

## Contribution to the 64<sup>th</sup> Session of the UN CESCR

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*Introduction:* MAPS' contribution re-introduced a 1985 recommendation by the World Health Organization (WHO) Expert Committee on Drug Dependence that was never followed: "urge countries" to conduct therapeutic research with 3,4-methylenedioxymethamphetamine, known as MDMA, which possesses tremendous potential to improve public health by healing trauma. Clinical MDMA-assisted psychotherapy trials show promise in treating extreme, treatment-resistant Post-Traumatic Stress Disorder (PTSD) and in August 2017, the US Food & Drug Administration (FDA) designated MDMA-assisted psychotherapy for PTSD a Breakthrough Therapy. MAPS anticipates FDA approval of MDMA in 2021.

### **I. Policy Incoherence**

The Multidisciplinary Association for Psychedelic Studies (MAPS) was founded thirty years ago with the goal of increasing access to a specific medicine, MDMA, in response to the codification of a dangerous policy incoherence. In 1985, MDMA was listed as a Schedule I substance - a substance defined as possessing no medical use and high abuse potential - by both the United States Drug Enforcement Agency and in the United Nations Convention on Psychotropic Substances, despite a complete lack of relevant scientific research supporting those claims. In fact, research over the past thirty years has only proved to undermine MDMA's home in Schedule I.

The chairman of the WHO Expert Committee on Drug Dependence at the time of MDMA's scheduling, Dr. Paul Grof, "felt that the decision on the recommendation should be deferred awaiting, in particular, the data on the substance's potential therapeutic usefulness and that *at this time international control is not warranted* [emphasis added]." [1] The only scientific evidence referenced by the committee was the research on a different but related compound, MDA, administered to rats in frequent and high doses. At the time of MDMA's scheduling, the WHO's 22<sup>nd</sup> report of the Expert Committee on Drug Dependence even stated: "No data are available concerning [MDMA's] clinical abuse liability, nature and magnitude of associated public health or social problems." [2] Though MDMA had been administered therapeutically for over a decade at the time of its criminalization in 1985, the Expert Committee on Drug Dependence determined that there was inadequate research supporting MDMA's therapeutic use. However, the Committee was impressed by the non-clinical reports. The Technical Report Series from the WHO Expert Committee on Drug Dependence (1985) reads:

*It should be noted that the Expert Committee held extensive discussions concerning the reported therapeutic usefulness of 3,4-methylenedioxymethamphetamine [MDMA.] While the Expert Committee found the reports intriguing, it felt that the [limited, existing] studies [at the time] lacked the appropriate methodological design necessary to ascertain the reliability of the observations. There was, however, sufficient interest expressed to recommend that investigations be encouraged to follow up these preliminary findings. To that end, the Expert Committee urged countries to use the provisions of Article 7 of the Convention on Psychotropic Substances to facilitate research on this interesting substance. [3]*

The WHO and CND have since failed to promote MDMA research. MAPS, a privately-funded non-profit research organization, has conducted the only medical research attempting to evaluate the therapeutic benefit of MDMA. So far, results from MAPS' Food and Drug Administration (FDA)-approved Phase II [4] research have been incredibly promising for the treatment of chronic, treatment-resistant Post-Traumatic Stress Disorder (PTSD); in fact, the Phase II research indicates that MDMA-assisted therapy dramatically outperforms current methods of PTSD treatment, and in August 2017 FDA granted MDMA-assisted psychotherapy its Breakthrough Therapy designation. Additionally, as part of that process, Phase I clinical trials demonstrated that MDMA can be administered safely in pre-screened subjects, [5] disproving the Schedule I assumption that MDMA cannot be used safely, thus further undermining its placement. Research only crystallizes the egregious incoherence of current policy governing MDMA access, and merits encouragement to expedite access to MDMA as a tool for treating trauma.

