King & Spalding

Client Alert

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For more information, contact:

Lisa M. Dwyer
+1 202 626 2393
ldwyer@kslaw.com

Lauren Roth
+1 202 626 9277
lroth@kslaw.com

D. Kyle Sampson
+1 202 626 9226
ksampson@kslaw.com

David Farber
+1 202 626 2941
dfarber@kslaw.com

Scott Dziengelski
+1 202 661 7866
sdziengelski@kslaw.com

Allison Kassir
+1 202 626 5600
akassir@kslaw.com

Jackson Grubbe
+1 202 626 8980
jgrubbe@kslaw.com

King & Spalding

Washington, D.C.
1700 Pennsylvania Avenue, NW
Suite 900
Washington, D.C. 20006
T. +1 202 737 0500

Administrative, Congressional, and State Interest Signal a Potential Breakthrough Moment for Psychedelics

The development of innovative pharmaceuticals targeting refractory mental health conditions has stagnated for decades. In recent years, however, psychedelics have garnered scientific and public attention for their potential use in difficult-to-treat conditions, such as treatment-resistant depression, major depressive disorder, post-traumatic stress disorder, substance abuse disorders, and generalized anxiety disorder. Given psychedelics' therapeutic and commercial potential, the market in the United States has been projected to grow to nearly $7 billion by 2027, attracting companies and investors.[1]

This shift in scientific and public interest has led to increasing attention from policymakers as well. Federal health agencies have taken steps in recent years to facilitate research and innovation in psychedelic drugs. This increased focus appears poised for a major new boost, however, with the incoming political leadership of federal health agencies. Among the new leadership—including confirmed appointees and others tapped for senior roles—several leaders have expressed support for innovation in this space. Likewise, growing interest among federal and state legislators showcases momentum across different levels of government.

These developments suggest that development of psychedelics as a treatment option for some mental health conditions may be at a "tipping point." Will we soon see even more rapid, significant change? Although uncertain, there may be opportunities for sponsors, investors, providers, and patients who may in the future benefit from greater access to safe and effective psychedelic medicines.

KEY FEDERAL REGULATORY DEVELOPMENTS IN RECENT YEARS

Policymakers' interest in the potential benefits of psychedelics, although growing, is not new. For its part, the U.S. Food and Drug Administration

(FDA) has taken steps in recent years to help promote research and development among this class of drugs. In June 2023, FDA issued a new draft guidance highlighting fundamental considerations for clinical trial conduct, data collection, subject safety, and new drug application requirements.[2] By prioritizing this topic for guidance, the agency demonstrated its desire to aid research and development in this space. And while the draft guidance expressed caution about the "unique" characteristics of psychedelics that make clinical study challenging, it included recommendations for how sponsors could address these challenges and design studies that would be capable of yielding interpretable results to support future drug applications.

Along with FDA's draft guidance, federal health agencies have convened public workshops with the goal of further advancing research and development of psychedelic medicines.[3] Workshop participants reflected a range of stakeholders, including researchers, clinicians, patient advocates, ethicists, industry representatives, and regulators. Workshop topics generally focused on considerations in designing scientifically sound preclinical and clinical studies to examine the safety and efficacy of psychedelics, as well as ensuring the safety of clinical trial participants. Some presentations, such as those presented during workshops hosted by NIH and FDA, involved deeper dives into considerations around studying specific substances for specific indications. These included the use of MDMA for the treatment of post-traumatic stress disorder; the use of psilocybin for smoking cessation; and ketamine-assisted psychotherapy for the treatment of substance abuse disorders.

Through the prism of specific individual product submissions, FDA has further articulated its views about whether and how psychedelic drugs might meet regulatory criteria for review and approval. Notably, the agency has granted Breakthrough Therapy designation—which is reserved for drugs that are intended to treat "serious or life-threatening conditions" and for which preliminary clinical evidence demonstrates that the drug may have "substantial improvement" on at least one clinically significant endpoint over available therapy—to six psychedelic drugs.[4] Of those, the agency has approved one product for mental health indications: Spravato® (esketamine) is approved for the treatment of adults with treatment-resistant depression or major depressive disorder with acute suicidal ideation or behavior.[5] Although FDA recently declined to approve an MDMA-assisted therapy for the treatment of adults with post-traumatic stress disorder due to concerns about aspects of the clinical trial data that called into question their interpretation and complicated the benefit-risk assessment for the product, the action represents an important case study for future psychedelic drug developers to consider.

These regulatory developments provide a foundation on which developers of psychedelic drugs may construct potentially successful premarket programs. This progress, coupled with signals of dedicated interest from policymakers at all levels of government, suggests that the next few years could yield meaningful opportunities for innovation, regulatory engagement, and, ultimately, new therapies for patients.

