From Print to Presentations: The Importance of Communicating Findings from Psychedelic and Cannabis Studies

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Posttraumatic stress disorder (PTSD) is a condition that disrupts and constricts people’s lives, and remains a topic of interest to researchers and health professionals. The increasing scope of PTSD research is occurring in the face of treatments with high dropout rates that are ineffective for many, has led to a growing number of published reviews and thought pieces addressing the nature and treatment of PTSD. When published in established, peer reviewed journals, these articles can serve as key references for healthcare professionals and are used as guideposts for understanding treatments and research for PTSD. Websites with medical news and perspectives are also frequently referenced by healthcare professionals to access the latest information, including information on conditions such as PTSD.

MAPS is working to develop MDMA-assisted psychotherapy as a PTSD treatment, with Phase 3 trials starting in the summer of 2018, and Breakthrough Therapy Designation received from the U.S. Food and Drug Administration (FDA) in August 2017. Two review articles published in 2017 addressing PTSD or its treatment failed to mention MDMA-assisted psychotherapy or cannabis, despite both being under investigation in these clinical trials. Shortly afterward, a misleading and uninformed opinion piece in the prominent health-related news site Medscape criticized MAPS’ studies of MDMA-assisted psychotherapy as inherently problematic because of “bias” in the research. The author, Dr. Jeffrey Lieberman, considered MDMA to be a “feel good” drug, by definition having high potential for abuse. After encountering these articles, we sprang into action, penning responses to both review articles and crafting a rebuttal to Lieberman’s opinion piece, to reduce misinformation and ensure that the research is being recognized.

First, a review in the New England Journal of Medicine, a respected medical journal with high impact in the medical and scientific community[1], surveyed causes and models for the etiology (cause and development) of PTSD. The section on treatment included descriptions of existing treatments and innovative approaches, including neurofeedback, transcranial magnetic stimulation and D-cycloserine, but failed to mention MDMA-assisted psychotherapy or cannabis.

On the heels of the New England Journal of Medicine report on PTSD, the psychiatric periodical Biological Psychiatry published a “consensus statement” on pharmacotherapy for PTSD [2]. The article was written expressly to describe the current state of available medications and the future of drug therapies for PTSD. The authors of the report stated that they searched for both completed and ongoing studies, reporting that
they used the national clinicaltrials.gov trial registry and accepted all ongoing and completed studies, both with and without reported results. The consensus statement asserted that there is a need to develop novel trial designs or methods that target specific symptoms of PTSD, and to examine optimal combinations of medications and psychosocial treatment. They called for a greater evaluation of “real life” treatment effectiveness. While the piece mentioned “cannabinoid receptor modulators,” it failed to mention MDMA-assisted psychotherapy or cannabis as potential PTSD treatments, despite several trials for both being listed in the clinicaltrials.gov registry.

We responded to the omissions in the New England Journal of Medicine review by referring to findings from MAPS’ Phase 2 studies, describing potential mechanisms of action for MDMA’s use in therapy, including fear extinction and greater ease in facing emotionally upsetting memories, and providing clinicaltrials.gov reference numbers for MDMA and cannabis studies [3]. We also noted that in terms of risk analyses, ketamine (a legal prescription drug increasingly used off-label as an antidepressant and in psychotherapy) appears to have more risks than cannabis, notable since the authors expressed concerns about the abuse potential of cannabis, but not ketamine. In order to be considered for publication, letters to the NEJM had to be sent within three weeks of the article they referred to, leading to the rapid and intensive submission of our response.

Our response to the Biological Psychiatry consensus statement about PTSD was more expansive. We had the space to note the inconsistency of omitting MDMA-assisted psychotherapy and cannabis from the list of innovative treatments despite their meeting the authors’ established criteria [4]. Our response noted the additional hurdles to research for Schedule I drugs, and the FDA’s decision to grant MDMA-assisted psychotherapy Breakthrough Therapy Designation. These two responses, published in widely-read medical research journals, corrected the oversight of the original reviews and introduced MAPS’ research to a wider audience of physicians and medical researchers.

The third article that we responded to was an opinion piece published on Medscape by Columbia University Psychiatry Chair, Dr. Jeffrey Lieberman [5], in the form of a video blog and written transcription. While not a peer-reviewed journal, Medscape reaches a broad cross-section of physicians, nurses, therapists, and other healthcare professionals, so we felt it important to respond. In the article, Lieberman opined that MDMA-assisted psychotherapy would not succeed as a treatment because MDMA can produce euphoria, and he believes in a division between “feel good” and “genuinely therapeutic” drugs. He also expressed wariness about research findings from MAPS’ studies because of “bias,” as if this were a problem unique to research on MDMA-assisted psychotherapy. In expressing concern for study participants developing tolerance to MDMA, Lieberman appeared unaware that our Phase 2 study designs involve administration of MDMA only a few times, not daily dosing.

The inaccuracies and moralizing of the opinion piece stoked the flames of our motivation to respond [6]. Unlike peer-reviewed journals, Medscape doesn’t have a formal outlet for rebuttals beyond the limited user comment space on their website. Lacking this outlet, MAPS Director of Strategic Communications Brad Burge wrote to the editors at Medscape presenting our rebuttal and explaining the importance of clarifying the misinformation from Dr. Lieberman. Medscape’s executive editor agreed our rebuttal was well-founded, and published our response as an original op-ed piece on Medscape.

Education and outreach are a key part of MAPS’ mission, and a service that we at MAPS Public Benefit Corporation (MPBC) are cultivating to bring our perspectives to the public. This includes participating as members of the research and science community. Peer-reviewed journal articles command more attention within the scientific community than news reports, and their impact lasts longer as well, since science journals remain in libraries and are routinely cited by other researchers in publications. For those reasons, we felt that correcting these omissions and inaccuracies would have a lasting impact.