## **II. Public Health**

According to the World Health Organization (WHO), Post-Traumatic Stress Disorder (PTSD) afflicted approximately 3.6% of the world's population in 2012 alone [6]. PTSD develops in response to a wide range of traumatic life experiences, including: violence, rape, natural disasters, poverty and racism [7]. PTSD is also widely under-diagnosed [8], even in hospitals where people are privileged enough to have access to clinicians capable of diagnosing them. [9] PTSD shares high comorbidity rates with addiction, suicidality, and other psychological and physical illnesses [10]. PTSD therefore can have devastating impacts on those close to the individual suffering. Family members have been shown to experience secondary trauma[11]; they also dedicate significant time and resources to caring for a loved one with severe mental illness. Unfortunately, PTSD can wreak the most damaging effects on the children of those suffering, and even on generations to come. Described as intergenerational trauma, "there is now considerable evidence that the effects of trauma experiences are often transmitted across generations, affecting the children and grandchildren of those that were initially victimized," [12]. Thus, an individual suffering from PTSD endangers a community: effective PTSD interventions must be a public health priority.

Currently, treatments for PTSD are incredibly costly, ineffective, and sometimes deadly. The only currently approved medications for PTSD in the United States are Zoloft and Paxil, both SSRIs which fail to help approximately half of their users, and only partially help to decrease PTSD symptoms in others [13]. By contrast, 83% of MAPS' Pilot Study participants

suffering from chronic, treatment-resistant PTSD no longer qualified for PTSD after participating in MDMA-assisted therapy [14]. MAPS' subsequent research, including a long-term follow up[15], demonstrate similar results. In Phase II trials, 68% of subjects did not meet PTSD criteria 12 months after their MDMA sessions. This is particularly notable because when participants were evaluated 2 months after the MDMA therapy sessions, only 61% did not meet PTSD criteria. This implies that MDMA therapy not only treats a significant percentage of treatment-resistant PTSD, but also that people improve over time. These results led to FDA and MAPS agreeing to a Special Protocol Assessment in July 2017 then FDA designating MDMA-assisted psychotherapy for PTSD a Breakthrough Therapy in August 2017. MAPS anticipates starting Phase III in the fall of 2018, and FDA approval as early as 2021.

We applaud the WHO's recommendation in contrast to the American Psychiatric Association guidelines that antidepressants are "not recommended as a first-line treatment for adults because of the small effect size of these drugs for the treatment of PTSD;" [16] however, WHO offers limited alternative treatments. Due to ineffective treatment modalities for PTSD, treatment costs skyrocket: medical systems are forced to pay for treatment for long periods of illness, and over the span of years often pay for a variety of ineffective medicine and treatment. Further, as PTSD impacts families and generations to come, the cost of PTSD treatment extends beyond the individual. The incredibly promising results from MDMA-assisted psychotherapy research for PTSD demand the expansion of therapeutic research with MDMA for PTSD, to address one of our world's most urgent public health needs.

### **III. Advancing Human Rights**

MDMA-assisted psychotherapy for PTSD advances specific iterations of the human right to health. Article 12 of the International Covenant on Economic, Social and Cultural Rights recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," including "(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases." The relationship between PTSD and its comorbidity with other psychological illnesses, as described above, is well documented and endemic to both specific occupations and populations, as well as to entire regions that experience violent conflict. It is impossible to secure the "highest attainable standard of physical and mental health" of those populations and those regions without treating PTSD. Thus, support for MDMA-assisted psychotherapy for PTSD falls directly within the purview of Article 12.

