

## PSYCHEDELICS & EMERGING THERAPIES

Husch Blackwell has a long track record in counseling those engaged in research and commercialization of novel—and controversial—therapies. We were one of the first large national law firms to establish a practice group devoted to cannabis, and as the utility and acceptance of psychedelic therapies have gained a foothold across the medical community, our firm is once again at the forefront in developing a multidisciplinary team to represent clients in this growing area of treatment.

Similar to the early days of the medical cannabis movement, psychedelic drugs such as MDMA, psilocybin, LSD, ketamine, and DMT are emerging in a complex and difficult legal and regulatory environment that can frustrate efforts to develop new therapies. Our team guides researchers, manufacturers, investors, clinicians, and other participants around and through the myriad obstacles that result from the patchwork of state and federal laws regulating Schedule I controlled substances, including the Controlled Substances Act (CSA), Money Laundering Control Act (MLCA), various criminal statutes that cover the sale and consumption of psychedelics, and various state legal and regulatory regimes.

Our team is multidisciplinary by nature and integrates subject-matter authorities who can drill down into relevant issues at every phase of research, development, commercialization, and medical practice. We assist entrepreneurs and investors in forming ventures and developing governance structures best suited for operation in the psychedelic industry. Once established,



*They have a rock-solid grasp of the science.*

— Chambers USA  
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clients turn to our regulatory and finance lawyers to assist with operationalizing and funding the enterprise. Our clients benefit from our attorneys' comprehensive experience in Food & Drug Administration (FDA) regulations and scientific expertise, handling matters involving development of premarket strategies for controlled substances, preparing and prosecuting investigational new drug (IND) exemptions and new drug applications (NDA), compliance with current good manufacturing practice (cGMP) requirements applicable to botanical drug substances and products, as well as enforcement matters for pharmaceuticals, digital technologies, and medical devices. Additionally, our team comprises lawyers from our nationally recognized healthcare industry group who have deep experience with clinical trial frameworks, including third-party contracts with contract research organizations (CROs), principal investigators (PIs), and contract manufacturers of investigational drug substances and products; informed consent; and interactions with institutional review boards (IRBs) concerning protocols and study monitoring. Further, we have assisted businesses in opening ketamine clinics, handling issues ranging from corporate formation to compliance with healthcare regulations in various states.

Our team provides its psychedelic and emerging therapies clients with a full suite of legal services that bear upon the development of new products and therapies, including:

Corporate

Corporate & Medical Real Estate

Employee Benefits & Executive Compensation

FDA, DEA, and State Law Regulation and Compliance

Immigration

Intellectual Property

International Trade & Supply Chain

Labor & Employment

Litigation & Alternative Dispute Resolution

Products Liability

Securities & Corporate Governance

Tax