traumatic events vary over a broad spectrum: witnessing death, sexual/physical abuse, natural disasters, or other violent events. What makes the event traumatic to the individual person is subjective, but the underlying emotions are utter helplessness and vulnerability. A survivors’ entire world views are changed as they use the event to relate to daily life and themselves.

These are the reflections of an American war veteran who was medically discharged from the military for PTSD, a severe anxiety disorder caused by a traumatic event:

The war, it's over, but not for us [...] we have a war that I think will not end soon, if at all. It will be over when God says so. And the things we have done may be forgiven by Him, but never by ourselves. Thus, prolonging our internal strife, until our last breath escapes us.²

After the bombing of his convoy, he was given five minutes to recover from the blast and continue in combat. Despite returning home, he was faced with a new and different kind of internal war, experiencing symptoms of intense anxiety, dizziness, chronic insomnia and even vomiting, and was ultimately determined as 100% disabled by medical doctors.³ Many veterans returning home have been rendered handicapped, unable to return to normal life, gain employment, or maintain relationships. They require a caretaker to help them complete daily tasks and to intervene when an episode is triggered. However, veterans are not the only ones at war; PTSD can strike anyone who has experienced a traumatic event such as sexual violence, natural disaster, combat, physical abuse, or refugee displacement. The DSM-V (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition) describes PTSD as, “exposure to actual or threatened death, serious injury or sexual violation [in which] the disturbance, regardless of its trigger, causes clinically significant distress or impairment in the individual’s social interactions, capacity to work or other important areas of functioning.”⁴ After experiencing the traumatic event, one may experience prolonged anxiety, flashbacks, sleep disturbance, or increased irritability.

Costly in human lives and financial resources, the rate of PTSD rates continue to rise around the world while treatment remains inadequate. As of September 2014, the RAND Corporation (Centre for Military Health Policy Research) has reported that at least 20% of 2.7 million American veterans from the Iraq and Afghanistan wars have PTSD.⁵ Even so, it

² Wall Street Journal, 2012, [Online video] 0:36.

³ Ibidem, [Online Video] 3:24.

⁴ American Psychiatric Association, 2013, p.1.

⁵ Tanielian and Jaycox, 2008, p.62.

is estimated that the rate of PTSD is even higher due to lack of reporting and treatment seeking. Moreover, only half of those seeking medical attention are receiving ‘minimally adequate’ treatment and even less than half are receiving quality care.⁶ Insufficient treatment leads to prolonged symptoms of PTSD, lower recovery rates, and larger economic and social repercussions. The costs associated with PTSD have been estimated between \$4.0 to \$6.2 billion.⁷ Consequently, scant mental health care has caused concern for the high rate of suicide among American veterans. A report published by the Department of Veterans Affairs (VA) in 2012 found that rates of veteran suicide range between five to eight thousand a year.⁸

It is also important to highlight other significant groups of trauma survivors who are considerably more vulnerable and less likely to receive or seek treatment: survivors of sexual assault and refugees. Sexual assault is the most common cause of PTSD in women and approximately 50% of those diagnosed experience a lifetime prevalence.⁹ Meanwhile, there is a wide discrepancy over the rates of PTSD amongst refugees due to unreliable data collection, lack of attention to refugee mental health, and incompatible diagnostic guidelines. It has been estimated that 10-12% of refugees are affected by PTSD while some estimates are as high as a third.¹⁰ Beyond the dizzying statistics, numbers are a safe way to describe the scale of PTSD, but fail to understand the consequences that manifest biologically, psychologically, and sociologically.

Intense trauma can affect the neural, endocrine, and immune systems, altering them and making those suffering more susceptible to secondary disorders or diseases. The body’s

⁶ Ibidem, summary: xxii.

⁷ Fluctuation of costs are due to the inclusion/exclusion of lives lost to suicide. These estimations do not include costs for other groups such as rape survivors or refugees (Ibidem, p.215).

⁸ An estimated 22 veteran suicides per day in the calendar year of 2012 (Kemp and Bossarte, 2012, p.15).

⁹ Chivers-Wilson, 2006, p.112.

¹⁰ Andermann and Simich, 2014, p. 76.

response to stress becomes unregulated due to the increase of Cortisol and an over-reactive Hypothalamic-Pituitary-Adrenal (HPA) axis which is responsible for regulatory processes.¹¹ Effectively, the regulatory processes within the body are biologically altered and contribute to inappropriate fear reactions and depression. These systemic changes manifest themselves psychologically and produce symptoms of avoidance, withdrawal, fear, guilt, shame, and mistrust, making it even more difficult for those to seek treatment. Even more, individuals may find social integration difficult post-trauma and have trouble fostering relationships and maintaining employment.

Additionally, PTSD can produce detrimental effects on the individual's social network, particularly immediate friends and family. Mathew Friedman, executive director of the National Centre for PTSD, explains the sociological impacts as a 'rippling effect' which affects the families' sense of security, sense of themselves and other family members, as well as their perception of the world.¹² As a result, individuals who remain without treatment can pass on secondary trauma to future generations. This further accentuates the utmost importance for trauma survivors to receive the most effective medical treatment available due to its destructive impact on the individual, community, and society.

I.II What is MDMA?

MDMA is a semi-synthetic¹³ psychoactive drug. Though the media brands it with the colloquial term 'Ecstasy,' it should not be conflated with pure MDMA. Ecstasy (X, XTC, E, Rolls) usually contains other substances in addition to MDMA, such as ephedrine (a stimulant), dextromethorphan (a cough suppressant), ketamine (an anaesthetic), caffeine, co-

¹¹ Cortisol is a hormone released by the HPA axis (the feedback system) in response to stress (Chivers-Wilson, 2006, p. 112).

¹² Dart Center 2012, [Online Video] 0:43.

¹³ MDMA is related to many chemicals already found in nature. For example, nutmeg and saffrafras root contain a precursor chemical to the synthesis of MDMA (Holland, 2001, p. 8.).

caine, and methamphetamine.¹⁴ Throughout the 60s and 70s, psychotherapists had been using the drug to assist patients during therapy, and by the 80s it became a popular recreational drug. It was first synthesised in 1912 by the German pharmaceutical company, Merck, while trying to create a medicine that stopped bleeding.¹⁵ Contrary to popular belief and public reports, it was not used as an appetite suppressant or used during World War I. MDMA belongs to the family of phenethylamines which are related to, but should not be confused with amphetamines such as its analog¹⁶ 3,4-methylenedioxy-amphetamine (MDA)¹⁷. The most common misconception is that MDMA is a hallucinogenic substance, when in fact it has many similar chemical effects as Fluoxetine, an anti-depressant.¹⁸ The effects, however, are more profound than anti-depressants. Widely described as having euphoric properties, the most common psychological effects are: entactogenesis (“touching within”)¹⁹, empathogenesis²⁰, and an enhancement of the senses.

Alexander Shulgin, famously known as the ‘Godfather of Ecstasy,’ was accredited for introducing MDMA to the scientific community as a therapeutic treatment in 1978. They were so impressed by the effects of MDMA that thousands of therapists started to utilise it as a therapeutic tool. In the early 1980s, a psychiatrist George Greer administered MDMA to 29 individuals as part of therapy and wrote about their subjective experiences.²¹ The majority reported positive effects on their well-being and an improved ability to resolve any relationship issues without any physical complications from the drug. However, as word spread about MDMA from the medical community, it became a very popular recreational

¹⁴ Anderson, 2014.

¹⁵ Holland, 2001, p. 11.

¹⁶ A chemical compound with similar structure and properties.

¹⁷ Quite often MDA and other similar substances are sold as MDMA, putting its users at risk and misconstruing statistical accounts of deaths or hospitalisations. (Ibidem, p. 8.)

¹⁸ Ibidem, p. 8.

¹⁹ “Feeling at peace” or feeling positive about oneself and the world.

²⁰ Evoking feelings of empathy or emotional closeness to others.

²¹ Sessa, 2006, p. 2.

drug which provoked an emergency scheduling in 1985 by the American Drug Enforcement Agency (DEA) and in the UK.²²

I.III Scheduling of MDMA

Previously referred to as ‘Adam’ or ‘Empathy’ by the scientific community, MDMA was rebranded as ‘Ecstasy’ to give it an alluring name to its consumers.²³ In Texas, a group of entrepreneurs started manufacturing MDMA, making it easy to acquire by calling a toll-free number and paying by credit cards.²⁴ It became so popular that users could buy it over the counter at certain nightclubs, and it was even taxable, just like cigarettes. Naturally, this drew a lot of national attention to what was happening in Texas as it exploded into the most popular party drug. The senator of Texas, therefore, started to pressure the DEA to make it an illegal drug.²⁵

On 31 May 1985, the DEA announced that it would not await the hearing for the scheduling of MDMA based on reports that the substance was being highly abused throughout the United States. According to the law, a drug may be scheduled without a hearing on an emergency basis for the period of one year if it poses a possible threat to public safety.²⁶ After the emergency scheduling, a series of hearings were held to determine how the drug should be categorised based on its medical value and potential risk of abuse. The Administrative Law Judge (ALJ) for the DEA concluded that there was a need for research to investigate the real risks and benefits of MDMA and suggested that it be classified as a Schedule

²² Ibidem, p. 2.

²³ ‘Adam’ signifying “the condition of primal innocence and unity with all life.” ‘Empathy’ because of its ability to foster understanding of others (Holland, 2001, p. 13).

²⁴ Holland, 2001, p. 13.

²⁵ Ibidem, p. 13.

²⁶ Ibidem, p. 14.

III: not containing a “high potential” for abuse.²⁷ The DEA, however, decided to throw out the recommendation of the ALJ and continue with its own agenda. MDMA was seen as a threat to the nation’s set of morals and was promptly prohibited, ignoring the petitions and recommendations by the scientific community.

As a result, according to the criteria under the Controlled Substance Act (CSA) 1970, it became a Schedule I substance:

(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.²⁸

The DEA also urged the criminalisation of MDMA at an international level, where it was also categorised as a Schedule I by 11 February 1986. Despite findings for its potential therapeutic uses, it was grouped with other substances such as heroin and cocaine which are known to be highly addictive and have no current medicinal uses. The World Health Organisation (WHO) agreed with the scheduling of MDMA but also felt it was a substance of interest which should be researched for its therapeutic potential.²⁹ Many psychiatrists, psychotherapists, patients, and researchers attested to the potential uses of MDMA and argued that there was not enough sound scientific research to declare it a Schedule I. In fact, the decision was appealed in the US based on the arbitrary ruling of *Grinspoon v. Drug Enforcement Administration* [828 F2d 881] in 1987 since the DEA failed to provide adequate evidence against medical properties of MDMA.³⁰ Used correctly and in a safe environment, it proved to be very beneficial, but decision-makers only saw it as a component of rave culture which threatened their morals and it was permanently placed in Schedule I by 1988. Following the hearing, officials responded with increased governmental control, police surveillance, and harsh penalties.

²⁷ Smith, 2007, p. 298.

²⁸ 21 U.S.C. § 812 (1970).

²⁹ Holland, 2001, p. 14.

³⁰ Smith, 2007, p. 299.

I.IV Structure and Methodology

The therapeutic advantages and uses of MDMA are entering the lime-light as research is slowly gaining ground. The Scheduling of MDMA makes it very difficult for researchers to have their studies approved, and when granted permission, there are strict regulations and guidelines. As a result of the Afghanistan and Iraq wars, the Multidisciplinary Association for Psychedelic Studies (MAPS), a non-profit research and educational organisation, has been granted permission to conduct clinical studies with a cohort of PTSD-resistant US veterans due to the high rates of suicide. Even so, legislation, stigmatisation, and ethical obstacles make it very difficult for veterans and all other trauma survivors to gain access to this potentially life-saving and pain-relieving treatment. Individuals suffering from terminal diseases such as AIDS, cancer, and Hepatitis C are vetted with the option to choose experimental treatment that has not yet been approved by the Food and Drug Administration (FDA). Meanwhile, trauma survivors are not allowed to seek MDMA treatment unless chosen to participate in clinical studies. This could be an indication of how society places the importance of addressing physical suffering over mental health.

First I will discuss two relevant theories which play an active role in policy making: the responsibility of the state and rights of the individual and legal paternalism (including the harm principle) and liberal autonomy. I highlight the negative effects of drug policy on public health and how its aim to reduce harm is counterproductive. Then I will address the arbitrary scheduling of MDMA by evaluating the actual risk potentials versus therapeutic application. Additionally, I will analyse the case of Friederike Meckel Fischer, a psychotherapist who was arrested for administering MDMA to consenting subjects and the verdict concerning the actual dangers of MDMA.

In the chapter concerning access to MDMA as a human right, I will analyse this under the Universal Declaration of Human Right 1948 (UDHR) based on the principles of dignity, autonomy, and self-determination. Also, I will pay specific attention ‘the right to the high-

est attainable standard of health' protected under multiple international conventions. Under this right, I will discuss whether it entails the right to expanded access of investigational drugs. Finally, I will argue that under the principle of human dignity, individuals should be able to access the most effective treatment as part of the right to be free from inhumane and degrading treatment. I will support the immediate and justifiable need for MDMA-assisted therapy. Being the most cost efficient and effective treatment, decision makers should begin to turn their attention towards and reevaluate MDMA.

In the fifth chapter, I will address the ethical concerns of MDMA. I will dispel those concerns rooted in myths and misinformation. In fact, MDMA-assisted therapy will prove to be the more humane form of treatment for PTSD in comparison to other techniques that risk re-traumatisation. I will address the concerns that if MDMA is recognised as a medically useful substance, what kind of message or 'moral risk' might it propose to society? The moral risk in this case has been stated that if we medicalise PTSD (defined as a condition primarily treated with medication) would it detract from the need for complimentary treatment such psychotherapy. Then I will look at how potential patients will be assessed, who gets access, and the appropriate age for treatment. Finally, it will be important to mention how MDMA will be administered and integrated into therapy to protect individuals and physicians from unsafe practices.

