

Psychedelics

Renewed interest in the therapeutic possibilities of psychedelic drugs—including psilocybin, DMT, ketamine, LSD, and MDMA—to treat mental health and substance abuse disorders has led to an upsurge in research and drug development, as well as an expansion of treatment options and investment opportunities.

But the research is progressing in a challenging regulatory environment. Psychedelic drugs remain classified as Schedule I controlled substances and are subject to not only federal law but also a patchwork of state laws and regulations. Entities that research, develop, commercialize, invest in, or use psychedelic drug products to treat their patients in the United States must carefully navigate this complicated legal and regulatory landscape and the divergent licensure obligations and other requirements and restrictions from state to state.

As a health care “super boutique,” Epstein Becker Green has extensive experience working with clients in the highly regulated health care and life sciences industries and is intimately familiar with developing, marketing, distributing, dispensing, and prescribing FDA-approved (and unapproved) drug products. We are also experienced at navigating the processes involved in performing clinical research with such substances, opening a ketamine clinic, and adding ketamine to a medical practice’s or clinic’s suite of services. That’s why researchers, academic medical centers, teaching hospitals, pharmaceutical manufacturers, investors, clinicians, and other stakeholders interested in psychedelic medicines turn to us for guidance. We help them understand the risks, opportunities, and obstacles that arise within the psychedelics space as they relate to the federal and state legal and regulatory frameworks governing psychedelics and other Schedule I controlled substances.

Focus Areas

Industries

Academic Medical Centers
Cannabis
Health Care Industry
Hospitals and Health Systems
Life Sciences Industry
Pharmaceuticals

Services

Behavioral Health
Corporate Practice of Medicine
Health Care
Life Sciences
Regulatory Strategy, Product Development, and Product Approvals

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We support our clients through every stage of a psychedelic drug's life cycle, from initial research (with associated grants and funding issues) and preclinical and clinical trials, all the way to submitting an IND or NDA, developing a strong marketing and distribution plan (including a favorable REMS), and obtaining appropriate coding, coverage, and reimbursement. We also advise on compliance and enforcement matters, product litigation, corporate practice of medicine and licensure considerations, scope of practice issues, and more. Whether you are a researcher exploring novel treatments, an investment firm seeking to support groundbreaking initiatives, or a clinician looking for alternative mental health and substance abuse therapies when traditional treatments are ineffective, we are a multidisciplinary team that can provide tailored guidance to help you deftly navigate the complexities of the emerging psychedelics field.

Disclaimer: *Several psychedelic compounds are still classified as Schedule I controlled substances by the U.S. Drug Enforcement Agency, and, as such, it remains a federal crime to possess, sell, distribute, and/or use those Schedule I compounds. Any content contained herein is not intended to provide legal advice to assist with the violation of any state or federal law.*

Media

Legal and Regulatory Landscape for Psychedelics as Therapies

Insights

Epstein Becker Green Receives *New York Law Journal's* 2023 Innovation Award

Firm Announcements | August 11, 2023

Lisa Gora Quoted in "N.J. Cannabis Attorneys Group to Expand Expungement Clinics, Drug Testing Guidance"

Media Coverage | *NJ.com* | June 8, 2023



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Magic Mushrooms in the Garden State? A Look into the Proposed
Psilocybin Legal Landscape in New Jersey
Media Coverage | *New Jersey Law Journal* | September 21, 2022

Erin Sutton
Jessika Tuazon
Eric Werner

James Boiani Quoted in "Psychedelic Meds Are Opening a New
Frontier for Legal Work"
Media Coverage | *Law360* | May 8, 2020