American College of Neuropsychopharmacology
bulletin



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The development of psychedelic-assisted therapeutics has advanced to the threshold of regulatory decision for treatment-resistant depression, PTSD, and other serious mental illnesses. For patients who face a profound need, this is a moment of significant scientific promise.

The American College of Neuropsychopharmacology (ACNP) has long held that scientific rigor and therapeutic innovation are interdependent rather than in tension. Accelerated regulatory pathways deliver patient benefit only when the underlying evidence withstands post-marketing scrutiny. Durable approvals will turn on a set of methodological questions specific to this class of compounds. These include functional unblinding, expectancy effects, durability of response, abuse liability assessment, and the detection of rare adverse events in small trials.

Pathways for access to investigational therapies, including those provided under the Right to Try Act, raise specific scientific considerations when applied to this class of compounds. The acute psychoactive effects of psychedelic drugs require attentive administration; meaningful capture of safety information, assessment of durability of response, and continuity of follow-up depend on the scientific infrastructure surrounding any access setting. Sustaining methodological standards across pathways ensures that clinical experience accumulated outside formal trials contributes to the broader evidence base that serves all patients.

These questions are difficult but tractable, and addressing them requires sustained, cross-disciplinary attention. To that end, the College is convening a standing scientific advisory group drawing on the breadth of expertise within its membership to serve as a resource on the technical questions facing regulators, sponsors, and clinicians in this period. The College will advance these

discussions through commentary and methodological analysis in its peer-reviewed journals, and, in collaboration with allied scientific organizations, will convene briefings that bring its members' expertise to discuss trial design, real-world evidence, and the implementation infrastructure on which durable approvals depend.

For more than six decades, ACNP's role has been to advance the science that translates into safe and effective therapies for serious mental illness. The College intends to play that role in this moment as well, committed to the patients these therapies aim to help, to the integrity of the evidence on which their approval will rest, and to the long arc of scientific progress that continues well beyond any single regulatory decision.