NEW POLICYMAKER PERSPECTIVES MAY FUNDAMENTALLY CHANGE THE LANDSCAPE IN COMING YEARS

Policymakers' interest in psychedelic medicines continues to widen at both the federal and state levels of government. This year, in particular, the attention on psychedelics appears poised to receive a significant new boost, especially from the incoming leadership of key federal health agencies.

FEDERAL REGULATORS

Although these are "early days" for the incoming Administration, the scientific and policy priorities of new health agency leadership are rapidly taking shape. Among the emerging priorities, a redoubled focus on potential psychedelic treatments appears possible. Statements by several officials—including the Secretary of Health and Human Services (HHS), the FDA Commissioner, and the Secretary of Veterans Affairs (VA)—indicate greater

interest in exploring the potential therapeutic value of psychedelics than was generally suggested by their predecessors.

In widely-reported comments, HHS Secretary Robert F. Kennedy Jr. has previously indicated his support for decriminalizing psychedelics and exploring their potential therapeutic uses, and he has criticized FDA's decision not to approve MDMA-assisted treatment for post-traumatic stress disorder.[6] Further reinforcing Secretary Kennedy's policy focus, it was reported in recent weeks that HHS has hired Matt Zorn, a drug policy lawyer, to work on psychedelics policy issues.[7]

As FDA Commissioner, Dr. Martin Makary has confirmed that supporting the development of evidence on the therapeutic effects of psychedelics is now one of FDA's "top priorities." Striking a moderate tone, the Commissioner stated, "I'm not saying they're effective; I'm not saying the evidence is strong. I'm saying we have to listen to doctors that have these experiences [treating patients with psychedelics]." In reference to data coming out of ongoing psychedelic clinical trials, Dr. Makary described a need for an "expeditious and rapid review" while conducting "proper independent evaluations."[8]

Veterans Affairs Secretary Doug Collins expressed his interest in exploring whether psychedelic drugs can treat post-traumatic stress disorder or traumatic brain injuries during a U.S. House Appropriations subcommittee hearing in May. Secretary Collins affirmed that he is "willing to look at the possibility for any of these [psychedelic] treatments that can work," and he noted that the VA currently is administering 11 clinical trials involving psychedelic drugs and that "we've seen some good results there."[9]

The U.S. Drug Enforcement Administration (DEA) plays an important role in the regulation of psychedelics, which are mostly classified as Schedule I controlled substances.[10] Last month, the Church of Gaia in Spokane, Washington—which uses ayahuasca as part of its sacrament—successfully petitioned the DEA for a religious exemption from the Controlled Substances Act (CSA) pursuant to the Religious Freedom Restoration Act.[11] Yet, less is publicly known about the incoming leadership of the DEA with respect to therapeutic use, as opposed to religious use, of psychedelics. Federal law presents unique requirements for clinical research of Schedule I controlled substances, including DEA licensure requirements for researchers that add time and complexity to the clinical trial process.[12] These registration requirements are more stringent for Schedule I controlled substances than for Schedule II-V controlled substances. Beyond that, Schedule I researchers have a more limited ability to perform chemical analysis and conduct instructional activities with controlled substances than, for example, Schedule III researchers.

Petitions to outright reschedule psychedelics have so far been unsuccessful. However, in recent years, DEA has taken incremental steps that would help enable clinical research activities, such as increasing the aggregate production quotas for certain psychedelics to be used in research.[13] It remains to be seen whether incoming DEA officials will continue to take actions to reduce obstacles to clinical research.

FEDERAL LEGISLATORS

There is increasing support for federal legislation addressing psychedelics research and development. Most recently, the 2024 National Defense Authorization Act directed the U.S. Department of Defense to establish a process for funding clinical research into the use of certain psychedelic substances to treat post-traumatic stress disorder and traumatic brain injury.[14] And a bi-partisan group of Representatives have introduced the Innovative Therapies Centers of Excellence Act of 2025 which, if enacted, would direct the VA to create at least five dedicated centers of excellence to study the therapeutic uses of psychedelic substances to treat various battlefield-related conditions.[15]

Legislators are becoming more vocal about their support of psychedelics. Reps. Lou Correa (D-CA) and Jack Bergman (R-MI) launched a Psychedelics Advancing Therapies (PATH) Caucus, which aims to address the national

mental health care crisis through psychedelic science and research.[16] Rep. Morgan Luttrell (R-TX), a former Navy SEAL, stated that psychedelic therapies—specifically ibogaine and 5-MeO-DMT—saved his life after multiple brutal combat deployments.[17]