In the conclusion, I will make some policy recommendations and open up the discussion to a wider context which would prescribe treatment for refugees who suffer from PTSD. My methodology of research will include making a legal analysis of International Human Rights Law, case-law from the European Court of Human Rights, and US federal code. My research will primarily review academic journals, interviews from leading experts, and the current work of the Multidisciplinary Association for Psychedelic Studies (MAPS). The context of my discussion will mainly focus on United States because of its influence on the international scheduling of MDMA and regulations for medical use. I have specifically chosen to focus on treatment for PTSD because of its profound impact on society and the

rising phenomenon from the wars and incoming refugees. Advocating for access to MDMA-assisted therapy is the first step to opening up more research in psychedelics for the treatment of other mental illnesses.

II. Relevant Theories

II.I Legal Paternalism, Moralism, and the Harm Principle

Legal paternalism (LP) is the premise that the law should prevent individuals from harming themselves, whereas moral paternalism (MP) aims to preserve and protect the morality of individuals.³¹ Most drug policies use a combination of LP and MP which morphs into a legal moralist approach. Legal moralism has a pluralistic definition in which the law's function is to enforce 'morality' by preserving a traditional way of life and reducing harm to the individual and society, referred to as the Harm Principle. Legal moralism can be evaluated by these two conditions:

- (a) If the conduct of type A is regarded as (or is) immoral, this can provide a sufficient reason for the state to criminalise A, even though A-type conduct does not cause (or risk causing) someone to be harmed.
- (b) *Only* harm matters in deciding what forms of conduct ought to be made (or remain) criminal.³²

Henceforth, the rationale behind criminalising a substance is two-fold. Most proponents of MP will consider taking a substance to alter the 'state of being' or for recreational use as threatening to the values and order of society regardless of whether or not it is causing harm. The majority of LPs argue that permitting drug use puts the individual at risk for addiction. In order to have a discussion on the rationale behind criminalising a substance, it is essential to further examine the premises of LP and MP.

MPs employ the 'pleasure principle' to justify drug policy in which happiness is judged as having no inherent value and morally condemnable at worst.³³ Consuming a substance with

³¹ Holliman, 2010, p. 9.

³² *Ibidem*, p. 81.

³³ Scott, 2014, p. 29.

the sole intent to achieve pleasure is criticised as immoral by policy makers. This justification for drug prohibition is inconsistent with the regulation of the practices of consuming food, alcohol, and tobacco for enjoyment, because these practices are ingrained in cultural norms. In order to demonstrate the subjectivity of the pleasure principle, one could question the inherent value of substances designed solely for enjoyment like roller coasters and fireworks. If each of these are unregulated or used by the wrong person they could possibly cause harm. Since they have no other value than to produce pleasure, according to MP's pleasure principle, we should criminalise them. Despite this example, morality does have a place in drug policy as it should reduce harm and promote well-being.

LP proponents use the harm principle to evaluate an action as a criminal act. According to this principle, the only condition in which power can be exercised over an individual is when they risk harming themselves or another.³⁴ LPs also defines harm as taking away an individual's ability to exercise free-will. Therefore, it is the responsibility of the state to protect the users from becoming 'enslaved' to the drug. From this perspective it assumes that an individual cannot take a drug and maintain free-will at the same time. It is important to accurately cite the source of harm when creating legislation that exercises power over free-will. Take for example the situation in which a driver hits a pedestrian while driving under the influence. Was it is fault of the car, the alcohol, or person? It was the way in which the driver used alcohol in combination with the vehicle to cause harm. To reduce this type of harm we create boundaries and limits around how much alcohol can be consumed when driving a vehicle. We do not criminalise vehicles or alcohol. Drug policy has misplaced the cause of harm on MDMA. When MDMA became a popular club drug, the number of hospitalisations increased reported as caused by MDMA.³⁵ These reports were misleading because many of the cases involved poly-drug use and unregulated MDMA, mean-

³⁴ Petersen, 2011, p. 82.

³⁵ Policy makers categorised MDMA without sufficient evidence — '*Correlation does not equal causation.*'

ing that these individuals had rarely ingested pure MDMA. So therefore, MDMA wasn't itself the cause of the harm but the way the drugs were ingested. Nevertheless, policy makers saw this substance as the direct cause of putting human life at risk, declaring it immoral and punishable by law.

The majority of civil society has recognised that the global drug regime which emphasises overly oppressive approaches is failing. For decades, governments have relied on repression and punishment to dissuade any involvement in drug use or drug trade. The war against drugs has encouraged extremely expensive control policies which have failed to achieve the goal of reducing the scale of the illegal drug market. In the effort to exercise control over drug use, human rights have been sacrificed. The risks of drug misuse and addiction cannot be totally eliminated from society, but alternative methods can be employed to reduce harm and ensure the balance of human rights.

II.II Liberal Autonomy

Autonomy is generally understood as the capacity of an individual to be one's own person and to govern one's own decisions based on one's own motives and reasons without the influence of external forces. According to the Stanford Encyclopaedia of Philosophy:

Autonomy plays various roles in theoretical accounts of persons, conceptions of moral obligation and responsibility, the justification of social policies and in numerous aspects of political theory. [...] relatedly [autonomy], connects to questions of moral responsibility. It is also seen as the aspect of persons that prevents or ought to prevent paternalistic interventions in their lives.³⁶

A person who is acting autonomously bases their decisions, according to Kant, on a set of universal moral laws which are grounded in moral obligation and how we perceive we should be treated by others and ourselves.³⁷ An individual's conception of morality, or what is good or bad, reflects how these principles interact differently with the intention of creating a better life. Liberal autonomy allows individuals to decide what is in their best interest

³⁶ Buss, 2014.

³⁷ Ibidem.

instead of enforcing paternalistic laws which treat society as a homogeneous population with the same needs. The fundamental goal of autonomy in a liberal political scheme is to delineate oppression and reflect interest of the state's citizens rather than the state's personal agenda, a bottom-up approach to legislation. The aim of state institutions should be to maximise the welfare of its citizens based on their collective preferences.

States should allow individuals to develop their own definition of 'good' and 'bad.' A person's set of morals may be widely influenced by religion, culture, and personal experience. Western society generally accepts the use and consumption of alcohol, but it is not reflective of the population as a whole. There are many religious communities (i.e. Amish and Mormons) within the United States which condemn the use of alcohol. While this moral value is concrete in their religious code, it is also important to mention that values are constantly evolving. Alcoholics Anonymous, for example, is a collective group of people who had to change the way they valued alcohol to improve the quality of their lives. In general, alcohol may pose little threat, but for an addict, it is a tool of destruction. Just because alcohol may be used to harm part of a population, criminalising it would violate the personal autonomy of the majority. The principles of the law must be legitimised by citizens and their representatives through collective discourse and deliberation.

In support of liberal autonomy, Habermas confers that, "legitimacy and justice cannot be established in advance through philosophical construction and argument, as was thought to be the case in natural law traditions in which classical social contract theory flourished and which is inherited in contemporary perfectionist liberal views."³⁸ In other words, policy should not be based on philosophical theory but should be informed by an evidence-based analysis of its effects. The consequences of limiting liberal autonomy can be observed in the global drug regime. Policy makers have launched a huge campaign to abolish drug use,

³⁸ Ibidem, *see source*: Habermas, Jürgen (1994). *Between Facts and Norms*, William Rehg [trans.], Cambridge, MA: MIT Press.

drug trafficking, and to reduce rates of addiction. The result has led to an increase in punitive charges and the marginalisation of vulnerable groups. Instead of creating better economic opportunities for the impoverished, they are criminalised for the distribution and sale of illicit drugs. Additionally, by criminalising the possession and use of drugs, users are less likely to seek treatment fearing legal repercussions. Drug policy limits the pathways for individuals to make important decisions which would improve their lives. If drug policy were to take a liberal approach, it would decriminalise drugs, disseminate reliable information for harm reduction, and increase funding for rehabilitation programs. This puts the moral responsibility on the individual and further empowers the free-will.

Allowing for a more liberal drug policy would create space to address the complexities of the current issues at hand. Drug policy does not have the capacity to assess the needs of individuals with mental illness and often fails to provide them with the highest attainable standard of care. By decriminalising substances with medical application, it would allow the freedom to choose treatment and ensure that health needs are met. Instead of restricting drugs with medical value, drug policy can protect the well-being of society by disseminating accurate information for making informed decisions, requiring observation by a trained physician, and creating regulations which promote safety.

III. Counterproductive Drug Policy

III.I The Negative Impact of Drug Control on Public Health

The international drug control system is notoriously known for hindering access to controlled medicine due to its criminal justice approach instead of a public health perspective. The International Narcotics Control Board (INCB) and the United Nations Office on Drugs and Crime (UNODC) are both responsible for maintaining a balance between preventing illicit use and ensuring access to medically controlled substances.³⁹ Despite their obligation to ensure access to controlled medicines as a component of the right to health, international

³⁹ Global Commission on Drug Policy, 2015, p. 5.

bodies prefer to criminalise any form of drug abuse. Essential medications are continually undersupplied, stigmatised, and inappropriately prescribed due to fear and lack of knowledge propagated by intimidating legislation. Individuals lacking essential treatment are given the choice to continue suffering, develop unhealthy coping mechanisms, or risk criminal charges for seeking treatment through unofficial means. If drug policy focused on providing care for all drug users, their health and safety would be protected. Those with a legitimate need for treatment can safely obtain it, and others with substance dependence can freely seek treatment without being denounced as a criminal.

Considering MDMA is not yet an approved substance for medical use, we will examine the impact of drug control policy on the accessibility of pain-relieving opioid analgesics, such as morphine. The limiting of opioids provides an analogous scenario of the repercussions of denying access to MDMA-assisted therapy. Similarly, insufficient availability and inaccessibility of pain relieving medication has broader physical, societal, and economic implications. Imagine suffering from chronic pain every day; it would limit one's ability to focus, perform physically demanding tasks, and have adverse effects on the individual's health. Physical ailments are often accompanied by mental distress and vice versa. Untreated, chronic pain sufferers often have difficulty working or caring for their families, creating additional stress and economic burden for other family members.⁴⁰ In severe cases, chronic pain sufferers who lack access to any remedy fall into a state of depression and resolve to commit suicide as their only option for relief.⁴¹ Trauma survivors are akin to much of the same issues without access to treatment and arguably face greater obstacles obtaining effective treatment. Individuals with PTSD have high rates of psychiatric and medical comorbidity, making them more prone to secondary diseases. Trauma survivors are negatively continue to suffer while drug policy refused to recognise the medical applications of MDMA.

⁴⁰ Human Rights Watch, 2011.

⁴¹ Cooper, 2015, p. 18.

Even if MDMA is acknowledged for its medical application and reclassified as a Schedule II, individuals could still face the same difficulties accessing treatment. Schedule II substances are regarded as having a medically accepted use, but with very restrictive measures. Currently, opioids are categorised as a Schedule II substance. Every year, tens of millions of people suffering from disease which cause pain are estimated to be without remedy, leaving approximately 80% of the world's population without access to pain relieving opioids.⁴² The Global Commission on Drug Policy highlights how “this conflation of licit medicinal products with illicit substances contributes to an anti-drug environment where controlled medicines are demonised despite their necessity in healthcare settings.”⁴³ States must take greater measures to amend the deficiencies in their approach to drug control as it continues to block access to important medications. Currently only two FDA approved medications exist for PTSD, exhibiting moderate relief of PTSD symptoms: sertraline and paroxetine.⁴⁴ Non-pharmacological therapies, such as cognitive behaviour therapy (CBT), result in high drop-out rates (20%), and of those completing treatment, 58% still meet the diagnosis for PTSD.⁴⁵ Meanwhile, MDMA has proved itself to be the most effective treatment in conjunction with psychotherapy, especially in PTSD-resistant individuals. With few effective treatments available, individuals run the risk of getting a criminal record and jeopardising their personal health and safety by resorting to self-medication or underground/unregulated treatment.

Another way in which drug policy negatively affects accessibility is by stigmatisation and poor knowledge of these medicines. Societal attitudes around opioids are that they are extremely addictive; doctors fear prescribing them and patients don't want to be stigmatised for using a taboo medication. Health professionals and regulators lack proper knowledge of these medications because they are so strictly regulated. Similarly, drug policy has painted

⁴² World Health Organization 2011, p. 4.

⁴³ Global Commission on Drug Policy, 2015, p. 13.

⁴⁴ Brady et al. 2000; Tucker et al., 2001.

⁴⁵ Roughly 32-66% reach a good level of functionality (Hudson, 2011).

a daunting picture of MDMA as an extremely toxic and dangerous substance without any supportive scientific evidence. Some of the misconceptions are: it causes Parkinson's Disease, a single dose causes irreversible damage to the brain, it is an aphrodisiac, it is used as a 'date rape' drug, etc.⁴⁶ It is no mystery why MDMA faces scrutiny by policy makers. Consequently, the intention to scare people from taking drugs has a negative effect in which it puts the lives of stigmatised users in danger. Without proper knowledge about dosing and testing for the correct chemical compound, many users put their lives at risk when they ingest a mystery substance. Governments continually fund abstinence programs which further obscure information around the effects of drug use.

Drug policy's 'zero tolerance' approach to drug use can be reflected in the internationally launched DARE (Drug Abuse Resistance Education) program in the 1980s. Notoriously known to be ineffective and sometimes counteractive, the DARE program serves as a prime example of the ineffectiveness and consequences of drug prohibition. One of its methods is to educate adolescence on the dangerous effects of drugs, only adding to their misconceptions and stigmatisation. For example, DARE describes MDMA as an 'all-night club drug' and its effects producing "hypothermia, hallucinations, panic attacks, and mental confusion."⁴⁷ What they fail to mention is that these effects occur when MDMA is mixed with other drugs or taken at lethal doses. Even alcohol can lead to death if consumed in an abusive manner, but it is perceived as the lesser evil. A ten-year follow-up study on the effectiveness of the DARE program found that it had no effect in reducing drug use or peer-pressure resistance.⁴⁸ The program's motto is 'just say no' which preaches abstinence but does not prepare individuals with safety guidelines when experimenting. It is unrealistic to assume that young people will not experiment with drugs since the essence of adolescence is based off experiential knowledge. Safety is practiced when driving a car, working around

⁴⁶ Holland, pp. 54-57.

