

R/evolutionary Medicine, R/evolutionary Industry: The Role of Conscious Policy and Corporate Structures in Psychedelic Healthcare

BY THE MAPS POLICY & ADVOCACY DEPARTMENT

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THE NON-PROFIT MULTIDISCIPLINARY ASSOCIATION for Psychedelic Studies (MAPS) has spent over three decades ushering MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD) through the U.S. Food and Drug Administration (FDA) approval process to allow safe and effective access to MDMA-assisted psychotherapy for serious mental health concerns, with FDA approval for PTSD expected by 2022.

The non-profit Usona Institute has taken a similar path with psilocybin for major depressive disorder. Other non-profit efforts are emerging to steward education, governance, and ethical practices in the field, and new for-profit companies are simultaneously forming to participate in the psychedelic industry. Compass Pathways and its parent company, Atai Life Sciences, comprise the largest for-profit psychedelic drug development company; Compass is also developing psilocybin for treatment-resistant depression, and Atai recently purchased a portfolio of (non-psychedelic) ibogaine-related patents. Today, venture capital is beginning to hone in on psychedelics, leading to the proliferation of infant funds and start-ups interested in capitalizing on the psychedelic industry. Highlighting this trend, a recent Fortune headline announced that “Psychedelic Drugs Might Transform Mental Health Care: And Big Business Is Ready to Profit from the Revolution.”

MAPS has chosen to conduct its drug development through a public benefit corporation, ensuring that our work remains in alignment with service-oriented healing traditions. MAPS Public Benefit Corporation (MAPS PBC) is a wholly-owned subsidiary of MAPS; in other words, MAPS is the the sole investor in MPBC. This hybrid corporate model allows MAPS to prioritize developing MDMA into a medicine as a benefit to the public, instead of being legally bound to prioritize maximizing profit for shareholders. As traditional companies and venture capital begins to enter the space, and as local and state efforts to create psychedelic access begin to gain momentum, it is critical that policymakers create space for and encourage approaches that put access and care, rather than profit, first.

MAPS’ non-profit status gives us the mission discipline necessary to devote ourselves to addressing the social harms that are typically ignored and externalized in a free market. Assessing and repairing these social harms requires intentionality and impact, key characteristics of MAPS’ hybrid corporate form. Our non-profit, public benefit strategy removes the impetus of a quick profit turnaround to drive our work, instead focusing on the greatest possible public good.

Local movements to decriminalize psychedelic plants and fungi have recently formed, shedding bits of light into the underground and creating legal gray spaces. These approaches may constitute a significant piece of the foundation for a future legal psychedelic industry. The city of Denver, Colorado, made possession of psilocybin

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mushrooms by adults the lowest law enforcement priority by ballot initiative in the summer of 2019. Following that lead and expanding upon it, a citizen group, Decriminalize Nature (“DN”), successfully persuaded the city council of Oakland, California, to pass a resolution that reduced the prosecution of crimes related to personal possession and use of psychedelic plants and fungus to the lowest law enforcement priority. DN is now aiding like-minded activists in pursuit of similar measures in jurisdictions all over the United States, and is undertaking the first city-level effort at developing a framework for the distribution and sale of these substances in Oakland.

Additionally, state level movements are devising ballot initiatives to create alternate forms of regulated markets. In Oregon, a state-level initiative seeking a spot on the 2020 ballot has fashioned an imaginative, regulated psilocybin services industry. The “services” in this case would extend access beyond the medicalized, FDA-regulated approach. Meanwhile, an enthusiastic grassroots contingent is trying to get a different initiative on the 2020 ballot in California to decriminalize and legalize (read: lightly regulate) psilocybin mushrooms.

Commercialization in Context

Drug prohibition has made drug-related activity more dangerous. Prohibition and stigma have disincentivized or prevented people who use drugs from seeking support or accessing accurate education about safe practices. With intention and accountability, moving currently-illicit substances into the sunshine of the “above-ground” can provide an opportunity to remedy some of the lasting harms from the “War on Drugs.”

Our community has the opportunity to create a re-imagined psychedelic industry which attempts to repair some of the harms of old-fashioned drug policies, as long as the changes we implement include meaningful involvement from as many diverse stakeholders as is feasible. Imagine if the psychedelic industry could be driven by collective benefit, rather than just profit maximization for individual companies? What combination of infrastructure, policies, and norms would create the optimal set of incentives? What is the playbook for the pro-social mainstream integration of psychedelic substances?

Ultimately, no one form or framework alone will be adequate. Creating new healthcare systems and structures will happen most effectively and safely in a collaborative landscape that intentionally empowers non-profit organizations, cooperatives, public benefit corporations, and other public and private institutions to operate and ethically partner together.

MAPS’ statement on Considerations for the Regulation and Decriminalization of Psychedelic Substances (maps.org/policyreform) is anchored in valuing life, dignity for people who use drugs, evidence-based policy, stewardship and integration of cultural knowledge, and collective health and well-being. MAPS implements these values in tandem with its subsidiary MAPS PBC. These early days of the new psychedelic industry are already inspiring imaginative and iterative policy-making, and we hope that MAPS’ hybrid organizational structure will help

model the embodiment of these stated values while operating within the broader context of existing institutions. We also hope that the intention and implementation of this hybrid corporate form can act as a harm reduction intervention for some of the inherent or previously recognized harms associated with pharmaceutical healthcare delivery.

