Making MDMA a Medicine (II)

(Re)Scheduling for Schedule 1 Substances

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MDMA hasn't always been illegal — it hasn't even been illegal since the passing of the Controlled Substances Act (CSA) of 1971. In fact, the U.S. Drug Enforcement Administration (DEA) only first proposed placing MDMA in Schedule I in July of 1984. In response, MAPS Founder Rick Doblin, Ph.D., organized a group of psychiatrists and psychotherapists to request DEA hearings seeking to maintain MDMA's legal medical use which had rapidly spread over the preceding years. These hearings were granted, but despite positive media attention, DEA's Acting Administrator John Lawn placed MDMA on Schedule I using emergency scheduling powers, based in part on concerns about "potential neurotoxicity and the lack of accepted medical use or established safety for use of MDMA."

In May 1986, after two years of hearings, the DEA's Administrative Law Judge Francis Young recommended against placing MDMA on Schedule I. Notably, his opinion disagreed with the DEA's claim that Food and Drug Administration (FDA) approval of a drug was, "binding on the medical profession with respect to what is, or is not, accepted medical... use" and also acknowledged MDMA's past use in therapy, recommending that MDMA be placed in Schedule III. Despite the weight of the evidence undermining MDMA's placement in Schedule I, and the fact that the DEA had acted outside of its authority when it emergency scheduled MDMA, Lawn overruled Young and classified MDMA as Schedule I in October of 1986.

In 1987, Dr. Lester Grinspoon, a psychiatrist on the faculty of Harvard Medical School, sued the DEA on the grounds that DEA had ignored MDMA's medical use. The federal court agreed, finding DEA Administrator Lawn's ruling "unpersuasive." This decision vacated MDMA's Schedule I status. A month later, Lawn intervened again and reverted MDMA to its Schedule I placement, dismissing the expert testimony of psychiatrists discussing over 200 cases of MDMA-assisted therapy because they were not published in medical journals.

For the last thirty-six years, MDMA has stayed in Schedule I. And today, closer than ever to potential FDA approval, we confront a big question: **If MDMA is approved for medical use, how will it be scheduled?**

Normally, when a drug seeking FDA approval is approved and subsequently recommended for scheduling in Schedules II–V by the Secretary of Health and Human Services ("HHS"), the DEA has ninety days from the later of those two dates to issue what is called an interim final rule, placing the drug on a schedule according to federal scheduling criteria.

Unlike drugs with medical uses recognized by the FDA, drugs in Schedule I are determined by DEA to have "no accepted medical use." Substances in Schedule I may only be used in government-approved research projects, and are not eligible for prescription, dispensation, and/or administration to any patient other than a qualified research participant. Sometimes, when one of these Schedule I substances is the active ingredient basis for an FDA-evaluated drug product, the DEA will schedule that *drug product* in one of Schedules II–V, or remove it from scheduling altogether. Dronabinol, or synthetic THC, is an example: tetrahydrocannabinols (some of the active ingredients in cannabis) are in Schedule I, but FDA-approved dronabinol drug products are in Schedules II and III. Similarly, Epidiolex is a cannabis-derived cannabidiol drug product that was bifurcated completely out of federal scheduling controls after its approval by FDA.

Each state maintains a system of controlling some substances, similar to the federal CSA. So, in addition to the FDA-approval-triggered federal scheduling, which permits federal marketing and use of a once-Schedule I-controlled drug, each state — if similarly controlling that drug in their Schedule I equivalent — will also need to schedule the approved drug product in a manner that permits medical use in that state (i.e. in a schedule other than Schedule I). Most neatly, and very often, this means each state and Washington, D.C., controls newly-approved drugs, whether bifurcated or not, consistently with the federal scheduling decision—achieving what we call "parity" between the state and federal system.

Today, twenty-seven states have laws or regulations that trigger parity with the federal government upon or at some point after the federal scheduling decision. In other words, when the federal government places a substance or a pharmaceutical drug product into a schedule of the Controlled Substances Act, those states duly conform and place the substance into the same schedule of their state drug control statutes. Because those states automatically schedule controlled substances based on federal scheduling by DEA, that means that when DEA places MAPS' MDMA drug product in a schedule, the entities responsible for regulating controlled substances in these states will follow suit.

In the remaining twenty-three states that do not automatically maintain parity with federal scheduling decisions, scheduling of controlled substances is determined through a state-level legislative, regulatory, or administrative process. Thus, in order to facilitate timely access to MDMA-assisted therapy in these states following potential FDA approval, MAPS PBC needs to coordinate with the relevant state authorities to ensure the MDMA-containing drug product — though for the reasons above, not uncontrolled MDMA itself — is placed in a schedule other than Schedule I as quickly as possible after federal rescheduling. In states that require legislation to schedule or reschedule a controlled substance, we will work with state legislators, advocates, and other stakeholders to develop and pass legislation that ensures that FDA-approved drug products containing MDMA intended for medical use be excluded from Schedule I and placed in another appropriate schedule. By automatically triggering the appro-

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Ismail is licensed to practice law in the state of California, and is a founding board member of the Psychedelic Bar Association. He also currently serves on the board of the Sage Institute, contributes to Chacruna Institute's Council for the Protection of Sacred Plants, and participates on the advisory council for the Ayahuasca Defense Fund. He has also previously served as Chair of the Students for Sensible Drug Policy Board of Directors. Ismail is passionate about setting sustainable groundwork for a just, equitable, and generative post-prohibition world.