⁴⁷ DARE, 2016.

⁴⁸ Lynam et al., 1999, p. 593.

heavy machinery, or handling toxic chemicals; the natural law is that more accidents will occur without proper protocol. Abstinence programs can be compared to allowing people to drive around without seat-belts.

International drug policy needs to be re-evaluated, giving high priority to public health and human rights. This imbalance is reflected in the 100 billion USD invested in punitive responses versus the mere 7 million USD spent in harm reduction programs.⁴⁹ The criminal approach to drug control proves ineffective as costs to fight illicit drug use continue to rise. If the billions of dollars spent in the ‘war on drugs’ were redirected towards providing adequate care and access to treatment, public health would improve.

III.II MDMA and the Battle Against Anti-Drug Legislation

Drug policy has long been at odds with human rights advocates who point out the fallacies of its approach. Proponents for MDMA research and use have faced similar obstacles in trying to change its tainted perception. The inconsistencies will be demonstrated in the examination of the scheduling of MDMA in the US. The justification for scheduling of MDMA is invalidated and does not adhere to the criteria for Schedule I substances set out in the Controlled Substance Act (CSA). The outcome in the US played an influential role in classifying MDMA as a Schedule I substance internationally under the 1971 Convention on Psychotropic Substances. Setting the precedent on an international level only solidified the misconception of MDMA. This made it extremely challenging for scientists to conduct additional research that supports the medical potential and assesses the actual threat of abuse and dependence. When the trend in psychedelic use increased again in the last 35 years, the reaction of legislators was to impose more governmental control, stronger penalties for drug-related crimes, and allow for increased police intervention. This reactionary approach, however, does not protect individuals but increasingly marginalises drug users and obstructs their ability to make informed and responsible decisions. This has made the battle

⁴⁹ Count the Costs, 2012, p. 3.

for MDMA-assisted therapy an even greater challenge. After drawing attention to the unwarranted classification of MDMA, it should be apparent that the decision must be re-examined.

As previously stated, for a substance to be a Schedule I classification it must meet the three requirements: (1) it should have a high potential for abuse, (2) it has no medically accepted use for treatment, and (3) it is unaccepted as safe for use under medical supervision. The CSA clearly provides that a substance may not be placed in Schedule I unless it meets all criteria. When the Health and Human Services (HHS) evaluated MDMA, they did not consult any medical organisation or the FDA's expert Drug Abuse Advisory Committee.⁵⁰ Fearing that MDMA would be detrimental to society, there was a strong agenda to quickly schedule the substance without a fair hearing. Even-more, the National Institute of Drug Abuse wrote a letter citing that the DEA had incorrectly made an inference about the abuse potential of MDMA based on animal trials.⁵¹ Throughout the hearing for the scheduling of MDMA, evidence through testimonies from researchers, psychotherapists, and psychiatrists did not support the necessary criteria for Schedule I.

The Administrative Law Judge had originally recommended it be placed into a more appropriate classification, schedule III:

- (a) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- (b) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (c) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.⁵²

Despite evidence that MDMA met the criteria for Schedule III, the final decision was influenced by Doctors Inaba and Ingrasci whose opinions were rooted in the moral threat MDMA posed. Dr. Inaba reported that MDMA was most likely to be abused by “the gay male population, young professionals, and individuals with a history of hallucinogenic drug

⁵⁰ Scott, 1999-2000, pp. 467-468.

⁵¹ *ibidem*, p. 467.

⁵² 21 U.S.C. § 812 (1970).

use.”⁵³ The use of MDMA by homosexual males does not qualify as a justifiable reason; it is irrelevant and discriminatory. It is used to incite ‘moral panic’ among those who feel that homosexuality threatens the values of society. In order to protect those values, legislators saw it as their moral duty to marginalise its users by criminalising MDMA. Additionally, suggesting that MDMA is a ‘gay drug’ is grossly incorrect, while reports show that the uses of this drug is not unique to the gay community. It is merely an indirect tactic of discrimination, much like the way HIV/AIDS was used to stigmatise and isolate the gay community.

A statement by Dr Ingrasci reported that individuals were using MDMA in a non-therapeutic setting, mostly out of curiosity, recreation, and pleasure.⁵⁴ Again these findings do not support the criteria for schedule I classification as they detail the reasons *why* people are using MDMA but does not imply addictive or abusive behaviour. The ‘pleasure principle’ plays a pivotal role in the assigning of MDMA in which the government views the experience of pleasure or being ‘high’ as “detrimental and morally condemnable [by law].”⁵⁵ In the case of scheduling MDMA in the United states, the final decision forewent the statutory safeguards of the Controlled Substance Act to arbitrarily classify the substance based on moral paternalism rather than the letter of the law.⁵⁶ Threatened by the fact that people were enjoying or experiencing *too much* pleasure, the DEA felt the need to intervene on private life and limit individuals’ ability to experiment with personal boundaries.

Dr. Lester Grinspoon petitioned the United States Court of Appeals because he believed that the mandate of Schedule I controls impedes on research exploring the possible clinical uses for MDMA. He made his complaint on four grounds: (1) the Administrator had incorrectly interpreted the criteria for “currently accepted medical use in treatment in the United

⁵³ Scott, 1999-2000, p. 496.

⁵⁴ Ibidem, 1999-2000.

⁵⁵ Ibidem, 1999-2000, p. 450.

⁵⁶ Ibidem, 1999-2000.

States” and “accepted safety for use [...] under medical supervision,” (2) the Administrator failed to define a legal standard and relied on insufficient evidence, (3) the Administrator failed to acknowledge that classifying MDMA into Schedule I would create obstacles for further drug research, and (4) the Administrator based his ruling on incomplete and arbitrary recommendations by the HHS.⁵⁷ He contended that the Administrator’s failure to weigh all the relevant factors and the impact his decision has on research amounted to arbitrary and frivolous action. Research involving Schedule I substances creates a multitude of legal, administrative, and practical obstacles for approval. These obstacles include: mandatory FDA approval,⁵⁸ special registration with the DEA,⁵⁹ supplemental mandatory reporting and security procedures, delays due to bureaucratic procedure, difficulty obtaining volunteers for clinical trials, and complications attaining approval from institutional review boards.⁶⁰ Although the Administrator does not have to take into consideration the impact it will have on future research, the scheduling classification creates a paradox where the abuse potential can neither be refuted nor supported.

The magnitude of reliable, accurate, and applicable research on MDMA was limited during the time of the scheduling, therefore, lacking in supportive evidence for the potential risks. The administrator based his conclusion on animal and human behavioural studies that suggested MDMA had similar effects to other substances classified in Schedule I, but the question remains whether this was enough to justify his decision. Caution should be taken when making conclusions based upon research on MDMA and MDMA-analogs since many were animal trials in which the drug was administered at toxic levels. Moreover, studies should be conducted in primates before concluding the real potential hazards MDMA could have in humans, since the metabolism of amphetamines varies between species.⁶¹ The neuro-

⁵⁷ United States Court of Appeals, *Grinspoon v. Drug Enforcement Administration* 828 F. 2d 881.

⁵⁸ 21 C.F.R. § 1301.42(a)-(c) (2015).

⁵⁹ 21 C.F.R. §§ 1301.33, 1301.42 (2015).

⁶⁰ United States Court of Appeals, *Grinspoon v. DEA* 828 F. 2d 881.

⁶¹ O’Hearn et al., 1988, p. 2801.

physiological changes exhibited in mice or rats are not reliable indicators. When mice were administered MDMA there was a sustained loss in dopamine, but not in serotonin, while the opposite occurred in rats.⁶² Even two species that come from the same rodent family have very different reactions, suggesting that animal studies can only be relied on to a certain extent. The misuse of research to disproportionately assign MDMA provides evidence for an appeal to its Schedule I categorisation.

The legal avenues for MDMA research became even narrower when Congress introduced the Methamphetamine and Club Drug Anti-Proliferation Act in 2000. With the growing use in the nineties, policy reform enforced more severe penalties for MDMA-related offences and increased funding to control further production, distribution, and use.⁶³ This has had an additional impact in performing studies involving human subjects and accounting for an even greater lack of scientific knowledge on the properties of MDMA. It creates a paradoxical situation in which policy makers are stating there is not enough empirical evidence for the deregulation of MDMA, but financial and legal barriers make it difficult to collect more empirical evidence. A constructive debate on the control of MDMA should be based on the unbiased examination of potential abuse, dependence, and medical use.

III.III MDMA Abuse and Dependence

When evaluating the criteria for *abuse* and *dependence* it is important to understand the difference because they are often used interchangeably in error. Although interrelated, *substance abuse* is outlined in the DSM-V as: (1) recurrent use, (2) use in hazardous situations, (3) recurrent substance-related legal problems, and (4) continued use despite social and interpersonal problems.⁶⁴ However, this criterion is not exhaustive to all situations. Substance abuse can refer to one-time use and does not necessarily result in legal issues or social and

⁶²Robledo et al., 2004, pp. 338-339.

⁶³Smith, 2007, p. 299.

⁶⁴American Psychiatric Association (2013). *Fact Sheet: Substance-Related and Addictive Disorders*.

interpersonal problems. For instance, the abuse of alcohol is widely and socially accepted, and often used as a tool for social bonding. However, the common linking factor between all cases of abuse is that the individual jeopardises his or her health. An individual who has *substance dependence* will meet all of the above criteria for abuse with additional symptoms of tolerance, withdrawal, and unsuccessful efforts to control substance use.⁶⁵ An individual who abuses a substance does not suggest that they also have substance dependence, but the contrary is true.

III.III.I The Abuse Potential

Additional criteria for Schedule I require the substance to be assessed as having a *high* potential for abuse. However, the CSA does not provide a definition distinguishing high versus low potential and only sets out a standard for abuse, which grants the flexibility for interpretation. Borrowing regulations from the Food, Drug, and Cosmetics Act (FDCA), the CSA sets out that a substance has potential for abuse if:

- (1) Evidence shows that individuals are taking a substance which creates a hazard to their health or risks the safety of other individuals or the community; or
- (2) There is significant diversion of the substance through legitimate drug channels; or
- (3) Individuals are taking the substances on their own initiative rather than on the basis of medical advice from a licensed practitioner; or
- (4) The substance is a new drug which is related to another substance that is already listed as having potential for abuse making it likely to have the same potentiality for abuse, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or creating hazards to the health of the user or the safety of the community.⁶⁶

When appealing the Schedule I classification of MDMA, Dr. Grinspoon argued that these legal criteria only provided guidance for the minimum threshold needed to demonstrate abuse, which was enough to justify the placement of a substance as low as Schedule V,

⁶⁵ Ibidem.

⁶⁶ Controlled Substance Act, 21 U.S.C. § 811(h)(3).

meaning low potential for abuse.⁶⁷ These standards do not provide any criteria for assessing the magnitude of the abuse potential of a substance to warrant its placement in Schedule I. The administrator failed to justify its judgement by neglecting the necessity to clearly define high potential of abuse. The high potential for abuse in a substance is examined based on actual levels of abuse relative to other scheduled substances.

Alcohol and tobacco, which are exempt from controlled scheduled substances, could be evaluated by the previous criteria and fit the definition for Schedule I substances based on their high potentiality for abuse. A study in 2014 reported that 24.7% of Americans over 18 years old engaged in binge-drinking and ranking alcohol as the fourth leading cause of death.⁶⁸ It could be argued that alcohol is highly abused because it is easily accessible in comparison to other substances. When comparing two highly controlled substances, it can be observed that accessibility does not positively correlate with abuse potential. 4.6 million have reported cocaine abuse within the past year in 2014⁶⁹ and roughly 800,000 reported abusing MDMA.⁷⁰ When excluding statistics for mental and physical dependence, Cocaine is abused nearly six times more than MDMA while they are both Schedule I substances. Interestingly enough, a report by UNODC on the global trends of drug use found that since 2009 there has been a steady decrease in the prevalence of MDMA use and an increase in other strictly controlled substances, such as opiates.⁷¹ While many opiates are classified as having an accepted medical use, they remain to be the most problematic internationally. The National Survey on Drug Use and Health reported that within the past year only 3.5% had tried or used MDMA between the ages 18-25 years old with a decline in use as the

⁶⁷ United States Court of Appeals, *Grinspoon v. Drug Enforcement Administration* 828 F. 2d 881.

⁶⁸ Substance Abuse and Mental Health Services Administration (SAMHSA), 2014.

⁶⁹ Center for Behavioral Health Statistics and Quality, 2015.

⁷⁰ Substance Abuse and Mental Health Services Administration (SAMHSA), 2014, Table 2.46B—Alcohol use, binge alcohol use, and heavy alcohol use in the past month among persons aged 18 or older, by demographic characteristics: Percentages, 2013 and 2014, <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab2-46b>.

⁷¹ United Nations Office on Drugs and Crime, 2014, p. 1.

population ages.⁷² MDMA is susceptible to excessive use like all other substances, but it appears that its use is managed more responsibly demonstrated by lower rates and decreasing prevalence.