STATE GOVERNMENTS

A patchwork of state approaches is emerging, with several taking action to loosen restrictions on certain substances. For instance, Oregon and California have enacted legislation allowing psilocybin use in licensed "service centers" and "healing centers" under supervision, and New Mexico has enacted a law to decriminalize certain therapeutic uses of psilocybin and develop best practices for such uses.[18] Utah and Connecticut have launched pilot programs to provide psilocybin or MDMA-assisted therapy to patients for mental health conditions.[19] Still other states have directed research studies of psychedelics, such as Alaska, Maryland, Minnesota, Nevada, Texas, Vermont, and Washington.[20]

A 2025 Virginia bill directed the Board of Pharmacy to issue regulations concerning crystalline polymorph psilocybin upon FDA approval and DEA rescheduling, although the bill was vetoed.[21] The Texas House and Senate have passed SB 2308, which would provide $50 million in state funds for ibogaine trials for the purpose of seeking FDA approval for opioid use disorder, co-occurring substance use disorder, and other neurological or mental health conditions.[22] The bill awaits the Governor's signature.

Federal authorities have identified a need for more research in this area, and it appears states may produce some of this research. While the state patchwork is evidence of momentum behind exploring psychedelics, the patchwork may introduce complications for sponsors seeking FDA approval due to the variety of controls, methodologies, and substances authorized for study. Still, state developments may influence public interest in and support of efforts to promote research at the federal level. Sponsors and federal policymakers should monitor these developments.

POTENTIAL BREAKTHROUGH MOMENT FOR PSYCHEDELICS? KEY TAKEAWAYS.

Recent FDA actions, growing policymaker interest, and advances in the underlying science suggest that this may be a potential breakthrough moment for psychedelic medicines. To generate momentum, we offer three key takeaways for sponsors, investors, patients, and other stakeholders interested in advancing innovation in this space.

1. **Proactively engage federal policymakers regarding pathways and expectations for premarket approval**. Sponsors, researchers, patients, and other interested stakeholders should continue to engage both staff and leadership of federal health agencies, particularly FDA, in dialogue about methodologies to design clinical studies that will pass regulatory muster. Given FDA Commissioner Makary's signal that psychedelics research and evaluation are a top priority for FDA, companies should consider providing additional, specific feedback about how FDA's draft guidance on clinical trial designs could be updated—for instance, to reflect lessons learned from clinical research over the past two years, or to reflect applicable advances in technology that may aid clinical trial optimization, personalization of treatments, patient monitoring, and other uses. Updated FDA guidance that provides drug developers with additional clarity and predictability regarding the agency's expectations will further enable companies to invest in high-quality research and innovation.
2. **Proactively engage federal policymakers regarding research barriers associated with classification of psychedelics in Schedule I.** As noted above, because psychedelics are classified as Schedule I drugs under the CSA, they are subject to significant restrictions that impose complexities and costs on the clinical trial process and can hinder sponsor efforts to efficiently establish clinical trial sites for psychedelic studies. As part of engaging with federal policymakers, sponsors and researchers should consider advancing thoughtful policy solutions that balance public health concerns regarding the abuse potential of psychedelic substances with

public health interest in supporting scientific research into potential therapeutic uses of these drugs. For example, currently, there are specific rules designed to expedite marijuana research approvals,[23] and advocacy could be directed toward similar rules for psychedelics.

3. **Identify and address other potential barriers to patient access for potential future FDA-approved treatments**. FDA approval is only one, albeit important, gate to patient access to new treatments. Other barriers, such as acceptance by federal and private payers, as well as incorporation into medical billing and coding, will need to be addressed by policymakers and/or individual companies. To maximize opportunities for patients to access new therapies upon FDA approval, drug sponsors should integrate market access planning early in the drug research and development process.

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[1] The Petrie-Flom Center, *The Project on Psychedelics Law and Regulation (POPLAR)*, https://petrieflom.law.harvard.edu/the-project-on-psychedelics-law-and-regulation-poplar/ (last visited June 4, 2025).

[2] *See* FDA, *Psychedelic Drugs: Considerations for Clinical Investigations* (June 2023), *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/psychedelic-drugs-considerations-clinical-investigations.

