

THOUGHT LEADERSHIP

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Revolutionizing PTSD Treatment: MDMA's Potential Medical Breakthrough

The mental healthcare sector is on the precipice of a new era with the grant of Priority Review of Lykos Therapeutics's midomafetamine capsules (MDMA)-assisted therapy. This heralds a breakthrough in the psychiatric treatment paradigm, specifically targeting post-traumatic stress disorder (PTSD).

Administered in a clinical setting alongside psychological support, this therapy has the promise of altering the lives of millions battling the aftermath of trauma. This announcement could have several implications for attorneys, particularly those specializing in healthcare law and regulatory affairs.

Attorneys can anticipate a surge in activities surrounding the regulatory pathways and compliance frameworks for the introduction of this novel therapy to the market. Regulatory affairs specialists will need to navigate the complexities of adherence to new guidelines to this novel therapy, post-approval monitoring, and possibly, the negotiation of a Risk Evaluation and Mitigation Strategy (REMS) if deemed necessary by the FDA.

While the legal landscape adapts to accommodate this therapy, it is important to reflect on how the narrative surrounding MDMA has evolved. MDMA's journey from being classified as a Schedule I drug—thus deemed to have no accepted medical use—to a potential breakthrough therapy for post-traumatic stress disorder has been a long and dramatic exercise, but one enabled by MDMA's unique properties as an entactogen, which set it apart from both classic psychedelics and conventional pharmaceuticals.

Clinicians and researchers have seized upon MDMA's ability to promote introspection and personal reflection in patients under the proper circumstances and therapeutic support. MDMA-assisted therapy integrates guided psychotherapy with structured MDMA sessions. As described in clinical

trial protocols, participants undergo an intake and medical screening, followed by three preparatory sessions of 90 minutes each, setting the groundwork for the therapy. Next, they engage in three separate MDMA dosing sessions, where they recline in a calm setting with music and eye shades, allowing them to alternately focus inwardly and interact with their therapists in a supportive, non-directive manner. After the session, therapists assess participants' emotional well-being and psychological states and help them articulate and understand the significance of their feelings. Collaborating with medical staff, therapists ensure the participant's vitals and overall stability are checked before departure from the treatment site. They maintain a presence until each participant is safely discharged into the care of either a designated support person or a qualified professional, ensuring a comprehensive continuum of care.

While therapists and medical staff meticulously oversee the post-session wellbeing of each participant, such individualized care underpins the broader significance of the FDA's Priority Review status, which is reserved for treatments that demonstrate a significant leap forward in improving patient outcomes. Priority Review status is granted for treatments indicative of substantial advancements in the safety or efficacy of managing, diagnosing, or preventing grave health conditions when compared to existing treatment options. MDMA-assisted therapy's designation as Breakthrough Therapy back in 2017 unlocked doors to this fast-tracked assessment. Priority Review shortens the time of review of the NDA to six months.

With the advancement from Breakthrough Therapy to Priority Review, the focus now shifts to the Prescription Drug User Fee Act (PDUFA) target date, the date set by the FDA for reviewing and making a decision on a New Drug Application (NDA). It is typically established after the FDA accepts a drug application for review and represents the deadline by which the FDA aims to complete its evaluation. For drug sponsors, the PDUFA date is crucial as it provides a timeline for when they can expect to receive a decision from the FDA regarding the approval of their drug. This is critical for planning and regulatory strategy, and it is often closely monitored by investors, healthcare professionals, and the pharmaceutical industry as a whole. The PDUFA target action date for MDMA-assisted therapy is set for August 11, 2024.

As the PDUFA date draws near, the pharmaceutical community is laying preparations for the next pivotal phase. Should FDA approval be forthcoming, the drug sponsor must then embark on the complex and critical process of drug scheduling, which could shape MDMA's future accessibility. The sponsor, as the NDA applicant, is responsible for submitting detailed information addressing the potential for abuse, overdose data, and a scheduling proposal to the FDA. In response, the FDA, in collaboration with the Department of Health and Human Services, will then assess these submissions based on the Controlled Substances Act's eight-factor analysis criteria, considering factors such as the compound's abuse potential, its pharmacological effect, and the current state of scientific knowledge. If MDMA is deemed to possess abuse potential, the FDA will notify the Drug Enforcement

Administration (DEA) as required under 21 CFR § 314.104. The DEA then commences its rulemaking procedure to schedule the drug, incorporating assessments of abuse deterrence measures. Following this stage, the DEA is mandated to publish a final rule that officially schedules the drug, concluding the scheduling process.

The psychedelic industry's attention is fixed on how these regulatory developments will pave the way for this novel form of therapy in treating trauma after more than twenty years. Many mental healthcare practitioners are poised to incorporate this innovative therapy into their practices, offering new hope to those grappling with traumatic experiences. Consequently, it is critical for attorneys who advise physician groups and hospitals to gain a thorough understanding of the evolving regulatory framework. This knowledge will be essential for navigating the legal intricacies of integrating such groundbreaking treatments into patient care.

The potential regulatory approval of this new psychedelic treatment by August 11, 2024, should prompt healthcare attorneys to prepare playbooks for navigating compliance issues, healthcare regulations, reimbursement protocols, and complexities in securing market access for the novel drug. Meanwhile, corporate legal experts should be gearing up to counsel psychedelic enterprises on the nuances of corporate governance, adherence to securities regulations, and strategizing potential partnerships or collaborations. Concurrently, as business models adapt and expand to integrate this therapy, employment lawyers will become increasingly integral, drafting employment agreements and preemptively addressing legal challenges associated with organizational growth or workforce modifications. The outcome of the drug's approval process could have a profound effect on the valuation and business dynamics within the industry.

If MDMA-assisted psychotherapy receives FDA approval, it could transform mental health treatment and potentially catalyze a shift in the way the pharmaceutical industry and healthcare regulators think about novel treatments for mental health conditions. For attorneys, healthcare professionals, and patients alike, August 11, 2024, may well be a date that marks the beginning of a new chapter in fighting one of the most challenging disorders of mental health. Whatever the outcome, the journey of MDMA-assisted psychotherapy from the fringes of medical science to the forefront of therapeutic use has illuminated the crucial role that legal frameworks play in facilitating or forestalling the advent of novel treatments, affirming the essential partnership between law and medicine in advancing human health and welfare.