Leslie Booher, J.D., M.B.A., (Policy and Advocate Associate) received her bachelor of science (B.S.) in business administration and her master of business administration (MBA) from Southeast Missouri State University, as well as her juris doctor (J.D.) from University of California, Berkeley, School of Law. Before joining MAPS, Leslie gained litigation experience at large and small law firms, from both the plaintiff and defense sides. Leslie is excited because her work at MAPS combines many of her passions: learning and educating others about our shared human physiology and psychology, striving for social contentment through imaginative socio-economic structures, aspiring for criminal justice reform, and calling attention to the unique role that altered states of perception play in conceptualizing, contextualizing, and coping with our own consciousness.

priate scheduling of our MDMA drug product upon FDA approval, this kind of legislation would allow for legal commercial sale (for medical and therapeutic use only) in the state as soon as possible after DEA rescheduling.

In states that require action by a regulatory or administrative body, we are working to educate the relevant decision-makers about the scientific evidence behind MDMA-assisted therapy and the need for timely action on their part to appropriately schedule the drug product following potential FDA approval.

We have begun this work in several states where legislative action is required. In Colorado and New York, we worked with state legislators who saw a major unmet need for PTSD treatments for their constituents, and introduced bipartisan legislation to ensure timely rescheduling of medicinal MDMA upon potential FDA approval. In both of those states, the bills were swiftly passed by both legislatures. In California, we are collaborating with a diverse coalition of advocates to advance a bill which would decriminalize the personal use of some psychedelics, create a commission to study the possibility of future regulated use, and also ensure that all drug products derived from Schedule I substances are appropriately scheduled. Our goal is for timely rescheduling to be secured in as many states as possible in 2022, and to pass similar bills in the remaining states that require legislative action in 2023, prior to prospective FDA approval.

To be sure, this issue extends beyond MDMA. Any Schedule I drug that gets developed into an approved drug product will have to look at examples like Epidiolex, Xyrem, and — soon — MAPS' MDMA to make similar changes to avoid confusion and delay for prescribing and use by practitioners at the state level. Whenever possible, MAPS hopes to create legal pathways that benefit the public by supporting the entire field of psychedelic healthcare - not just our products. Different jurisdictions with different political environments require different approaches and — as we can see with the wide variety of state-level reforms moving forward — have different tempos of reform. In some places, we'll have to focus our advocacy narrowly to ensure that at least MDMA will be able to be prescribed as soon as possible. In others, we'll be able to carve out larger permissions that will benefit the entire field.

In addition to creating medical access to psychedelic substances, MAPS was also founded to usher in a post-prohibition environment for the safe and responsible use of psychedelics for spirituality, exploration, and personal growth. Even with medical scheduling, this will not be possible as long as psychedelics remain criminalized. Currently, prosecutors and judges look to the U.S. Sentencing Commission (USSC) to make decisions about what consequences to associate with behavior related to psychedelics and other drugs and related activities. While MAPS PBC works toward ensuring appropriate scheduling of a future MDMA drug product, MAPS has simultaneously worked toward changing sentencing guidelines by reducing the punishment for people using, manufacturing, or distributing presently-illicit MDMA.

In 2017, the USSC almost reviewed the MDMA sentencing guideline — MAPS submitted a **testimony** at the time — but the review didn't occur, and the USSC hasn't had a quorum since then. Perhaps soon, science will prevail over politics and the sentencing guidelines will be reviewed — even as the first psychedelic drug product is placed somewhere in the CSA (other than Schedule I).

Joy Sun Cooper (Chief of Patient Access and Head of Commercialization) co-founded and served as Chief Operating Officer of Groups, a venture-backed healthcare services company that is tackling the opioid epidemic in rural America. Groups operates more than 50 outpatient clinics in six states that is pioneering a value-based model for the treatment of opioid use disorder.

Prior to starting Groups, she helped launch GiveDirectly, a global nonprofit that gives cash to the ultra-poor with no strings attached using mobile payments technology and conducts rigorous, experimental evaluation to measure impact. She previously was an engagement manager at McKinsey & Company in the healthcare and agriculture practices and Director of Operations at the Clinton Health Access Initiative (CHAI), where she designed and implemented large-scale HIV treatment programs in Sub-Saharan Africa.

Joy holds an M.B.A. from Stanford University Graduate School of Business and a B.S.in international affairs from Georgetown University School of Foreign Service.