[3] For instance, between 2022-2024, agencies within the Department of Health and Human Services (HHS) hosted at least four meetings, including:

- In 2022, a National Institutes of Health (NIH) workshop examining gaps, challenges, and opportunities in psychedelic drug development (*see* https://www.niaaa.nih.gov/news-events/meetings-events-exhibits/nih-workshop-psychedelics-therapeutics-gaps-challenges-and-opportunities);
- In 2023, an Office for Human Research Protections (OHRP) workshop examining the ethical and practical considerations for conducting clinical research of psychedelic drugs (*see* https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/2023-workshop/index.html);
- In 2024, a workshop cohosted by FDA and the Reagan-Udall Foundation for the FDA (Reagan-Udall) focusing on advancing psychedelic clinical study design (*see* https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/public-workshop-advancing-psychedelic-clinical-study-design-01312024#event-information); and,
- Also in 2024, a second workshop by Reagan-Udall focusing specifically on understanding potential therapeutic uses of ketamine (*see* https://reaganudall.org/news-and-events/events/understanding-current-use-ketamine-emerging-areas-therapeutic-interest). We note that, although ketamine is not a "classic" psychedelic, but rather a dissociative anesthetic, it is often included in discussion of psychedelics, given that it produces some similar effects and its potential therapeutic uses overlap significantly with psychedelics.

[4] For instance, FDA has granted breakthrough designation for:

- Intranasal esketamine for treatment-resistant depression and symptoms of major depressive disorder with acute suicidal ideation or behavior (*see* https://www.jnj.com/media-center/press-releases/esketamine-recieves-breakthrough-therapy-designation-from-us-food-and-drug-administration-for-major-depressive-disorder-with-imminent-risk-of-suicide);
- 3,4-Methylenedioxymethamphetamine (MDMA) for PTSD (*see* 2017.08.15-IND063384GrantBreakthroughTherapyDesignation1_Redacted.pdf);
- COMP360 psilocybin for treatment-resistant depression (*see* https://ir.compasspathways.com/News--Events-/news/news-details/2025/Compass-Pathways-Announces-Publication-of-Results-from-COMP004-Study-on-COMP360-Psilocybin-for-Treatment-Resistant-Depression/default.aspx);
- Psilocybin for major depressive disorder (*see* https://www.usonainstitute.org/updates/fda-grants-breakthrough-therapy-designation-to-usona-institutes-psilocybin-program-for-major-depressive-disorder);

- The psilocybin analog CYB003 as adjunctive treatment for major depressive disorder (*see* https://med.uth.edu/psychiatry/2024/06/03/fda-grants-breakthrough-therapy-designation-to-cyb003-a-deuterated-psilocybin-analog-being-investigated-as-an-adjunctive-treatment-for-major-depressive-disorder-mdd/); and,
- Lysergic acid diethylamide D-tartrate MM120 for generalized anxiety disorder (*see* https://ir.mindmed.co/news-events/press-releases/detail/137/mindmed-receives-fda-breakthrough-therapy-designation-and-announces-positive-12-week-durability-data-from-phase-2b-study-of-mm120-for-generalized-anxiety-disorder).

[5] The Spravato label and regulatory history is available on FDA's website at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/211243s019lbl.pdf. Note that ketamine, the parent compound of esketamine, was approved as an anesthetic in 1970.

[6] *See, e.g.*, Nidhi Subbaraman, *What Has RFK Jr. Said About Weight-Loss Drugs, Antidepressants and Psychedelics?*, WSJ.com (Jan. 29, 2025), https://www.wsj.com/livecoverage/trump-cabinet-confirmation-hearings/card/what-has-rfk-jr-said-about-weight-loss-drugs-antidepressants-and-psychedelics—eAaDAxA6vQaSVMeBPlEs; @RobertKennedyJr, X.com (Oct. 25, 2024, 5:25 PM), https://x.com/RobertKennedyJr/status/1849925311586238737; @RobertKennedyJr, X.com (June 5, 2024), https://x.com/RobertKennedyJr/status/1798501142777004505?lang=bn; @robertfkennedyjr, Instagram.com (Sept. 21, 2024), https://www.instagram.com/robertfkennedyjr/reel/DAL7BbAvfii/?hl=en.

[7] Erin Schumaker, *A Psychedelics Hire at HHS*, Politico.com (May 28, 2025), https://www.politico.com/newsletters/future-pulse/2025/05/28/a-psychedelics-hire-at-hhs-00371416.

[8] NewsNation, *FDA commissioner says research on psychedelic treatment 'top priority' | On Balance*, Youtube.com (May 16, 2025), https://www.youtube.com/watch?v=KEQFKBME668.

[9] House Appropriations Budget Hearing – U.S. Dept. Of Veterans Affairs (May 15, 2025), https://appropriations.house.gov/schedule/hearings/budget-hearing-us-department-veterans-affairs (see embedded video at 1:43:00-1:44:11).