All three responses were published. This is encouraging, possibly representing a shift in editors’ and reviewers’ attitudes concerning the proposed therapeutic uses of Schedule I drugs. Introducing physicians and medical researchers to the therapeutic potential of MDMA-assisted psychotherapy and cannabis in the treatment of PTSD will stimulate public interest, grow support for MAPS’ work, and possibly even challenge other researchers to devise their own trials.

Responding to incomplete and/or inaccurate publications is but one step in sharing our findings. A bigger and even more significant step will be publishing results from our Phase 2 research, including studies of MDMA-assisted therapies in the treatment of PTSD, social anxiety in adults on the autism spectrum, and anxiety in people confronting life-threatening illness. Adding these publications to the existing public record will give MAPS’ supporters and interested researchers a greater array of findings to cite, examine, and communicate to others. To that end, MPBC and MAPS have embarked on writing manuscripts reporting results from our Phase 2 MDMA clinical trials. Findings from our study of MDMA-assisted psychotherapy for veterans and first responders with PTSD, and findings from our Boulder, Colorado, study of MDMA-assisted psychotherapy PTSD study, have been submitted for publication.

Presenting posters or speaking at scientific conferences is another way we are fostering interest and understanding of our work. Many researchers are unfamiliar with the drug development programs for psychedelics, and still hold viewpoints based on the multitude of papers and inaccurate reports they have read, such as those treating findings from studies using high, often neurotoxic doses of MDMA given several times a day as if they are relevant for estimating the safety of MDMA-assisted psychotherapy. Over the past few years, MPBC staff have pre-
presented data from our Phase 2 MDMA studies at neuroscience conferences, military health research conferences, psychiatric Grand Rounds, and trauma conferences, and have supported collaborator presentations at various conferences and events. This education and outreach is helping to inform people in the scientific and medical community about the magnitude of the findings seen in the Phase 2 studies. Over 32 years of MAPS’ work is now beginning to be acknowledged beyond a small circle of supporters. Much to our surprise and excitement, in 2016, Allison Feduccia, Ph.D., (who co-wrote this article) received the Mental Health Treatment Award on behalf of MAPS at the Canadian Military and Veteran Health Research (CIMVHR) Forum for a presentation on MDMA-assisted psychotherapy [7].

With a growing number of published papers and news reports, and with more communication of our results at scientific conferences, we are building strong and lasting support for research on MDMA, cannabis, and other psychedelic plants and compounds. This, in turn, will increase the pace of discovery and development of psychedelic-assisted therapies into prescription treatments. It may also extend beyond clinical applications to foster interest and support in reconsidering current drug policy. If this happens, we have a greater chance of meeting our goal of creating medical, legal, and cultural contexts for the careful uses of psychedelics and marijuana.

REFERENCES


L. (Ilsa) Jerome earned a doctorate in psychology from the University of Maryland in 1999, with an interest in social cognition. Inside and beyond formal education, Jerome immersed herself in literature on psychopharmacology and what would soon become affective and social neuroscience. Ilsa was a member of the team that developed the initial 3,4-methylenedioxymethamphetamine (MDMA) Investigator’s Brochure. Jerome was the Clinical Research and Information Specialist at the Multidisciplinary Association for Psychedelic Studies (MAPS). At MAPS Public Benefit Corporation (MPBC), Jerome has retained the title, focusing on archiving, communicating and sharing information about studies into the effects, risks and benefits of MAPS’ primary study drugs, particularly MDMA and classic psychedelics. Seeking, understanding and communicating scientific information has been at the core of this role, while the details have changed. As clinical research and information specialist, Jerome has collected and summarized research as part of designing and developing the Investigator’s Brochure and Phase 2 studies. She has assisted in the revision and management of Psychedelic Bibliography scope and content, supported and communicated with medical monitors, and communicated with researchers within and outside of MAPS and sending findings into the world as published reports. She believes in the necessity of interpreting and sharing research knowledge that will best help MPBC produce transparent, thorough and honest documents and reports, and that spotting good questions is as important as knowing good answers. Ilsa is fascinated by sound and music, and fragrance and olfaction. She spent a couple of years as a DJ at a university radio station, but remains emphatically unhip. She can be reached at ilsa@mapsbcorp.com.

Alli Feduccia, Ph.D., received a bachelor’s degree in Biological Psychology in 2009 from Louisiana State University. After earning a Ph.D. in Neuropharmacology from the University of Texas at Austin by utilizing rodent models to study the effects of MDMA on behavior and neurochemical release, she held a postdoctoral research position in the Preclinical Development Group at Ernst Gallo Clinic and Research Center at the University of California San Francisco where her experiments aimed to discover novel treatment strategies for alcohol dependence by elucidating the mechanisms of action of medications used to treat substance use disorders. In 2012, she received a Postdoctoral Research Training Award from the National Institutes of Health that enabled her to work on clinical trials at NIAAA/NIDA investigating novel therapeutics for alcoholism, as well as, human fMRI studies oriented to understanding the neural underpinnings of addiction. At MAPS PBC, Alli is currently serving as the Clinical Data Scientist, performing various tasks to ensure clinical data is analyzed and communicated in the highest quality for regulatory documents, scientific publications, and public presentations. She also makes online e-learning modules and creates content for a web-based learning management system to host training and educational material for site and therapy teams, Zendo Project, and other public educational outreach. Alli is passionate about starting a MAPS-sponsored trial of ayahuasca for treatment of alcohol use disorders and is currently applying her translational perspective to the development of a new protocol. Recognizing this as a monumental time in history, Alli highly regards the opportunity to participate in efforts to generate scientifically based evidence on the therapeutic and spiritual potential of psychedelics. She can be reached at alli@mapsbcorp.com.