In assessing the abuse potential of MDMA, the Administrator supported his claim based on the fourth criterion laid out in the CSA in which a substance's abuse potential is determined using the rates of abuse of another chemically similar substance or a substance with similar pharmacological effects. MDA, the analog chemical to MDMA, had previously been placed in Schedule I effectively warranting the same placement of MDMA. Despite being from the same chemical family, it is not an indicator of the actual effects MDMA will have on the human body. MDA and MDMA are metabolites⁷³ but vary in intensity, duration, and toxicity due to the differences in metabolic handling. When comparing the effects of MDA and MDMA on serotonergic axon terminals⁷⁴, it was found that MDMA was less neurotoxic than MDA when administered at the same dose.⁷⁵ The question also begs to differ whether MDA was appropriately classified as Schedule I in the first place since previous research only demonstrated the effects of MDA at highly toxic levels in animals. Additionally, the pharmacological effects of MDMA were likened to cocaine, which are both stimulants to the central nervous system (CNS). The Administrator unjustly made this comparison, suggesting that MDMA is just as harmful as cocaine. Considering that caffeine is also a CNS stimulant producing the same pharmacological effects, clearly it cannot be implied that MDMA has a high potential for abuse based on these grounds.⁷⁶

⁷² National Institute on Drug Abuse, 2013.

⁷³ Products of metabolism.

⁷⁴ Where serotonin binds to the neurone.

⁷⁵ In this study, the doses were approximately 5-10 times higher than doses typically use in humans for therapeutic and recreational purposes (O'Hearn et al., 1988, p. 2801).

⁷⁶ Kalant, 2001,p. 920; Gawin and Ellinwood Jr., 1988.

When considering the Congress' intended use of the word 'potential,' one could infer that the Administrator should "not be required to wait until a number of lives have been destroyed or substantial problems have already arisen before designating a drug as subject to the controls of the bill."⁷⁷ The Administrator supported his decision by heavily relying on this interpretation. Instead of the immediately placement of MDMA, the first step would have been to set up regulatory safeguards which would still allow for data collection. Despite all the evidence demonstrating that MDMA does not hold the same abuse potential as Schedule I, a peremptory decision was made.

III.III.II The Scope of Physical and Psychological Dependence

There are two major theoretical models of drug dependence: one is a physiological manifestation of addiction referred to as neuroadaptation and the other a behavioral model defined by psychological indicators. Neuroadaptation is explained as "the complex functional changes in brain chemistry that occur, following repeated substance administration, to oppose the substance's effects in order that brain systems can maintain homeostasis."⁷⁸ This model explains the development of substance tolerance and withdrawal symptoms, which perpetuates drug use and a high probability of relapse. In this model of physical dependence the individual may crave the drug or *want* the drug, but not *enjoy* the euphoric effects of the drug.⁷⁹ Physical dependence is arguably the more dangerous form of addiction because the body no longer has the capacity to self-stabilise without the aid of a chemical substance. Consequently, abrupt withdrawal can endanger the individual's life. Psychological dependence is explained by *operant reinforcement* and *classical conditioning* models, which are focused on directly observable behaviour. The operant model is a type of learning which occurs due to the relationship between behaviour and consequences by increasing behaviours that are rewarded through social or sexual reinforcers and through preferred

⁷⁷ Comprehensive Drug Abuse Prevention and Control Act, 84 Statute 4602.

⁷⁸ Degenhardt, Bruno, and Topp. 2010, p.2

⁷⁹ Ibidem, 2010, pp. 2-3.

cognitive effects such as increased attention or removing of negative stimuli.⁸⁰ Someone who experiences anxiety in social settings may consume a substance to reduce feelings of anxiousness and to make social interaction more pleasurable. Consequently, the individuals become increasingly intolerant to feelings of anxiety. The latter model is based on a conditioned response which is paired with a cue and elicited upon exposure to that cue. It is posulated that when exposed to a cue previously associated with substance administration, the conditioned response is precipitated and may ultimately lead to relapse.⁸¹ A longtime abstinent user who is no longer physically dependent may be triggered by an environmental setting that elicits the desire or craving to use. For example, if a recovering addict hears a song that they used to play while using, they may experience a craving for the substance. Both physical and psychological dependence have neurological underpinnings, but the difference lies in the mechanisms in which the desire or need to use is produced.

Evaluating the dependence syndromes of a substance plays an important role in determining whether a substance will be a hazard to the user or the safety of the community. There are many substances on the market which are unscheduled because of their cultural and social significance despite the well-known risks of abuse and dependency. Regulations on tobacco, for example, limit the age of consumption and place warnings on the package informing its users of the potential health risks. In this case, the state does not intervene despite the high addictability of tobacco or the risk of cancer and the coinciding costs of health care. The general consensus is that it is relatively safe in moderate use and poses little to no threat to society. On the other hand, alcohol is widely abused by addicts and non-addicts and has put countless lives at risk. Just within the US, roughly 16.3 million adults

⁸⁰ Ibidem, 2010, p. 3.

⁸¹ Ibidem, 2010, p. 3.

suffer from Alcohol Use Disorder,⁸² resulting in nearly 88,000 alcohol-related deaths annually.⁸³

Although MDMA produces rewarding effects (i.e. the release of dopamine), research is still disputing its physical and psychological dependency. A study compared the difference between low dosages and high dosages of MDMA and found that only high dosages exhibited rewarding effects and anxiogenic or anxiety-producing effects.⁸⁴ Therapeutic doses of MDMA are evidently lower than recreational doses, which avoids the risk of chemical dependency and undesirable side effects from treatment. As with many chemical substances, administering the inappropriate amount endangers the recipient's health. While it has been very difficult to track the physical dependency of MDMA in humans due to sporadic use, one animal-study tried to chronically administer MDMA at appropriate concentrations. It was found that after chronic MDMA administration, classical somatic withdrawal symptoms were not observed in mice and suggested the absence of physical dependence.⁸⁵ Other studies exploring the properties of MDMA chose to examine high dosages which are not normally observed in recreational use. When comparing the addictability and dangers of MDMA, it is very difficult to evaluate due to limited, unreliable, and skewed data because physical dependence is disputed by research, few experiments investigate the effects of moderate use, and data largely reflects the illicit use of *Ecstasy* which does not always contain MDMA. Additionally, poly-drug use creates uncertainty when assessing dependence because of the blending and interchanging of substances. Many MDMA users are poly-drug

⁸² Substance Abuse and Mental Health Services Administration (SAMHSA), 2014, Table 5.8A—Substance dependence or abuse in the past year among persons aged 18 or older, by demographic characteristics: Numbers in thousands, 2013 and 2014, <http://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs2014/NSDUH-DetTabs2014.htm#tab5-8a>.

⁸³ Centers for Disease Control and Prevention (CDC), <http://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm>.

⁸⁴ Robledo et al., 2004, p. 347.

⁸⁵ *Ibidem*, 2004, p. 338.

users, making it difficult to rely on self-reported dependence because they cannot attribute symptoms to a specific substance.

Research has demonstrated the absence of withdrawal symptoms, further questioning the actual addictability of MDMA. In 2015, a survey was circulated to gauge the prevalence of MDMA dependency compared to other recreational drugs like cocaine, mephedrone, and ketamine. Beforehand, it was reported that the prevalence of MDMA dependency ranged between 4 and 59%; meanwhile, the current survey concluded that 25.8% of MDMA users identified with three or more DSM-V criteria for dependency.⁸⁶ The dependence potential was measured based on self-reported DSM-V criteria substance use disorder, but it should be kept in mind that it does not differentiate between substance abuse or substance dependence.⁸⁷ In investigating the prevalence of dependence based on subjective accounts, this study highlights the difficulties in collecting reliable data to paint an accurate picture of MDMA. It does not consider that the positive aspects of MDMA use may offset the negative effects. The subjects themselves have difficulty reporting MDMA dependence because the recreational form is more often than not mixed with other substances. Additionally, many use MDMA sporadically and less frequently under certain circumstances which does not fit the criteria for recurrent use. It becomes difficult to make a thorough conclusion about the addictability of MDMA because the current criteria cannot adequately assess the addictability of psychedelic substances due to their unique properties.

In the same study on self-reported dependence, MDMA users were less likely to report additional symptoms of substance dependence or feelings of suffering from MDMA use when compared to other drugs.⁸⁸ Due to these low feelings of suffering, many who identified as being MDMA dependent did not feel the need to seek treatment or reduce use. It is unique

⁸⁶ Ibidem, 2015, p. 80.

⁸⁷ Uosukainen, Tacke and Winstock, 2015, p.81.

⁸⁸ Ibidem, 2015, p. 81.

in this aspect when compared to cocaine users who are more likely to report distress. Possibly, MDMA users do not fit the traditional definition of dependence because they do not suffer the same consequences of addiction. The dependence nature of MDMA has been proposed as a duo-factorial structure which provides a better model for evaluation the data based on *compulsive use* (use despite causing significant problems, giving up important activities, unsuccessful attempts to stop or control, withdrawal or excessive time spent obtaining or using) and *escalating use* (increased tolerance, using more than intended for longer periods).⁸⁹ Using this paradigm would allow legislators to better assess the potential dependence of MDMA in comparison to the other Schedule I substances and appropriately place it into another class.

Another way in which MDMA is unique and does not fit the classical definition for addictive substances is that it is in fact used to treat addiction. MDMA has been used by many psychotherapists to treat people with addictive and compulsive behaviours. In one account, a compulsive sex addict is able to gain insight into his addictive behaviours. In-so doing, he differentiates the pleasure he experiences from MDMA and the rewarding effects from his compulsive behaviours:

I didn't really think that I could become addicted to the experience in the sense of being addicted to alcohol or to sexual excess [...] I perceive those as addictions precisely because of their compulsive quality, the quality of never actually obtaining a satisfying, whole, pleasant experience. With the experience of MDMA, on the other hand, I feel none of that compulsion.⁹⁰

This seems to be a common consensus amongst users; they do not feel compelled to take MDMA in order to achieve an escape through immense pleasure. It offers a sense of completeness which continues after the effects of the drug have worn off. Alcoholics, for example, drink in order to satisfy the urge to drink and never really attain the pleasurable experience desired. Thus, continuing a vicious cycle which leads to compulsive and addictive behaviours. Eventually the rewarding effects diminish and require larger doses to relieve

⁸⁹ Degenhardt et al., 2010, p. 7.

⁹⁰ Holland, 2001, p. 188.

withdrawal symptoms. Although psychological dependence cannot be ruled out, it is generally agreed upon by the medical community and users that MDMA is not physically addictive.

III.IV Accepted Medical Use

The emergence of the use of psychedelic substances for psycho-spiritual healing is not a recent phenomenon, it has been a common practice for thousands of years by various non-western cultures. After the discovery of LSD in 1943, many psychedelic drugs were researched for psychiatric applications, but this ended in the 1970's due to widespread recreational use.⁹¹ Nevertheless, an underground community continued to exist that used psychedelics for psychotherapy. Albeit MDMA had remained one of the few unscheduled psychedelic substances until the 1980s, MDMA-assisted therapy was discreetly practiced out of fear that it would become criminalised. The strict regulation of MDMA triggered an uproar of displeasure amongst researchers, physicians, and patients because of its prospective medical value. Dr. Friederike Fisher, a German psychiatrist in Switzerland, was delivering individual and group psycholytic therapy illegally until her arrest in 2009.⁹² The medical community was so confident and passionate about the beneficial properties of MDMA, that many individuals were willing to risk their professional careers. MDMA has always been acknowledged for its therapeutic potential and the medical community has been campaigning for more research to better understand the value of this substance for the past thirty-five years. Legislators ignored supporting scientific evidence and relied on technical interpretations of the law to prescribe MDMA in the most restrictive category.

The original recommendation of the ALJ to place MDMA in Schedule III was overturned based on a different interpretation of 'accepted medical use.' It was understood to mean that in order for a substance to have an accepted medical use it must be evaluated by the

⁹¹ Sessa and Fischer, 2015, p.1

⁹² Ibidem, 2015, p. 1.

FDA. On this assumption, “the Administrator reasoned that because the FDA has not approved a new drug application or investigational new drug application [...], MDMA cannot be lawfully marketed and has neither a currently accepted medical use in treatment in the United States nor an accepted safety for use under medical supervision.”⁹³ The Administrator was referencing to the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), in which FDA must evaluate and approve the safety of a substance to enable interstate marketing.⁹⁴ However, these are insufficient grounds for denying the medical potential of MDMA, the purpose of FDCA is to protect the consumers and give liability to corporations marketing products to the public. The fact that MDMA was not yet an approved marketable drug is not indicative of its medicinal properties. Additionally, the Administrator has interpreted the provision referencing the ‘accepted safety of use under medical observation’ to infer that the substance must be approved by the FDA in order to consider the substance *safe*.⁹⁵ Effectively saying that the FDA sets out the agreed set of standards which deem the substance as safe for public consumption. Since the FDA held no opinion on the medical use and safety of MDMA, the Administrator determined that MDMA has no accepted medical use.

In Dr. Grinspoon’s appeal, he interpreted ‘accepted’ as meaning that “ the medical community generally agrees that the drug in question has a medical use and can be used safely under medical supervision.”⁹⁶ It is possible for a drug to have an accepted medical use and be considered safe under medical supervision without FDA approval. Under the provisions of the CSA, it is not a condition for interstate market approval to indicate accepted medical use. In fact, during the drafting of the Comprehensive Drug Abuse Prevention and Control Act (CDAPCA 1970), two representatives of the Bureau of Narcotics and Dangerous Drugs (BNDD, the DEA predecessor) testified that the medical use of a drug should be deter-

⁹³ United States Court of Appeals, *Grinspoon v DEA*, 828 F.2d 881

⁹⁴ 21 C.F.R. 2.355 (2015).

⁹⁵ United States Court of Appeals, *Grinspoon v DEA*, 828 F.2d 881.

⁹⁶ *Ibidem*.

mined by the medical community and only placed in Schedule I if they conclude that it has no medical value.⁹⁷ The administrator erroneously interpreted that the lack in FDA approval of MDMA to mean that the medical community determined that MDMA has no legitimate use.

