The Right to Science and Freedom of Research with Scheduled Substances:

MAPS at the United Nations 61st Commission on Narcotic Drugs

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On March 15th, 2018, the Multidisciplinary Association for Psychedelic Studies (MAPS) and the government of the Czech Republic hosted a panel event at the United Nations 61st Commission on Narcotic Drugs in Vienna, entitled the "Right to Science and Freedom of Research with Scheduled Substances." The event educated delegates about both barriers to and potential for increased research with psychoactive substances currently scheduled by the Single Convention on Narcotic Drugs. Originally drafted in 1961, the Single Convention is the primary international drug control treaty; the substances included on its list are internationally criminalized, outside of limited exceptions for research and medical use.

MAPS hosted the event and participated in the UN Commission on Narcotic Drugs thanks to the United Nations Economic and Social Council (ECOSOC), which granted MAPS official consultative status in the spring of 2017, after a two-year application process. In addition to co-sponsoring the event with the Czech government, MAPS also partnered with fellow non-governmental organizations (NGOs) including the International Center for Ethnobotanical Education Research and Service (ICEERS), Veterans for Medical Cannabis Access (VMCA), the Foundation for Alternative Approaches to Addiction (FAAAT), and Associazone Luca Coscioni.

Our panel was moderated by former Italian senator Marco Perduca, who currently coordinates international activities for the Associazone Luca Conscioni. In April 2018, Perduca also organized the World Congress for Freedom of Scientific Research (**freedomofresearch.org**) at the European Parliament in Brussels, and invited MAPS' founder and executive director Rick Doblin to speak.

Dr. Ludovica Poli, International Human Rights Law Professor at the University of Turin, opened the panel by reviewing existing international frameworks as they pertain to the human right to science. She explained that the right to "enjoy the benefits of scientific progress and its applications" is enshrined in the International Covenant on Economic, Social and Cultural Rights, part of the International Bill of Human Rights. Part III, Article 15 declares that:

> *The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity…[and] the steps to be taken by [States] to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.*

Dr. Poli explained that when the bill was drafted in the 1950s, science was heralded as a powerful vehicle to implement human rights, thanks to excitement around new medical and agricultural advances. By the 1970s, however, the international community had grown more fearful and suspicious of science and technology impinging on human rights.

The next presenter on our panel was psychologist Dr. Jose Carlos Bouso, Scientific Director of ICEERS. Bouso focused on the limitations of the Western clinical model of research on psychedelic plants, He argued that the largest barrier to this research is the regimented methodology of Western science, which is compounded by the dominant political and scientific ideology that stigmatizes psychedelic plants. These stigmas, he said, have given birth to onerous, bureaucratic requirements for research, and even

Vienna, Austria: Panelists at the United Nations Commission on Narcotic Drugs side event, Right to Science and Freedom of Research with Scheduled Substances (left to right): Jindrich Voboril (National Coordinator for Drug Policy of the Czech Republic), Michael Krawitz (Founder and Excecutive Director of Veterans for Medical Cannabis Access), Natalie Ginsberg, (Policy & Advocacy Director for MAPS), Dr. Jose Carlos Bouso, (Scientific Director for ICEERS), Dr. Ludovica Poli (Law Professor at University of Turin) and Marco Perduca (Coordinator of International Activities at Associazone Luca Conscioni)

more problematically, have also produced a hierarchy of research that assigns more value to some types of evidence over others.

The randomized, double-blind, placebo-controlled trial is the gold standard of scientific research, but, Dr. Bouso asks, how can you give a shaman placebo ayahuasca? According to Dr. Bouso, it is "impossible to differentiate the traditional medicine from the culture." He believes this lack of distinction makes modern clinical research poorly suited to replicate or evaluate traditional practices with psychedelic plants.

Next, I presented an update about MAPS' clinical drug development research and the barriers we face, particularly in researching cannabis, from my perspective as MAPS' Policy and Advocacy Director. Many in attendance were surprised to discover that MAPS encounters more difficulty conducting research with cannabis than with MDMA, due to the U.S. government's monopoly on cannabis for federally regulated research. Since 1967, the National Institute on Drug Abuse (NIDA) at the University of Mississippi has been the only federally legal cannabis cultivator, despite the proliferation of legal state cannabis programs. Because there are no private cannabis producers, there is no cannabis eligible for the Phase 3 drug development research in the U.S. In the U.S., though the Drug Enforcement Administration (DEA) announced its intentions to grant more licenses in the summer of 2016, current Attorney General Jeff Sessions is not allowing those licenses to be granted.

By comparison, the UK has issued private cannabis cultivation licenses although it has not yet legalized medical cannabis. For example, UK-based GW Pharmaceuticals developed and now sells Sativex®, the first cannabis-derived medicine to receive prescription approval, which has helped GW Pharmaceuticals maintain its approximately $3 billion market value. In April 2018, an FDA advisory panel also determined their support for GW's new cannabis product, Epidiolex®.

In my presentation, I also explained that the greatest difficulty for MDMA research is funding: though the U.S. government has spent millions of dollars on research trying to discover the harms of MDMA, it has not funded any research into its potential benefits. At the time of MDMA's scheduling in 1986, the chairman of the World Health Organization (WHO) Expert Committee on Drug Dependence was Dr. Paul Grof, who happened to be the brother of Dr. Stanislav Grof, one the founders of the field of psychedelic therapy. At the time, Dr. Grof objected to MDMA's placement in Schedule I, which should be reserved for drugs with no medical use and a high potential for abuse, explaining that the only research referenced in the scheduling decision was on a different but related compound (MDA) that had been administered to rats in frequent and high doses. At the time of MDMA's scheduling, the WHO's 22nd Report of the Expert Committee on Drug Dependence stated that "No data are available concerning [MDMA's] clinical abuse liability, nature and magnitude of associated public health or social problems." Though MDMA had been administered legally in therapeutic settings for over a decade, the committee determined that there were insufficient controlled, clinical data supporting MDMA's therapeutic use. Since then, MAPS has privately fundraised and sponsored the only therapeutic research with MDMA since its scheduling.

