

118TH CONGRESS  
1ST SESSION

# H. R. 4242

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to issue guidance on considerations for conducting clinical trials for psychedelic assisted therapy.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 21, 2023

Mr. CRENSHAW (for himself, Mrs. MILLER-MEEKS, and Mr. KHANNA) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to issue guidance on considerations for conducting clinical trials for psychedelic assisted therapy.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. GUIDANCE ON CONSIDERATIONS FOR CON-**  
4 **DUCTING CLINICAL TRIALS FOR PSYCHE-**  
5 **DELIC ASSISTED THERAPY.**

6 The Secretary of Health and Human Services, acting  
7 through the Commissioner of Food and Drugs, shall—

- 1           (1) not later than 180 days after the date of  
2           enactment of this Act, issue for public comment  
3           draft guidance on considerations for conducting clin-  
4           ical trials for psychedelic assisted therapy, including  
5           how those seeking an investigational use exemption  
6           for such clinical trials should request interactive sup-  
7           port by the Food and Drug Administration; and  
8           (2) not later than 180 days after issuing such  
9           draft guidance, finalize such guidance.

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