The FDA's main role is to protect public health by ensuring the safety, efficacy, and security of marketed drugs for humans; to speed innovations that make medicines more effective, safer, and affordable; to provide accurate, science-based information about medication for the public to improve their health; and regulate the distribution, marketing, and manufacturing of drug.⁹⁸ The FDA does not decide whether a substance has medical value but rather how a new drug will integrate into society. Even more, one of their goals is to improve the quality of health by modernising medical treatment and essentially ensuring the highest attainable standard of health. The FDA should be regarded as an agency that cooperates with the medical community in advancing medicine rather than one which inhibits medical innovation. Only recently, the FDA has approved two research proposals for MDMA-assisted therapy for patients with PTSD and those with terminal cancer who experience anxiety.⁹⁹ According to the Administrator's previous interpretation of the provision in question, a substance is considered to have medical value if it has been evaluated by the FDA. The endorsement of the FDA to conduct human trials is a clear indicator that the FDA accepts MDMA has medical value. Despite the support of the medical community and the FDA, legislators still find it very difficult to accept that MDMA might be beneficial to society.

It is very difficult changing deeply rooted perceptions of psychedelic drugs. It is important to analyse unbiased scientific research in trying to form a comprehensive picture of the risks and benefits of MDMA. A treatment which outweighs the risk will have valuable

⁹⁷ Ibidem.

⁹⁸ United States Food and Drug Administration, <http://www.fda.gov/AboutFDA/WhatWeDo/>.

⁹⁹ Smith, 2007, p. 305.

medical application. George Greer, a strong proponent for the therapeutic use of MDMA, designed a protocol which outlined the purpose, procedures, and legalities with research.¹⁰⁰ This was all in preparation to conduct research through legal and ethical avenues. Dr. Greer was the first to complete a fully comprehensive study on the effects of MDMA on 29 subjects.¹⁰¹ The majority of subjects in a follow-up questionnaire reported positive changes in work, relationships, mood, and attitude after one session. It was additionally noted that half of the individuals reported decreased use of mood-altering drugs. Greer concluded: “the single best use of MDMA is to facilitate more direct communication between people involved in a significant emotional relationship. Not only is communication enhanced during the session, but afterward as well.”¹⁰² The aim of his study was to demonstrate the therapeutic benefits of MDMA and encourage funding for further exploration.

Despite promising findings, the DEA considered his results nullified due to the methodological issues and ascertained that it was impossible to make any inferences regarding the medical potential of MDMA. Considering that the study was self-published, Greer did not have the financial means to execute an exhaustive experiment. The lack of standard scientific procedure does not invalidate the *potentiality* of MDMA; rather it produces uncertain results that need validation through further experimentation. This is the scientific process: a question is asked, the relevance of the question is explored, and then tested and re-tested to produce the most accurate data.

MDMA was in the first stages of the scientific process and produced results which could confirm the therapeutic uses supported by the therapist and psychiatrists around the world. Currently in the UK, US, and Switzerland, permission has been granted for controlled clinical trials. As research makes headway, it provides even more evidence for clinical utility and the urgent need to reschedule MDMA to remove barriers which hinder further research.

¹⁰⁰ Greer, 1981.

¹⁰¹ Greer, 1983.

¹⁰² Greer, 1983, p. 12.

In the US, a study on the effects of MDMA on treatment-resistant PTSD showed that 85% of the participants no longer fit the criteria after three sessions.¹⁰³ These are remarkable results considering the prevalence of PTSD and the length of treatment normally required to reduce symptoms. With the looming threat of suicide in certain cases, recovery time becomes the most vital factor. A follow-up study on the durability of MDMA-assisted therapy reported that the effects were sustained for 3.5 years without further intervention.¹⁰⁴ This alludes to another benefit which allows patients to reduce or even discontinue psychiatric medication. Hopefully after the same results are repeated, legislators can begin to trust the acclaimed medical uses of MDMA and contribute towards transforming psychiatric care. The case of Dr. Meckel Fischer demonstrates the slight and on-going shift in the perception of psychedelics for therapeutic value.

III.IV.I Friederike Meckel Fischer - The Therapist Arrested for Administering MDMA to her Patients

Friederike Meckel Fisher is deemed as a pioneer in psycholytic psychotherapy who was able to successfully practice until reported by a disgruntled client in 2009. This was a landmark case for the psychedelic community because it demonstrated how MDMA could be successfully integrated into therapeutic practice and provide viable clinical intervention for patients. There was a brief period of time in which Swiss legislation allowed for psycholytic therapy, which may have accounted for the lenient sentence Friederike received. Nevertheless, it demonstrated a new understanding of the potential clinical uses of MDMA by legislative authorities. Dr. Fisher faced being charged with 20 years of custodial jail, but instead she was fined 2000 Swiss Francs (1800 EUR) and 16 months suspended sentence with a probation period of two years.¹⁰⁵ Based on her history and testimonies by other therapist and neuroscientists, she was able to prove that she was not endangering society. She

¹⁰³ Mithoefer et al., 2010, p. 448.

¹⁰⁴ Mithoefer et al., 2013, p. 33.

¹⁰⁵ Sessa and Fischer, 2015, p. 5.

previously trained with Dr. Stanislav Grof, who is well known for developing LSD-based therapy and breathing techniques to access non-ordinary consciousness as an integrative approach psychedelic therapy. Her method of drug-assisted psychotherapy was to administer low to moderate doses over a stretched period of time as opposed to other traditional approaches which administer a single high dose.¹⁰⁶ Fischer was a highly trained professional who developed a judicious method of evaluating individuals for MDMA-assisted therapy and fastidious protocol for treatment. She took great care in attending to the set and setting of the therapy, proving otherwise to the accusations of profitable dealing and hedonistic drug use.

The judge had given Fischer the opportunity to openly discuss her work with psychedelics and determined that she had taken careful consideration for the health and welfare of her clients. The charges of endangering society and dealing for profit were ultimately dropped, and she was only charged with violating narcotic law by distributing illegal substances.¹⁰⁷ Prohibitive drug policy can put the well-being of patients and practitioners at risk as seen in the case of Fischer. Fischer risked her profession for the sake of carrying out important work and ultimately paid the price of losing her license and credibility. Under normal circumstances, clinicians are able to consult with other colleagues for supervision, bringing to light weaknesses or new angles for therapy. Additionally, therapists are protected by lawyers and medical insurance when issues arise with patients. Legislation forces the community underground, undermining each party's rights and leaving them vulnerable. If drug policy continues to play ignorant to the medical applications of MDMA, no standards can be put into place for the protection of individuals.

¹⁰⁶ Sessa and Fischer, 2015, p.1.

¹⁰⁷ Ibidem, 2015, p. 5.

III.V Conclusion

The approach of the policy makers seems to be stuck in the sixties with the emergence of heavy psychedelic drug use, viewing it as something that will destroy the youth and compromise the values of society. It is hypocritical to apply the ‘harm principle’ by taking precautionary measures to ensure that MDMA is safe for human consumption when the opposite approach is often taken in respect to industrial chemicals. Common practice allows industrial chemicals to freely exist on the market until otherwise proven hazardous.¹⁰⁸ Legislation has sacrificed the well-being and health of individuals for a legal moralist approach to drug use. In order to reduce harm, legislators, physicians, and community members must be properly educated through reliable and scientific-based evidence.

MDMA is placed alongside other drugs like heroine which are more addictive and dangerous. This makes it difficult for researchers to acquire the necessary permits since the law views MDMA as a highly abusive substance. The process is time consuming, expensive, and resources are often limited. For example in the UK, licenses cost around £5000, excluding fees incurred for criminal background checks, extra-secure pharmacy safes, and inspections.¹⁰⁹ Moreover, manufacturers and distributors also require licenses which in turn escalate the costs and limits the availability of clinical-grade MDMA for research. As more evidence suggests that MDMA is not as addictive or neurotoxic as other Schedule I drugs, clearly the next step is to re-evaluate and appropriately classify it to make it more accessible to researchers and strengthen scientific knowledge. MDMA no longer fits the criteria for Schedule I because abuse is sporadic and infrequent compared to other strictly regulated substances, classical withdrawal symptoms are absent and dependency is low, and it is already being used in clinical trials to treat various illnesses. After nearly 35 years, it cannot be ignored by legislative authorities that it is their duty change this in order to protect the well-being of drugs users and provide more effective treatment for the ill.

¹⁰⁸ Heilig, 2002, p. 130.

¹⁰⁹ Sessa and Nutt, 2015, p. 5.

IV. Human Rights and Access to MDMA

Under the international drug control framework of the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances, it is imperative that states maintain a balance between minimising illicit drugs use while ensuring access to controlled substances for medical and scientific purposes:

Determined to prevent and combat abuse of such substances and the illicit traffic to which it gives rise, *Considering* that rigorous measures are necessary to restrict the use of such substances to legitimate purposes, *Recognising* that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted.¹¹⁰

The preamble expresses a serious commitment to battling drug abuse and illicit trafficking through restrictive legislation, but in a final remark it reminds legislators that efforts should not create barriers that render important controlled substances inaccessible for medical use or research. Regardless of, current drug policy mainly focuses on preventing illicit drug use and trafficking. MDMA has proved to be an invaluable tool for the treatment of mental illness, yet States have ceased to realise their obligation under international drug conventions to remove legal barriers which make it indispensable.

Drug control actors such as the Commission on Narcotic Drugs (CND), International Narcotics Control Board (INCB), and United Nations Office on Drugs and Crime (UNDOC) have maintained a strong focus on combating illicit drug use and trafficking. The WHO appears to be the only actor with a mandated agenda to ensure medical access to controlled substances. Article 3 of the Single Convention gives the WHO an advisory role to the CND with respect to assigning or amending the schedules of any substances.¹¹¹ Under Articles 19 and 20 of the Single Convention, states must submit annual estimates for medical and sci-

¹¹⁰ A/RES/3443, 9 December 1975, *Preamble*.

¹¹¹ A/RES/3444, 9 December 1975, Art. 3(1).

entific controlled substances and statistical returns to the INCB.¹¹² Although the aim of these provisions tries to safeguard the availability of medically controlled substances through monitoring supply and demand, its ulterior motive is to rigorously monitor the extent of illicit drug use. As a result, many states under-estimate their legitimate needs for medically controlled substances out of fear that drug dependence and drug-related offences will increase. At the same time, a report by the Global Commission on Drug Policy highlighted the ineffectiveness of present drug policy due to the annual increase in drug misuse.¹¹³ This demonstrates that increasing restrictive measures does not reduce illicit drug trafficking or use. Therefore, the legitimacy of this approach to drug control must be reevaluated and shift towards a policy which respects human rights.

The basic principles of human rights are violated by virtue of compromising the dignity, autonomy, and self-determination of those suffering from mental illness. The unavailability and inaccessibility of controlled medical substances leaves countless people with inadequate medical treatment, denying the right to the highest attainable standard of health. Policy makers refuse to recognise the gravity of mental illness and the destruction to which it subjects the individual, violating a person's right to freedom from torture and inhuman or degrading treatment. In this section, it will be demonstrated how drug policy has violated the rights of trauma survivors by not taking the appropriate and timely steps to realise the medical potential of MDMA and disregarding the particular needs of this vulnerable group.

IV.I Human Dignity, Autonomy and Self-Determination

Ensuring that human dignity, autonomy, and self-determination are respected is the first step to creating an effective drug policy with a balanced approach to human rights and public health. Human dignity, the basis of human rights, plays an important role in the realisation of the right to health and freedom from degrading treatment. Justice Frank Iacobucci of

¹¹²A/RES/3444, 9 December 1975, Art. 19 and 20.

¹¹³Global Commission on Drug Policy, 2011.

the Canadian Supreme Court (markedly recognised for his commitment to the principle of human dignity) wrote:

Human dignity is harmed by unfair treatment premised upon personal traits or circumstances which do not relate to individual needs, capacities, or merits. It is enhanced by laws which are sensitive to the needs, capacities, and merits of different individuals, taking into account the context underlying their differences.¹¹⁴

Decision makers should understand that the needs of trauma survivors suffering from mental illness are different from the general population in regards to the use of MDMA. Rigid drug policy severely compromises the dignity of those individuals. In fact, it disempowers trauma survivors and lacks respect for their psychological integrity.

Patient autonomy and self-determination are also overlooked when authorities often assume a paternalistic role, believing themselves to have better agency than individuals when it comes to making treatment decisions. The ability of an individual to make their own decisions about personal issues and their fate is a basic and fundamental right, a priority for terminally-ill patients. Although PTSD is not a terminal disease, it should be regarded with equal austerity since many resort to suicide. The longer legislators delay the rescheduling of MDMA, the greater the disregard of individuals' right to make autonomy and medical decision making.

IV.II Right to the Highest Attainable Standard of Health

Under numerous international instruments, it is recognised that the enjoyment of the right to health is conducive to living a life of dignity. In accordance with article 12.1 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), states must affirm “the right of everyone to the enjoyment of the highest attainable standard of physical and *mental* health.”¹¹⁵ Although not all states may be able to afford the same standards, the

¹¹⁴ *Law v Canada (Minister of Employment and Immigration)*, (1999) 1 SCR 497, 170 DLR (4th) 1, p. 530 SCR

¹¹⁵ United Nations, Treaty Series, vol. 993, p. 3

ICESCR enumerates that states should plan and make goals to eventually achieve the full realisation of this right.¹¹⁶ Additionally, the General Assembly adopted Resolution 46/119 which outlined a set of principles specifically protecting persons with mental illness and with the aim of improving mental healthcare.¹¹⁷ It asserts that “all persons have the right to the best available mental health care.”¹¹⁸ These provisions do not elaborate on the meaning of *available* and whether the ‘best treatment available’ must be accepted by authorities or by the medical community. The right to health remains quite vague and international conventions refrain from making specific obligations since it is a costly and slowly realised right in comparison to civil and political rights.