In the next panel presentation, Michael Krawitz—longtime UN cannabis activist and VMCA founder and executive director—provided heartfelt testimony about American veterans' demand for more cannabis research in order to find alternatives to current treatments for a variety of conditions. Medical practitioners and insurance companies are resistant to recommending cannabis without clinical research, which leaves veterans, in Krawitz's words, "stuffed full of oxycodone." He described how the two U.S. Food and Drug Administration

(FDA)-approved psychiatric medications for PTSD (sertraline/Zoloft® and paroxetine/Paxil®), list suicidality as a side effect, and wonders how an acceptable "side effect" can be the same as the worst symptom. In many states, he added, if veterans test positive for cannabis, they can lose access to treatment and their other medications.

Krawitz explained that the current placement of cannabis in the most restrictive schedule, which makes cannabis research extremely difficult or impossible in most countries, has not been reviewed since 1935. The treaty, he emphatically explained, "was created in antiquity." For context, the inaugural U.S. "drug czar" from 1930–1962, Harry Anslinger, who helped launch the global war on drug users, wrote at the time that most cannabis users:

> *…are Negroes, Hispanics, Filipinos, and entertainers. Their Satanic music, jazz, and swing, result from marijuana use. This marijuana causes white women to seek sexual relations with Negroes, entertainers, and any others.*

Krawitz concluded on an encouraging note. In June 2018, the 40th meeting of the WHO Expert Committee on Drug Dependence will review current scientific knowledge about the cannabis plant and its various preparations and components, and may recommend changes in cannabis' international scheduling if the committee draws different conclusions based on the substantial research that has occurred since 1935.

The panel concluded with comments from Jindrich Voboril, National Coordinator for Drug Policy of the Czech Republic. Voboril is known as one of the world's most progressive "drug czars," as he is a vocal advocate for harm reduction, decriminalization, and other evidence-based approaches to the drug regulation. I first connected with Voboril at the 2016 UN Commission on Narcotic Drugs, where he expressed support for MAPS' research and interest in learning more about our treatment model. He has worked for decades with people who use drugs and who struggle with problematic substance use.

On the panel, Voboril spoke about the Czech Republic's rich history of supporting psychedelic research, and current possibilities for research in his country. Voboril described how Czechoslovakia hosted LSD research long after other countries shut down programs, starting in the 1950s when Dr. Stanislav Grof began his LSD research in Prague. When Czech research came to a temporary halt in 1974, Voboril explains that it "was not because there wasn't a will to continue, but because [there was] no money." The Czech Republic has restarted its psychedelic research program in recent years, and is currently the only national government funding research on psychedelics that is not focused exclusively on their potential harms. Voboril explained that it is "very much up to the boldness of the country to make the move forward" because "conventions are administrative barriers, [and] cannot stop us from research."

In 2017, Voboril attended the MAPS MDMA Therapy Training Program in California, along with several Czech therapists and researchers who will be hosting a MAPS-sponsored European Phase 3 site. Voboril concluded his presentation with this observation:

> *As a person from the treatment area, I don't understand—if there is a medicine, why not use it? How can anyone point to the conventions and say it's not possible, because we know it's possible? As much as we are critical of the Conventions, still even under the Conventions, [the] people who were drafting it were swearing that this will be accessible to all substances that we call drugs for medical purposes, so I see no reasons this should be stopped.*

As if in response to Voboril's call to be bold, the first comment from the audience was posed by a member of the American delegation who works for the FDA, offering his support and time! He identified himself as "the guy who writes the federal registry notice at the FDA" and who was "on the human use committee for cannabis use at one time." He continued:

> *I just want to say thanks very much. I don't disagree with [you that there are] the barriers [you list, but] there is another side of the story, on the government side, and I'll just have you know that at the FDA, our job, our purpose, is to make safe and effective medicines available. Our number one thing. We're not on a different team, we're on the same team…I'm available if you have any questions."*

Amidst a less-than-encouraging experience at the Commission on Narcotic Drugs over all, where countries failed for the first time in the CND's 61 years to find consensus, this side event offered hope and a way forward for many of us in the room. The need for more medical research should not be controversial, and fortunately representatives from across the political spectrum agree. Our work ahead internationally, similar to our work in the U.S., will continue to focus on providing frameworks for those who vocally support eliminating research barriers to actually take political action.

Natalie Lyla Ginsberg, M.S.W., *earned her Master's in Social Work from Columbia University in 2014, and her Bachelor's in History from Yale University in 2011. At Columbia, Natalie served as a Policy Fellow at the Drug Policy Alliance, where she helped legalize medical marijuana in her home state of New York, and worked to end New York's racist marijuana arrests. Natalie has also worked as a court-mandated therapist for individuals arrested for prostitution and drug-related offenses, and as a middle school guidance counselor at an NYC public school. Natalie's clinical work with trauma survivors spurred her interest in psychedelic-assisted therapy, which she believes can ease a wide variety of both mental and physical ailments by addressing the root cause of individuals' difficulties, rather than their symptoms. Through her work at MAPS, Natalie advocates for research to provide evidence-based alternatives to both the war on drugs and the current mental health paradigm. She can be reached at natalie@maps.org.*