[10] The Controlled Substances Act classifies controlled substances into one of five schedules depending on their potential for abuse. Drugs are classified into Schedule I if they have a high potential for abuse, no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug under medical supervision. *See* 21 U.S.C. § 812(b).

[11] Tod Stephens, *Spokane psychedelic church gets first approval of its kind from DEA to possess ayahuasca*, THE SPOKESMAN-REVIEW (May 23, 2025), https://www.spokesman.com/stories/2025/may/23/spokane-psychedelic-church-gets-first-approval-of-/.

[12] 21 C.F.R. § 1301.18.

[13] *See, e.g.*, 89 Fed. Reg. 407, 411 (Jan. 3, 2024) (increasing aggregate production quota for psilocybin in response to comments and quota applications from DEA-registered manufacturers).

[14] National Defense Authorization Act for Fiscal Year 2024, Pub. L. No. 118-31, tit. VII, 137 Stat. 306 (2023).

[15] Innovative Therapies Centers of Excellence Act of 2025, H.R. 2623, 119th Cong. (2025).

[16] Office of Rep. Lou Correa, *Reps. Correa, Bergman Re-Launch Bipartisan Caucus to Explore Psychedelic Research for Mental Health* (Mar. 2, 2023), https://psychedelicalpha.com/news/forging-a-path-to-access-congressmen-correa-and-bergman-on-the-future-of-psychedelics-in-the-u-s.; *Forging a Path to Access: Congressmen Correa and Bergman on the Future of Psychedelics in the U.S.*, PsychedelicAlpha.com (March 4, 2025), https://psychedelicalpha.com/news/forging-a-path-to-access-congressmen-correa-and-bergman-on-the-future-of-psychedelics-in-the-u-s.

[17] Office of Rep. Morgan Luttrell, *Former Navy SEAL Morgan Luttrell bashes FDA after agency delivers blow to psychedelic medicine which saved his own life amid PTSD struggle: 'It's a poor decision'* (June 6, 2024), https://luttrell.house.gov/media/in-the-news/former-navy-seal-morgan-luttrell-bashes-fda-after-agency-delivers-blow.

[18] *See* Oregon Health Authority, *Oregon Psilocybin Services*, https://www.oregon.gov/oha/ph/preventionwellness/pages/oregon-psilocybin-services.aspx (last visited June 4, 2025); Colorado Department of Regulatory Agencies, *Welcome to the Natural Medicine Program*, https://dpo.colorado.gov/NaturalMedicine (last visited June 4, 2025).

[19] Medical Amendments, S.B. 2066, 65th Leg. (Utah 2024); An Act Adjusting the State Budget for the Biennium Ending June 30, 2023, Concerning Provisions Related to Revenue, School Construction and Other Items to Implement the State Budget and Authorizing and Adjusting Bonds of the State, H.B. No. 5506, C.G.A. (Conn. 2022).

[20] *See* An Act establishing the Alaska task force for the regulation of psychedelic medicines approved by the United States Food and Drug Administration; and providing for an effective date, H.B. 228, 33rd Leg. (Alaska 2024); Task Force on Responsible Use of Natural Psychedelic Substances, S.B. 1009, 446th Sess. (Md. 2024); Omnibus Health Appropriations, S.F. 2995, 93rd Leg. (Minn. 2023); An Act relating to controlled substances; requiring the Department of Health and Human Services to establish the Psychedelic Medicines Working Group to study certain issues relating to the therapeutic use of entheogens during the 2023-2024 interim; prescribing the membership and duties of the Working Group; and providing other matters properly relating thereto, S.B. 242, 82nd Sess. (Nev. 2023); An Act relating to a study on the use of alternative therapies for treating post-traumatic stress disorder, H.B. 1802, 87th Leg. (Tex. 2021); An act relating to the establishment of the Psychedelic Therapy Advisory Working Group, S.114, 2023-2024 Leg. Sess. (Vt. 2024); Making 2021-2023 fiscal biennium supplemental operating appropriations, S.B. 5693, 67th Leg. (Wash. 2022).

[21] Crystalline polymorph psilocybin; regulations for prescribing, etc., S.B. 1135, 163rd Leg. (Va. 2025), *available at* https://lis.virginia.gov/bill-details/20251/SB1135.

[22] An Act relating to the establishment of a consortium to conduct United States Food and Drug Administration's drug development clinical trials with ibogaine to secure the administration's approval of the medication's use for treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health conditions for which ibogaine demonstrates efficacy and to the administration of that treatment, S.B. 2308, 89th Leg. (Tex. 2025).

[23] *See* 21 U.S.C. § 823 (requiring the DEA to respond to a researcher's application to manufacture marijuana for research purposes within 60 days).