The ‘war on drugs’ through strict control efforts has negatively impacted human rights and lead to even greater human costs. Restricted access to controlled substances has hindered investigations into the medical safety and uses of MDMA. The potentiality of MDMA continues to struggle to gain credibility among legislating authorities and contributes to the lack of access to an effective remedy. As a result, the demands of those suffering from chronic mental illnesses are severely ignored and their human rights are violated. In examining the way in which already medically controlled substances are regulated in the health system, it can be demonstrated how drug-policy fails to protect well-being and health. Failure to address chronic illness can have profound effects of the quality of life and can have additional physical, psychological, and social consequences. A report by the WHO demonstrated that 83% of the world’s population has insufficient access to pain treatment, mainly due to the lack of access to medication such as morphine.¹¹⁹ The right to health is further violated as lack of treatment makes individuals more susceptible to other illnesses. Despite being an essential drug as proclaimed by the WHO, the prohibitive approach to drug con-

¹¹⁶ Ibidem.

¹¹⁷ A/RES/46/119, 1991.

¹¹⁸ “Principles for the protection of persons with mental illness and the improvement of mental health care” (A/RES/46/119, 17 December 1991).

¹¹⁹ World Health Organization, 2012.

trol undermines the right to health. Even so, if MDMA manages to become a medically approved substance like morphine, it is unlikely that it will become easily accessible.

The failure of drug policy is constantly reiterated as illicit drug use continues to rise and essential medicines remain largely inaccessible. Human rights violations are hardly addressed as a concern when drafting drug policy by controlling forces such as the INCB and the UN which are only starting to highlight the vicious cycle created by prohibitive measures. A beginning was made during the 2016 UNGASS on Global Drug Policy in which references were made to human rights, but disappointingly civil society and non-governmental organisations were largely shut out from the conversation. Until a cross-disciplinary approach is taken, drug control will continue to result in a serious public health deficit. It is the obligation of states to ensure policy and legal framework which develops a plan for the implementation of access to health services. Due to lack of political will, the process of approving a medical substance is often stagnant and inaccessible during clinical trials.

IV.II.1 The Right to Expanded-Access to Investigational Drugs

International and federal drug control institutions play an integral part in the realisation of the right to health, yet the restrictions they place on innovative medical treatment has detrimental effects on high-risk patients. As it stands, it is unclear whether an individual has the right to access experimental treatment. Resolution 46/119 does, however, offer *informed consent* as a precondition for patients to be admitted to clinical trials or given experimental treatment.¹²⁰ This protects the subjects' right to knowledge before participating in a clinical trial, but does not offer the right to choose experimental treatment over approved treatment. Even if the participants are able to volunteer for clinical trials, they are unaware of whether they are taking the experimental drug or placebo due to double-blind procedures for control. The question remains whether individuals should be granted the right to access

¹²⁰A/RES/46/119, 17 December 1991, principle 11, para. 5.

experimental medication as a right to health and respect for individual autonomy and self-determination.

The FDA has developed a system of expanded access which offers patients with serious illnesses the option to receive experimental drugs which are still awaiting approval. The average time for new drug approval rose from 2.5 to 8 years despite Congress requiring the FDA to act on new-drug applications within 180 days.¹²¹ The bureaucratic failure of the FDA to fulfill its obligation gave rise to this system of expanded access so that patients could increase their treatment options. The criteria for making an investigative drug available through an expanded-access program for individual use requires: (1) the disease or condition must be seriously or immediately life threatening, (2) that there is no satisfactory alternative therapy, (3) the potential benefits justify the potential risks as determined by the FDA and the physician.¹²² In accordance with these criteria, trauma survivors suffering from PTSD should rightfully be granted access to MDMA-assisted therapy. Individuals with PTSD are subject to high rates of comorbidity and are at a greater risk for chronic disability, distress, and suicide, justifying the criteria determining the seriousness and threat of the disease. Additionally, the existing and available treatments for PTSD have low response rates and even more decreased rates of remission. A mere 20-30% achieves full relief when treated with selective serotonin re-uptake inhibitors (SSRIs).¹²³ Clinical trials with MDMA have sufficiently demonstrated that it more successful, especially with treatment-resistant PTSD. Concerning the risk assessment needed by the FDA and the prescribing physician, it has already been demonstrated as beneficial reflected in the testimony and utilisation by numerous psychotherapists, neuroscientists, and medical doctors.

¹²¹ Darrow et al., 2015, p. 279.

¹²² Ibidem, 2015, p. 280.

¹²³ Berger et al., 2009, p. 179.

In 2001, the FDA approved the first protocol to investigate the therapeutic potential of MDMA.¹²⁴ In light of this approval, the FDA would have had to determine that the benefits outweighed the risks to allow human trials. However, expanded-access has yet to be granted and the development of MDMA as an FDA-approved medication is estimated to take an additional five years if everything progresses accordingly. It is the obligation of the state to actualise the progress of new and effective drugs which improve public health, but is continually delayed due to the stigmatisation of MDMA ignoring the fact that individuals have the right to choose MDMA-assisted therapy under the protocol of expanded-access.

As it stands, the European Court of Human Rights (ECtHR) does not recognise access to experimental drugs as a fundamental right. In *Hristozov and Others v Bulgaria*, the court ruled that denying access to experimental drugs was not in violation of Article 8 (right to respect for private and family life), Article 2 (right to life), or Article 3 (prohibition of torture and of inhuman or degrading treatment).¹²⁵ Despite the emerging trend in which states have authorised the ‘compassionate use’ of experimental drugs for serious illnesses, the court determined that this practice could not be justified by customary law. It was also concluded from *Durisotto v Italy* that the applicant had no right to experimental treatment based on the lack of scientific basis for said therapy.¹²⁶ However in the wake of the Ebola outbreak, the WHO issued an unprecedented statement that it was ethical to release unapproved drugs in dire situations.¹²⁷ In addressing a humanitarian crisis, whether it is Ebola or PTSD, there is an established hierarchy of infectious disease over mental illness, but the risks of releasing an unapproved drug are the same. It was unclear whether the new drug for Ebola would be effective or what kind of side effects it would have, but to public health is considered greater than the risk of an experimental treatment. A case can be made, that PTSD poses a great enough threat to public health to warrant the use of an experimental

¹²⁴ MAPS, n.d., <http://www.maps.org/research-archive/mdma/protocol/index2.html>.

¹²⁵ Registrar of the European Court of Human Rights, 2012a.

¹²⁶ Registrar of the European Court of Human Rights, 2014.

¹²⁷ AP Archive, 2015, 0:46.

treatment. But the response to the threat of PTSD is staggeringly minimalistic since the development of MDMA-assisted therapy has waited approval since 2001.

Another aspect of an individual's right to the highest attainable standard of health is a question of whether an individual has the ability to assess the risks and make informed decisions on treatment. The court fails to respect the fundamental rights of patients who are capable of making informed treatment decisions with their physician. Especially when the stakes are high (i.e. patient is contemplating suicide), the individual should be afforded the ability to assess their own risk-benefit threshold when agreeing to experimental treatment—an exercise of the right to private life and individual autonomy. The US Supreme court did hold an expanded opinion of the right to privacy, however, which included personal decisions related to health such as the right to refuse treatment. Asserting that: “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”¹²⁸ Following this acknowledgement by the Supreme Court, it can be assumed that one should conversely hold the right to elect experimental treatment by determination of one's own fate. In 2006, the Abigail Alliance for Better Access to Developmental Drugs asserted of the right to access unapproved drugs is provided by the Supreme Court, but the decision was overturned a year later.¹²⁹

In an attempt to fulfill the right to health and simultaneously influence constitutional law, some US states have legislated the ‘Right to Try’ laws which conflict with federal statutes and regulation. If the decision of *Abigail Alliance v Von Eschenbach* still stood, the putative substance of the Right to Try laws would have become constitutionalised, allowing for new legislation to remove FDA oversight from the process of expanded access.¹³⁰ Currently there are three states in the US where the ‘right to try’ laws exist, “allowing [doctors] to

¹²⁸ *Canterbury v. Spense* 464 F.2d 772.

¹²⁹ *Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach* (495 F.3d 695).

¹³⁰ *Adriance*, 2014, p. 150.

provide experimental medicines to terminally ill patients without FDA authorisation, purportedly eliminating certain obstacles to expanded access.”¹³¹ These laws propose a decentralisation of drug control held by federal institutions, where the physician treating the individual can make a better informed opinion than can the state. Institutions, such as the FDA, do not have adequate resources to evaluate each case and are not sufficiently qualified to replace a physician. As a result of this centralised control, the process of drug approval reluctantly progresses. The ‘Right to Try’ laws are a testament to individual autonomy and a response to the failure of the state to provide access to the best available treatment.

The ethical argument against access to experimental drugs follows that patients’ ability to make decisions are compromised due to their vulnerable state, making them more likely to overlook the health risks or become victims of fraudulent medication. Considering that most patients lack the skills to evaluate pharmacologic, clinical, and statistical information, risk comprehension is low among the general public and possibly even more in chronically ill patients.¹³² This justification for denying access is actually the reason we need to grant controlled safe access to experimental treatments because the desperation level of these particular patients drives them to pursue treatment regardless of legality. When personal autonomy is undermined by state-assumed paternalism, the individual who pursues self-determination loses the protection of the state. Although chronically ill patients are afforded a way to participate in clinical trials, it does not guarantee access to experimental treatment. The current clinical experimentation procedure is exclusive, limited to a small patient population who fit specific criteria. For that small population there is no guarantee of access to the treatment due to control groups within the experimental sample receiving the placebo. Out of desperation, patients resort to measures which are potentially dangerous. For example, in order to obtain unavailable medications some travel to foreign countries, use home-

¹³¹ Darrow, 2015, p. 283.

¹³² Ibidem, 2015, p. 284.

made drugs, or resort to guerrilla clinics.¹³³ This makes the individual extremely vulnerable without the protection of a proper physician or guarantee of being treated with medical-grade MDMA. With the failure of drug policy leaving many without access to arguably one of the most promising treatments in psychiatry, control measures need to be re-evaluated to protect public health rather than moral health. In respecting the dignity of those individuals, the court should allow the freedom to take the necessary measures to alleviate extreme suffering.

IV.III Freedom from Torture and Inhuman or Degrading Treatment

PTSD is most often regarded as *treatable* or *manageable* rather than *curable*. In fact, ‘cure’ is a rarity in the psychiatric field. A VA psychologist claims that there is no cure for PTSD, while the only option is to manage the symptoms to a functional level.¹³⁴ In the first randomised pilot study for treatment-resistant PTSD using MDMA-assisted therapy, 83% of the subjects no longer met the criteria for PTSD versus 25% of the placebo group.¹³⁵ The remaining 75% of the placebo group who did not respond were then treated with MDMA, resulting in a clinical response rate of 100%.¹³⁶ Since then other phases of clinical trials have been completed, showing the same unprecedented results. MDMA-assisted therapy is the best available treatment, but it remains inaccessible due to barriers created by drug policy. It is like dangling a treat in front of hungry eyes; the cure is visible, but patients are left to continue suffering from PTSD.

Reducing access to essential medicines is considered a violation of the right to be free from torture and inhumane or degrading treatment since states are obliged to provide a minimum standard of health care by ensuring the availability of WHO essential medicines. In a sub-

¹³³ Underground clinics, known as guerrilla clinics, exist in nearly 40 US cities (Lombard, 2007, p. 182, *see supra* note 124).

¹³⁴ Quinn, 2013.

¹³⁵ Mithoefer, 2011, p. 448.

¹³⁶ *Ibidem*, 2011, p. 448.

mission to the Committee against Torture, the Special Rapporteur on the right to the enjoyment of the highest attainable standard of physical and mental health proclaimed that gross human rights violations had resulted from excessive punitive approaches to drug policy.¹³⁷ The restrictive drug regime limited the availability of medicines and prolonged suffering. The Special Rapporteur reiterates the importance of access to controlled medicines for people with life-limiting illnesses.¹³⁸ This should entitle patients access to MDMA-assisted therapy for a number of reasons: (1) MDMA is a controlled substance which is currently accepted as a medicine by the medical community, (2) PTSD is an extremely ‘life-limiting’ disorder with low prospects of recovery, and (3) obstructing access to the most effective treatment known to psychiatry is inhumane treatment. The field of psychiatry is often compared to palliative care since mental illnesses have low clinical response rates and patients are often lost to suicide. Mental illness not only causes extreme emotional suffering but exacerbates physical health. The pain and suffering can be very similar to if not the same as somatic diseases. This calls for a shift in the way mental illnesses are perceived and the need to urgently address suffering of trauma survivors with equal importance as we do HIV or cancer.

The applicants of *Hristozov and Others v. Bulgaria* claimed that denying experimental treatment to which they believed would be beneficial was a violation of Article 3 of the ECHR. The ECtHR found no violation of Article 3: “It could not be said that by refusing the applicants access to a product – even if potentially life-saving – whose safety and efficacy were still in doubt, the authorities had directly added to the applicants’ physical suffering.”¹³⁹ In this decision, the court was taking into consideration the potentiality of the drug being ineffective or unsafe and held that withholding experimental medication was a safety measure laid down in legislation. However, MDMA-assisted therapy has been used by

¹³⁷ UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 2012.

¹³⁸ Ibidem, 2012, p. 5, para. 7.

¹³⁹ Registrar of the European Court of Human Rights, 2012b, p. 3.

trained psychiatrists for the past 35 years, and research has produced insurmountable evidence that the benefits far exceed the risk potential. Withholding this experimental treatment directly affects the lives of trauma survivors, leaving them to suffer. The state does have a responsibility to protect life when there is a clear and imminent threat. In this case, the state believes that the potential risks of an experimental treatment outweigh the risks of suicide in patients who are experiencing mental suffering.