Reducing Harm

Our statement referenced above discusses “full-spectrum harm reduction,” which incorporates all people who use all drugs in all ways, as well as the political, social, and environmental contexts surrounding that use. The guiding principles are the same as traditional harm reduction, but incorporates a wider number of factors associated with drug use to further reduce stigma and indignity.

This approach can also be applied to the harms that inherently come with the scaling and establishment of an industry. Some of the risks of commercializing and “above-grounding” controlled substances can be observed in the story of cannabis reform, where the people most marginalized by society who need the medicine are still unable to receive insurance coverage, and cannot afford state-legal prices or social stigma still attached to cannabis. Healthcare driven solely by profit maximization continues to cause unintended harm. The psychedelic industry can, and must, be intentional to be different.

Other circumstances, like MDMA’s current placement in Schedule I of the Controlled Substances Act and the associated stigma, builds additional guardrails into the mainstreaming process MAPS is navigating. While some may see the challenges of non-profit drug development of stigmatized substances as overly onerous, we appreciate the additional level of external oversight and review, recognizing it as valuable and even essential to achieving our desired outcome of safe, effective psychedelic-assisted medicine. Victoria Hale’s article in this issue expands upon this idea in more detail.

Health Equity, Privacy, and Dignity

MAPS has also witnessed and participated in cannabis policy reform; however, after over 30 years of advocacy, numerous barriers to cannabis research and medical care continue to exist. The pursuit of profit over community welfare has generally failed to create the proper incentives for a socially-conscious industry. Thankfully, the longer run-up time to legal psychedelic medical access has allowed us to engage in a robust dialogue about how to create market and social incentives most likely to lead to just outcomes.

Health equity is a framework that brings awareness to the impact that discriminatory policies have on the wellbeing of individuals, communities, and ecosystems. The goal of health equity is to leverage healthcare interventions and policy towards repairing related disparities in medical and psychological care. Actors in the psychedelic healthcare space should strive to counteract the impacts of health inequity, and policy should ensure that creative solutions are given resources and support. This

extends beyond clinics or companies developing drugs to cross-sector partnerships, in order to create more holistic and effective systems of wrap-around care.

As psychedelic interventions are paired with technology in the age of big data, new ethical dilemmas will emerge, such as the use of medical (or medical-adjacent) records and psychological profiles. Digital information has become a powerful resource in our society, and hasty or predatory data use practices could have unforeseen consequences for people simply seeking mental wellness. Such practices may disproportionately harm people already at risk of being targeted by law enforcement or unscrupulous corporations. MAPS is committed to the safety of the physically, economically, legally, and digitally vulnerable people who ought to have access to psychedelic care, and we do everything we can to encourage up-and-coming industry actors to be accountable and transparent.

Obstacles and Incentives

Non-profit research and development fills a gap in society which for-profit businesses and government have not yet had sufficient incentives to pursue. This has historically been true with Schedule I substances, which have faced more regulatory hurdles and public stigma than most new drugs. Pharmaceutical firms typically rely on patent monopolies and projected earnings to justify entry into a new market, and have therefore been unwilling to take the cultural and financial risks associated with securing approval for psychedelic substances.

These profit-oriented motives in healthcare delivery have also negatively impacted the quality or availability of care—so how can the psychedelic industry optimize patient care without relying on traditional business methods? How can we work to ensure that primarily growth-driven companies don't automatically outpace those that grow with intention and place the patient first?

In addition to bringing otherwise neglected modalities to market, charitable, social impact, and benefit-oriented initiatives have the opportunity to use their unique roles to re-imagine institutional structures and implement visionary healthcare innovations. This could mean guarding against ineffective over-regulation, incentivizing cooperative ownership, arranging charitable caregiving services for the delivery of care, and/or creating partnerships and strategies to subsidize treatment for low-income people.

Transformational Alternatives

In summary, the medical approval of psychedelics could provide essential access to millions of people who are diagnosed with PTSD and other mental health disorders. However, this only represents a limited segment of the population who might benefit from the careful use of psychedelics in their lives. Legal shifts will continue to create more points of access, such as through decriminalization or other regulated legal frameworks. To ensure the most secure backdrop of support, partnerships between non-profit, public, and private institutions should be driven by

principles of harm reduction and equitable access. MAPS' non-profit/public benefit approach hopes to inspire more ingenuity in our collective shift toward collective well-being. Such hybrid pharmaceutical frameworks offer an alternative, competitive force to traditional for-profit healthcare.

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Natalie Lyla Ginsberg, M.S.W., Director of Policy and Advocacy, received her B.A. in history from Yale, and her master's of social work (MSW) from Columbia. Before joining MAPS in 2014, Natalie worked as a Policy Fellow at the Drug Policy Alliance, where she helped legalize medical cannabis in her home state of New York, and worked to end New York's race-based marijuana arrests. Natalie has also worked as a therapist at an alternative-sentencing court for prostitution and drug-related offenses, and as a middle school guidance counselor. At MAPS, Natalie works to disentangle science from political partisanship on Capitol Hill, at the United Nations, and beyond. She is also co-developing a psychedelic peace-building study with Imperial College, working with Palestinians and Israelis. Natalie is particularly inspired by the potential of psychedelics for healing systemic, intergenerational trauma, for building empathy and community, and for inspiring creative and innovative solutions.