

Medicinal Psychedelics: A Potential Pathway to Treating Mental Health Conditions

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A seismic shift in how we discuss mental health has occurred over the past few years. A willingness to engage in the topic beyond mere lip service at home, in our communities, and in our places of work is a testament to the profound progress that has been made in reducing the stigma associated with these conditions in a relatively short amount of time. Equally as profound are efforts by clinicians, researchers, and state and federal legislators to find and implement new treatment options for mental health conditions. These efforts have been focused on an area of pharmacology that one might think strange or even absurd at first blush: psychedelics. Psilocybin (“magic mushrooms”), MDMA (“ecstasy,” “molly”), LSD (“acid”), and dimethyltryptamine (“DMT”) are all being researched as medications to treat a wide variety of mental health and substance use disorders. Why? Because clinical research has shown – and is continuing to show – that these compounds may have superior efficacy compared to existing FDA-approved medications when combined with psychotherapy. In August 2017, the FDA granted Breakthrough Therapy designation to MDMA for the treatment of posttraumatic stress disorder (PTSD). In 2018 and 2019, it granted Breakthrough Therapy designations to psilocybin for treatment-resistant depression and major depressive disorder, respectively. Breakthrough Therapy designation is a process designed to speed up the development and review of medications intended for the treatment of serious conditions. It is granted on the basis of preliminary clinical evidence indicating that the medication under investigation may have potential for superiority over approved therapies on at least one clinically significant endpoint. FDA approval of MDMA for PTSD is expected in 2024, with approvals for psilocybin to follow.

While drug sponsors pursue the FDA approval route, several states have taken initiatives to create their own state-regulated frameworks to bring psychedelic compounds to their residents in controlled settings. Oregon was the first to pass legislation providing for psilocybin treatment centers. Connecticut and Colorado have since passed their own measures. New York has two proposed Assembly bills (A8569a, A7928) and one proposed Senate bill (S3520) that would establish regulated systems for the medical administration of psychedelics for mental health conditions. A8569a was introduced by Buffalo native, Assemblyman Patrick Burke. These state initiatives across the country are occurring at a time when psychedelics are still classified as illegal narcotics under the federal Controlled Substances Act. But federal bipartisan support for the use of these compounds as medications appears strong. In the past year, members of Congress have requested that the U.S. Department



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of Health and Human Services create a federal inter-agency task force to address issues of psychedelic use, therapy, and health care integration. Proposed pieces of legislation have been introduced to allow for psychedelic use under the federal Right to Try Act, and to amend the Controlled Substances Act to grant the U.S. Drug Enforcement Administration the ability to transfer Schedule I substances into Schedule II provided such substances have received either FDA Breakthrough Therapy designation or authorization for use in FDA’s expanded access program.

Finally, a bipartisan Congressional caucus entitled Psychedelics Advancing Clinical Treatments (“PACT”) was formed this past November to explore psychedelic research related to mental health conditions.

Medicinal psychedelics are coming to mainstream health care in the very near future. But the treatment protocols and clinical settings in which psychedelic care is delivered will be very different from any existing model in our health care system. Medical professionals and health care entities seeking to operate in this

new medicinal psychedelics space should consider engaging legal counsel who possess not only a strong comprehension of the law, but also an in-depth understanding of the science behind these drugs and their medical applications.

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