In the Netherlands, the Dutch Euthanasia Commission now grants assisted suicide to individuals with unbearable mental suffering caused by trauma where there is no prospect for improvement. This novel recognition and respect for the dignity of human life also affirms the right to be free from inhuman treatment. Denying the right to make autonomous decisions about personal health could subject the person to a slow and painful demise through self-mutilation or failed suicide attempts. In a controversial case, a young woman in her 20s suffering from debilitating PTSD was granted euthanasia after it was determined that she had exhausted all possible therapies and was declared ‘incurable.’¹⁴⁰ The PTSD caused by sexual abuse coincided with severe anorexia nervosa, chronic depression and suicidality, self-mutilation, and increasingly more somatic issues.¹⁴¹ Although a severe case, it is not uncommon that PTSD is linked to other illnesses which increase personal suffering and deteriorate the quality of life as illustrated in this case. It is interesting to highlight the inconsistency in attitudes towards self-determination where individuals are granted the right to die in order to avoid insufferable pain, but MDMA-assisted therapy remains inaccessible as a last resort for treatment-resistant PTSD. This calls for serious concern as it appears that drug control policy neglects its obligation to respect human rights. The unfortunate result of restrictive drug control measures has allowed for another bleak avenue where there is an

¹⁴⁰ Regionale Toetsingscommissies Euthanasie, 2015.

¹⁴¹ Ibidem, 2015, para. 2(a).

increase in the number of applicants seeking reprieve through euthanasia.¹⁴² In granting access to MDMA-assisted therapy, patients would have promising and alternative opportunities for relief. In order to protect human dignity, the framework of drug control must change to alleviate the suffering of mental illnesses.

IV.IV Conclusion

Authorities can no longer hide behind the false pretence of protecting public health through rigorous legislation; it has been demonstrated that it puts individuals at risk and violates their human rights. So affirmed in the UDHR, the parties of the United Nations acknowledge their “faith in fundamental human rights, in dignity and worth of the human person [...] and have determined to promote social progress and better standards of life in larger freedom.”¹⁴³ MDMA-therapy is indeed elemental to progress and development in the psychiatric field, which will drastically improve the lives of PTSD-sufferers. Withholding advancements in psychiatric care is a violation of the right to health and subjects at-risk trauma patients to prolonged suffering and inhumane treatment. Furthermore, refusing ‘compassionate care’ or expanded-access breaches the right to life and the right to private life. MDMA-assisted therapy restores the dignity once stolen by trauma. Living in constant turmoil due to lack of access to effective drugs is an abuse of the right to life, resulting in many lives lost. An individual has the right to choose treatment when consulting with a competent physician, allowing them to make a coherent and informed decision. The risks and benefits are better evaluated by the physician who personally knows the patient than narrow-minded drug legislation.

Ben Sessa, one of the leading psychiatrists advocating for MDMA psychotherapy, adds “data now has been stacking-up [against prohibitive drug legislation]. So there’s only one frontier left in which to fight the drug war now and that is — the moral one, they’re just

¹⁴² Boztas, 2016, <http://www.telegraph.co.uk/news/2016/05/11/netherlands-sees-sharp-increase-in-people-choosing-euthanasia-du/>.

¹⁴³ UN General Assembly, Universal Declaration of Human Rights, Preamble.

wrong.”¹⁴⁴ But denying access to MDMA-assisted therapy because psychedelics are considered immoral is shaky ground for legislators to rely on. Sole reliance upon the question of morality as legitimate grounds for legislation cracks open a Pandora’s Box of subjective opinions on areas of public life which have been previously considered beyond the scope legislative domain. Even so, if the original intention of prohibitive drug policy was to protect public health and safety, this approach has failed to achieve this outcome. Drug policy continues to hinder social progress and undermine human rights rendering the moral justification that ‘psychedelics are wrong’ entirely unsupported and irrelevant.

V. Ethical Parameters of MDMA-assisted Therapy

MDMA is unlike any other psychiatric medication or treatment available due to its unique psychedelic properties. Mental processes occur at many different levels, and psychedelic drugs are a powerful tool which allows the individual to dissolve the barriers of the consciousness and other states. Additionally, these substances have profound effects on perception and cognition allowing the mind to be better understood. To understand the difference between psychedelic drugs and traditional anti-psychotics: an anti-psychotic can be likened to ibuprofen which treats the symptoms of an illness by lowering the fever and psychedelic drugs are comparable to antibiotics which directly treat the disease. Introducing and integrating a novel treatment for mental health is going to raise ethical concerns for legislators, caring professionals, and patients. Authorities who view psychedelics as a threat to the moral health of society will fear a loss of cultural values and substance abuse. How will MDMA-assisted therapy change the public perception of psychedelics? And furthermore, how will this new treatment change the perception of the gravity of trauma?

Since the goal is to integrate MDMA into a therapeutic regime, issues of administration and protocol will need to be addressed. MDMA is dissimilar from prescribing the common SSRI; it is not taken daily or independently. It loses its therapeutic benefits without the

¹⁴⁴ Real Talk, 2015, 0:55.

proper setting and guidance and could put the user at risk when not under observation. A plan of implementation needs to be proposed which protects the health of patients and provides competent treatment methods. Lastly, parameters will need to be set for who will be eligible for MDMA-assisted therapy and criteria established for how prospective candidates will be assessed.

V.I “A Loss of Cultural Values?”

The main reason legislators are apprehensive to reform a more laxative drug control policy is because they believe psychedelics breed deviant behaviour. They believe that lessening the restrictions will encourage more people to take them and abuse them. When in fact, evidence shows that prohibitive drug policy does not dissuade individuals from seeking controlled substances. After the popularisation of MDMA in the 80s and the resurgence of the psychedelic research, public authorities and the media have attempted to portray it as a dangerous neurotoxic substance which is responsible for the deaths of out-of-control youth. Increasingly, public discourse has branded MDMA with debasing language such as ‘club drug’ or ‘rave drug’ to suggest hedonistic use. MDMA was quickly condemned by conservative whistleblowers as being immoral for its popular use in clubs, parties, and electronic music festivals, depicting its users as outcasts.

MDMA is often conflated with Ecstasy or other novel psychoactive substances¹⁴⁵ when reporting on drug-related hospitalisations or deaths. Without the proper means to identify novel psychoactive substances, MDMA often takes the blame for these unknown substances which are the real perpetrators. In addition, MDMA is often referred to in the media as ‘illegal’ or ‘illicit’ when it is in fact a *controlled* substance. This choice of commentary automatically criminalises its users and further marginalises them as deranged drug abusers.

¹⁴⁵ Novel psychoactive substances are ‘designer drugs’ which are technically legal because they are not yet scheduled.

The use of MDMA has been under attack with the Illicit Drug Anti-Proliferation Act, also called Reducing American's Vulnerability to Ecstasy (RAVE) Act which targets electronic dance culture by making promoters and organisers liable for drug use or encouraging the illicit use.¹⁴⁶ This type of legislation ultimately pushes users underground, which in turn exposes them to greater risk. Admittedly, MDMA is part of the dance/rave culture, but its main value is therapeutic which allows people to connect with and understand each other. MDMA may otherwise be considered to be an important part of ritual or cultural experience. On the other hand, substances like alcohol are used to diminish personal boundaries which can make its consumers vulnerable. Alcohol is the most commonly used substance in drug-facilitated sexual assault.¹⁴⁷ The attempt to preserve cultural values by condemning MDMA creates a paradox which threatens the health and safety of human lives. Truly this is a loss of cultural values!

The image of MDMA is misconstrued by the media and authorities, bolstering unfounded toothless fears. Allowing the safe use of drugs would embody a society that cares for its individuals by employing measures which protect against accidents. Supporting harm reduction programs would provide better access to accurate information for dosage, route of administration, and warnings for concurrent drug use. On average 29 deaths per year between 2010-2014 were attributed ecstasy in the UK, but cases involved impure samples, poly-drug use, and alcohol consumption.¹⁴⁸ Considering the millions of tablets which are distributed annually, this statistic is incredibly low in comparison to alcohol and tobacco; a total of 8,697 alcohol-related deaths and 78,000 tobacco-related deaths occurred in 2014.¹⁴⁹

¹⁴⁶ Anderson, 2014, pp. 48-49.

¹⁴⁷ RAINN, n.d., <https://www.rainn.org/articles/drug-facilitated-sexual-assault>.

¹⁴⁸ Office for National Statistics, 2015, pp. 6-7, Table 1: Number of drug-related deaths where selected substances which are commonly abused were mentioned on the death certificate, deaths registered in 2010 to 2014.

¹⁴⁹ Office of National Statistics, 2013, p. 2; Health and Social Care Information Centre, 2016.

This further provides evidence that the aim of drug policy is not to protect society, but to promote the notion that psychedelic drugs are immoral and corrupt society.

Once legislation prioritises public health, MDMA can finally renew its reputation as a life-saving and healing treatment. It might even change the public perception of other psychedelic drugs and pave the way for more innovative treatments for mental illnesses. One concern, however, could be the way in which society's perception of mental illness changes in response to MDMA-assisted therapy. If PTSD is now seen as a curable disorder, it could possibly undermine the seriousness of trauma. Society may confound the treatment as something which erases traumatic memories and returns the individual back to their original functioning self, diminishing treatment to the simple act of taking a pill. It will be important to inform the public on how these treatments operate. It is not a pill which is prescribed and taken unsupervised, it is a therapeutic tool which aids in psychotherapy. MDMA does not erase the individual's memories of the trauma but helps in processing the way in which the patient relates their self to the trauma. Another misconception is that MDMA erases the fear response and individuals are left incapable of assessing dangerous situations. MDMA restores the over-active fear response manifested by PTSD to normal levels.

If PTSD becomes a curable condition, those who no longer fit the criteria can theoretically return to normal life and resume working if they were on disability. There have been ethical concerns whether war veterans who have recovered and no longer meet the criteria for PTSD may be considered fit to return to the front lines. Using MDMA-assisted therapy to recycle soldiers may be considered unethical, because their pre-condition to mental illness makes them vulnerable. One would have to ask how it is different from clearing a soldier to active duty who has recovered from a physical injury versus recovering from a mental illness. Many against military funding of MDMA research believe that it would become a

‘weapon of war’ by “allowing soldiers to ‘feel better’ about war-related atrocities and perhaps return to commit them again, conscience-free.”¹⁵⁰ In truth, MDMA would not clear a veterans conscience, but rather teach them empathy and compassion which would allow them to make better decisions in combat. Dr. Sameet Kumar perfectly summarises: “To confuse the treatment of PTSD with complicity to murder or an unjust war reflects a profound lack of understanding about what war, politics, change, and therapy are all about.”¹⁵¹ Most people joined the military because they were drafted, are seeking better education or a profession, or out of family tradition, rather than lust for violence. Many veterans build their lives and careers around the military. Treating veterans with MDMA-assisted therapy could empower them and help them regain a sense of purpose by allowing them to return to active duty.

Consequently, there has been controversy over the funding and ethical use of MDMA-assisted therapy amongst researchers and therapists. The pharmaceutical industry is known for ‘selling disease’ by marketing and promoting prescriptions to prescribers and consumers. It may otherwise be called ‘disease mongering’: “widening the boundaries of treatable illness in order to expand markets for those who sell and deliver treatments.”¹⁵² Considering MDMA cannot be marketed alone and only used by psychotherapists who are licensed to performed drug-integrated therapy, pharmaceutical companies will have difficulty exploiting the medication. MAPS, which is currently a non-profit research organisation developing the use of psychedelic drugs, has formed a subsidiary body called MAPS Public Benefit Corporation (MPBC). Once the FDA and the EMA (European Medicines Agency) approves the prescription use of MDMA-assisted therapy, MPBC will manage the prescription sales and reinvest profits into further research and educational programs of the non-

¹⁵⁰ Doyle and Koster, 2005, p. 16.

¹⁵¹ Ibidem, 2005, p. 18.

¹⁵² Moynihan, Heath and Henry, 2002, p. 886.

profit.¹⁵³ This ensures the most ethical marketing of MDMA because the company is not looking to capitalise on consumers but support further research and sustain educational programs to ensure safe use.

V.II Who Gets Access and How are they Assessed?

There has been some debate over who would be eligible for MDMA-assisted therapy and its ethical application. When considering who will be included or excluded, it is important to first understand the risks of MDMA in order to know who is most vulnerable to them. MDMA toxicity is extremely rare even in uncontrolled settings, but commonly reported side effects after controlled administration include tight jaw, loss of appetite, difficulty concentrating, impaired gait or balance, and sometimes fatigue or low mood.¹⁵⁴ Participants must be fit to avoid any potential or serious adverse side effects. So, it is vital to examine the individual's medical history and conduct a psychiatric interview as is protocol before prescribing any treatment or medication. In a study protocol for MDMA-assisted therapy, the criteria excluded: (1) minors under 18, (2) pregnant women or potentially child-bearing, (3) physically unfit individuals, (4) history of psychotic disorder, bipolar affective disorder or borderline personality disorder, (5) illicit drug use within the previous 6 months, (6) and individuals who cannot safely withdraw from prescription medications.¹⁵⁵ While the majority of these criteria are to conduct valid scientific research, it also serves as a measure for protecting the health and well-being of patients. For example, an individual with cardiovascular disease might be exposed to certain complications because MDMA raises blood pressure.

Currently, there is no research exploring the potential of treating children and adolescents with trauma, but it is on the radar of many psychiatrists in this field. In fact, there is limited

¹⁵³ MAPS Public Benefit Corporation, Available from: <http://mapsbcorp.com/>.

¹⁵⁴ Multidisciplinary Association for Psychedelic Studies, 2010, p. 36.