Elaborating on Article 12, the Committee on Economic, Social, and Cultural Rights in General Comment No. 14 (2000) ("Comment 14") stated that the aforementioned right to physical and mental health "must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health." However, in many countries, the right to effective mental health care "facilities, goods, [and] services" is limited due to multiple factors like inadequate training, subpar facilities, unaffordability, or discrimination. According to OHCHR:

*[Mental] disabilities are often neither diagnosed nor treated or accommodated for, and their significance is generally overlooked. Adequate policies, programmes, laws and*

*resources are lacking... mental health care, including essential medication such as psychotropic drugs, is inaccessible or unaffordable to many.” [17]*

In the case of MDMA for PTSD, however, access is not limited by these factors; rather, it is primarily limited by its Schedule I placement and the subsequent reluctance of States to support research. Though research with Schedule I substances is possible, significant bureaucratic and stigma-related barriers exist that actively discourage research. Proof of Schedule I’s successful deterrence is the dearth of MDMA research in the wake of the Committee’s 1985 recommendation, despite the thriving community of MDMA therapists and researchers that existed before its criminalization.

Promoting MDMA-assisted psychotherapy for PTSD would advance the right to physical and mental health by encouraging States to actualize their commitment to the treatment of mental health disorders like PTSD. More concretely, the State obligations to respect, protect, and fulfill the right to right to physical and mental health apply to making MDMA research accessible for people with PTSD. The obligation to respect the right to health requires States to refrain from denying access to MDMA-assisted psychotherapy to persons suffering from PTSD by stifling research. The obligation to protect includes the duties of States to adopt legislation that protects and encourages research and access to mental-health-related services like MDMA-assisted psychotherapy. The obligation to fulfill requires States to recognize the right to mental health in national legal systems, including legislative implementation - like State support for MDMA research - that enable and assist individuals and communities to enjoy the right to mental health.

Finally, States that continue to engage in and perpetuate violent conflict that has measured and demonstrated psychosocial effects on the populations that come into contact with that conflict, including but not limited to PTSD, have an obligation to provide access to essential medicine – like MDMA – that can help them heal [18].

#### **IV. Potential Limitations**

Comment 14 acknowledges limitations of fundamental rights based on issues of public health. For instance, criminal limitations of the right to mental health resources like MDMA-assisted psychotherapy may be based on and justified by the perceived danger of allowing legal access to a drug like MDMA that has been stigmatized by its use in popular culture. However, “The Committee... [emphasized] that the Covenant’s limitation clause... is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States.” Further, “restrictions must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society,” and must be “proportional,” [Comment 14]. The continued State-level prohibition and criminalization of MDMA may be in accordance with present international law, but as demonstrated above, it is not aligned with international human rights standards, it is incompatible with rights protected by Article 12, and extensive research has shown that it is not necessary for the promotion of the general welfare.

MAPS’ current MDMA-assisted psychotherapy model features two co-therapists and one participant. However, MAPS recently received approval for a pilot study administering MDMA-

assisted therapy to a couple impacted by PTSD. Individual treatments limit MDMA-therapy's reach. Group-therapy models should be researched, to further increase MDMA's therapeutic access.

## V. Implementation

To bring this contribution to its expected results of promoting therapeutic research with MDMA and thereby increasing access to MDMA, the following political and institutional steps need to be taken:

1. The Secretary-General's High-Level Panel on Access to Medicines must echo the recommendations made by WHO's Expert Committee on Drug Dependence in 1985 and urge States to support therapeutic research of MDMA. States and WHO should be encouraged to fund MDMA research for the treatment of PTSD.
2. To facilitate research and remedy policy incoherence, MDMA must be removed from Schedule I of the UN Convention on Psychotropic Substances, in accordance with relevant scientific research concerning MDMA rather than MDA.

## References

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- [17] Office of the High Commissioner for Human Rights, Fact Sheet 31, Found at: <http://ohchr.org/Documents/Publications/Factsheet31.pdf>.
- [18] Indeed, Comment 14 states: "Since the adoption of the two International Covenants in 1966 the world health situation has changed dramatically and the notion of health has undergone substantial changes and has also widened in scope. More determinants of health are being taken into consideration, such as resource distribution and gender differences. A wider definition of health also takes into account such socially-related concerns as violence and armed conflict."