



August 23, 2023

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA–2023–D–1987 for “Psychedelic Drugs: Considerations for Clinical Investigations”

To Whom It May Concern:

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to submit comments on the Food and Drug Administration’s (FDA’s) draft guidance titled *Psychedelic Drugs: Considerations for Clinical Investigations*.

ABHW is the national voice for payers managing behavioral health insurance benefits. ABHW member companies provide coverage to approximately 200 million people in the public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness.

Our organization aims to increase access, drive integration, support prevention, raise awareness, reduce stigma, and advance evidence-based treatment and quality outcomes. Furthermore, through our policy work, we strive to promote equal access to quality treatment and address the stark inequities created by systemic racism. We are deeply concerned about health disparities in MH and SUD services in this country and are committed to promoting health equity in the healthcare system.

ABHW appreciates the issuance of guidance to provide general considerations to sponsors developing psychedelic drugs for treating psychiatric and substance use disorders. Having a wide range of treatments available to individuals with behavioral health conditions is important; however, ensuring clinical safety, efficacy, and medical appropriateness is a top priority of our members. We support ongoing research in the emerging area of psychedelic drugs and the FDA’s

continued adherence to the same regulations and evidentiary standards that the Agency upholds for other drug development programs.

Thank you for the opportunity to provide feedback on this draft guidance document. If you have questions, please contact me, Pamela Greenberg, President and CEO, at greenberg@abhw.org.

Sincerely,

A handwritten signature in black ink that reads "Pamela Greenberg". The signature is written in a cursive, flowing style.

Pamela Greenberg, MPP
President and CEO