¹⁵⁵ Mithoefer MD, 2009, p. 11.

research in the effect of psychotropic medications in children and adolescents. But there is a precedent amongst child psychiatrists to prescribe medications to children that have only been tested upon adults. More often than not, FDA medications approved for mood disorders, anxiety disorders, psychosis, and attention-deficit/hyperactivity disorder (ADHD) for adults are prescribed “off label” to the youth.¹⁵⁶ This means that the dosage and age-range are not specified by any drug administration and it is ethically accepted for the overseeing physician to make appropriate estimations. This is an accepted practice in order to prevent emotional and behavioral issues from becoming chronic, disabling, or irreversible. This is because these children are more vulnerable to expulsion from school, entering the juvenile justice system, and chronic illness leading to unemployment (creating an even greater financial burden).¹⁵⁷ The same could be true for administering MDMA-assisted therapy to youth who have experienced trauma as it would save years of emotional suffering and prevent the trauma from negatively effecting emotional development into adulthood. Ben Sessa explains: “maltreatment of children is the cause of mental illness, in my opinion. Once a person’s personality has been formed in childhood and adolescence and into early adulthood, it’s very difficult to encourage a patient to think otherwise.”¹⁵⁸ Although it is widely accepted that children should receive early intervention while they are still malleable, a proper age must be established for administering MDMA treatment since the child must first be capable of emotional processing. It may be difficult to establish an age-limit, because the age at which a child is able to process trauma may vary. In this case, when it comes to the trial of medicine in paediatric psychiatry the provider must: provide detailed feedback of the diagnosis, educate the youth and family on proposed treatment plan, ensure informed consent from guardians, and most importantly the youth must have a developmentally appropriate understanding.¹⁵⁹ Therefore, it may be best to identify the stage ado-

¹⁵⁶ American Academy of Child and Adolescent Psychiatry, 2012, p.11

¹⁵⁷ Harrison, Cluxton-Keller, and Gross, 2012, p.139.

¹⁵⁸ Wong, 2016.

¹⁵⁹ American Academy of Child & Adolescent Psychiatry, 2012, p.9.

lescence as the best guideline since this is when children begin to enter puberty and emotional development begins to increase.

V.III Administration and Therapy Integration

As lightly touch upon, MDMA will not be prescribed like other psychotropic medicines which are taken daily under the responsibility of the patient. MDMA will only be administered as part of an extensive treatment plan which requires specially trained therapist, controlled environments, various therapeutic approaches, preparatory sessions, and follow-up sessions. “The basic premise of this treatment approach is that the therapeutic effect is not due simply to the physiological effects of the medicine; rather, it is the result of an interaction between the effects of the medicine, the therapeutic setting, and the mindsets of the participant and the therapists.”¹⁶⁰ MAPS has further developed the therapeutic method in order to establish a standardised approach to treatment. In their manual they have laid out the elements of therapeutic approach as follows: (1) safety and wellbeing are the number one priority, (2) therapists must have the relevant training and experience, (3) patients require adequate preparation and orientation, (4) the proper set, setting, and support system must be created, (5) develop therapeutic trust and alliance over the course of treatment, (6) using a non-directive approach which allows the individuals own unfolding of experience and healing process, (7) therapists should encourage individuals to trust their inner healing process, (8) therapists must balance between facilitators and non-invasive empathetic witnesses, (9) enable processing of trauma instead of avoidance, (10) ensure that the individual is not re-traumatised, (11) address somatic manifestations of trauma, (12) use of tools such as music, breathe-work, etc. to evoke and support emotional experience, (13) integrate lessons learned in the non-ordinary state of consciousness with daily life in follow-up sessions, (14) thorough understanding of the non-linear manner of healing.¹⁶¹ The entire treatment plan is built upon the use of MDMA which makes it uniquely different. It requires a

¹⁶⁰ Mithoefer MD, 2013, p. 5.

¹⁶¹ Ibidem, 2013, pp.6-7.

lot of collaboration between the patient, overseeing physician, and therapist for the completion of treatment.

As with all pharmaceutical drugs, there is always a risk of abuse either by the prescriber or the patient by over-diagnosing, over-prescribing, or manipulation. However, there are several mechanisms by which this could be prevented with the prescription of MDMA. A national registry can be formed providing information on how many times a patient has received MDMA-assisted therapy, where and when they have applied for treatment, and whether they have been denied under certain criteria. This would ensure that patients are not manipulating the therapeutic use of MDMA for recreational activity. However, it would be highly unlikely that an individual would go through extensive psychotherapy and evaluation solely for the recreational use of MDMA when it can be obtained through easier avenues. Only a few therapists with the license to safely conduct drug-induced therapy will have the ability to authorize prescriptions. In fact, the use of MDMA for the treatment of mental illness may have a positive effect in reducing over-prescription of drugs. In assessment of the prescription drug claims for antidepressants, antipsychotics, ADHD medications, and anti-anxiety medications, it was found that more than one-in-five adults are taking at least one of these medications.¹⁶² The prescription of psychiatric medication is ever-increasing, which may suggest that doctors are over-diagnosing, over-prescribing, mental illness is rising, or current treatments are not adequately effective. MDMA is administered only a few times between weekly psychotherapy sessions and can even produce positive results after a single session. In a follow-up study, subjects required no further MDMA intervention and had reduced or discontinued the use of psychiatric medication.¹⁶³ Being that MDMA actively works with therapy to help the patient recover and reduces the overall need for additional psychiatric medicine, it achieves the ultimate goal of psychiatric care by treating the root of the disease rather than succumbing to symptomatic treatment.

¹⁶² Medco, 2011, p.2.

¹⁶³ Mithoefer, 2013, p. 38.

Although the current drug policy will have to change its entire perspective on psychedelic drugs with the introduction of MDMA-assisted therapy, the psychiatric care regime will also need to be entirely renovated. Psychiatrists will no longer view patients as a check-list of symptoms which are matched to a slew of prescriptions and patients will not have to endure the harsh side effects of mixing medications. The role of the therapist transforms from an authoritative expert to a guide aiding the patient in their recovery and meanwhile empowering the client to foster self-healing. The domains between psychiatrists and therapists become enmeshed as they work together in observing the active effects of MDMA and using it as a powerful tool for recovery.

V.IV Conclusion

Although it is important and necessary to discuss the ethical concerns of MDMA as a therapeutic treatment for PTSD, making it accessible should not be associated with a loss of moral values. It is time to discard this idea that drugs are *just bad*. This opinion is too often mistaken for fact and efforts cease to look beyond this common belief. The benefits of MDMA are supported by a growing field of research and the only moral decision is to grant access! Most likely MDMA will only be approved for adults, but it is encouraged that research look into its application for adolescents. Without treatment, PTSD could be extremely detrimental to the development of adolescents and severely impact their future as functional adults. Those who question the abuse potential and risks of MDMA should observe well rounded research which supports the safety and efficacy of MDMA-assisted therapy. In comparison to conventional psychiatric drugs which are administered daily over long periods of time (sometimes spanning an entire lifetime), MDMA is administered only a few times under direct observation. Being a part of an integrated therapeutic model ensures that patients are committed to healing instead of seeking recreational use. Additionally, the nature of MDMA has little to no potential for addiction, especially in a controlled environment. The real ethical issue at hand is the lack of access to MDMA-assisted therapy as an effective treatment for trauma survivors.

VI. Thesis Conclusion and Implications

“All substances are poisons: there is none which is not a poison. The right dose differentiates a poison from a remedy.” - Paracelcus (1493-1541)

A drug is mostly referenced as “an illegal substance that causes addiction, habituation, or a marked change in consciousness.”¹⁶⁴ Yet a drug can be any substance (legal or not) which produces a physiological effect, making everyone a drug user one way or another. Daily lives involve ingesting some kind of substance in order to sustain a homeostasis. One eats every day to keep hunger away and sustain energy levels to function. Just as food is the sustainer of life, it can also be the demise of an individual. Eat too little and one dies of starvation; eat too much and one dies from obesity related-diseases. This is the point that Paracelcus makes: that all substances are drugs with the potential to be poisonous when administered incorrectly or beneficial with the right dosage. This is how drugs should be understood and studied in order to know the true benefits and risks. However, the primary goal of drug prohibitionists is to obscure the facts by perpetuating the surrounding myths and misconceptions created by the media. MDMA faces an uphill battle against its tainted record in order to rebrand itself as an effective therapeutic treatment. In Griffin’s article on medicines and the media, he draws attention to the way media categorises medicine as either a “wonder-drug” or a “shock-horror.”¹⁶⁵ Only recently with the revival of psychedelic research investigating treatment for war veterans suffering from PTSD has the media reported more positively on MDMA. However, whenever a death occurs due to the illicit use of an unknown psychedelic substance, MDMA becomes the scapegoat of the media. It will take the strong force of an interdisciplinary collaboration of researchers, therapists, policy makers,

¹⁶⁴ Merriam-Webster, n.d., <http://www.merriam-webster.com/dictionary/drug>.

¹⁶⁵ Griffin, 1986.

and human rights activists to change the face of psychedelics as a respected therapeutic tool.

Throughout this thesis, we have made a comprehensive analysis of the legal status of MDMA in current drug policy, the human rights approach to access effective treatment, and how to address the ethical parameters of treatment. It has been shown that the current drug policy has proved to be ineffective in protecting public health and safety, it inaccurately schedules substances with medical value, and it inconsistently follows protocol in ensuring access to health care. It is urged that policy makers examine the true impact they have on public health and lend an empathetic ear to trauma sufferers who are denied access to valuable treatment. Annually, more people suffer as a result of unfair prohibitionist policy. Human rights are beginning to play a greater role in the discussion on the drug control regime and proponents are strongly advocating for change. MDMA does not pose the same threat as its fellow Schedule I drugs; it is preposterous to claim that it has the same addictive and abuse potential as heroin! All in the name of protecting ‘moral’ values, human rights (namely the right to the highest attainable standard of health) are shamelessly violated. There is complete disregard for the preservation of human dignity and individual autonomy. Drug policy has crossed the boundary and inserted its moral opinion into personal lives. Effective drug policy would enable the individual to exercise personal freedom, pursue the highest quality of life, and promote advancements in health care.

VI.I Recommendations

VI.I.I For Policy Makers

- (1) States should prioritise the human rights of people who use and need access to controlled substances; respecting the right to life, the highest attainable standard of health, freedom from discrimination, and freedom from torture, inhumane or degrading treatment.
- (2) Policy makers must reevaluate the scheduling of the substance with potential medical use based on unbiased and reliable scientific evidence. They should examine overly re-

strictive provisions which affect the accessibility, availability, and affordability of therapeutic substances.

- (3) States should comply with their obligation to ensure adequate availability and accessibility of controlled medicines for medical and scientific purposes. Legislation should not interfere with research involving controlled substances.
- (4) International and national drug control bodies should establish a better balanced policy which ensures access to controlled substances for medical use and preventing abuse. Current policy is heavily focused on preventing diversion which interferes with research, drug approval, and access to effective treatment.
- (5) States should recognise the ineffectiveness of abstinence programs and prohibitionist drug policy. In order to protect the health and safety of the public, harm reduction initiatives should be developed which can help users test the content and purity substances. Programs should provide accurate information about method of administration, dosage, and potential side effects. They should provide a safe place for users to seek help, creating a firewall between the users and the authorities.
- (6) States should allow researchers, therapists, and psychedelic users to participate in forming new drug policy.

VI.I.II For the Media and Public Discourse

- (1) News outlets and the media should take greater care when attributing the cause of drug-related deaths. They should refrain from disproportionate and arbitrarily selective coverage.
- (2) The media should take care when conflating ‘Ecstasy’ with ‘MDMA’; the concentration of Ecstasy is unknown and can be a mixture of many substances; it may not even contain MDMA.
- (3) Novel Psychoactive Substances which are often unidentifiable should not be assumed to be MDMA.

- (4) Public discourse should refrain from using language which stigmatises all drug users as addicts, irresponsible, deviant, or criminal.
- (5) Researchers, therapists, and those therapeutically benefiting from psychedelic use should continue to be strong advocates, representing the new face for psychedelic drugs.
- (6) Cultural movements where psychedelic use is prevalent should embody values of responsible drug use, safety, and a supportive community.

VI.II MDMA Within a Wider Context: Refugees

The aftermath of the Afghan and Iraq wars created an epidemic in which many returning US veterans diagnosed with PTSD were committing suicide due to inadequate treatment. In response to this growing problem, the FDA approved clinical trials for treatment-resistant US veterans. However, soldiers are not the only casualties of war. Refugees should also be represented as another group which deserves effective and adequate treatment for PTSD. Refugees are particularly vulnerable due to chronic exposure to traumatic events during pre-migration, migration, and post-migration. Additionally, systematic, cultural, and language barriers make it difficult for refugees to integrate with their host society and recover from traumatic experiences. Refugees suffering from PTSD will have an even more difficult time and could experience re-traumatisation during the settlement stage. They are about ten times more likely to have PTSD in comparison to the age-matched population of their host countries.¹⁶⁶ States should be motivated to provide the highest attainable standard of health in order to facilitate easier integration and avoid secondary financial costs incurred from the failure to provide mental health care for refugees. If refugees do not receive adequate care, PTSD could affect their ability to become self-sustaining and ultimately cost the state more financial burden.

¹⁶⁶ Fazel, Wheeler and Danesh, 2005, p. 1313.

The vulnerability of refugees is akin to mentally ill homeless people; these groups have very little stability or security in their lives causing them to be desperate for any promise of assistance. Therefore, the statelessness of refugees makes them more vulnerable to unethical practices. Due to language barriers, different cultural values, and perceptions of mental health it is difficult to conduct clinical trials with this population. However, researchers should consider permanently settled refugees as an important cohort to study the effects and benefits of MDMA-assisted therapy. MDMA-assisted therapy may be the best viable treatment since it requires fewer sessions of psychotherapy and uses a non-directive approach to therapy. Refugees, with limited ability to express their selves because of the language barrier, would not benefit from traditional therapy which requires many hours of clear communication. It would also be cost effective because treatment can be provided in only a few sessions and subjects would most likely reach stability without the aid of psychiatric medicine.

Policy makers and researchers should work together to realise the great potential of MDMA-assisted therapy to heal trauma survivors and improve the mental health of their country. Acknowledging that MDMA-induced therapy would not only benefit the lives of its already existing members but incoming members with trauma-related illnesses, policy makers would make important steps towards approving MDMA and making it accessible to all members of society. With greater numbers of displaced people, there is more incentive now than ever to support the evolution of psychiatric care for trauma survivors around the world.

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