

United States Senate

April 4, 2019

Director Francis Collins, M.D., Ph.D.
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Commissioner Scott Gottlieb, M.D.
U.S. Food and Drug Administration
1093 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Collins and Commissioner Gottlieb:

I am writing to request information regarding the latest efforts undertaken by the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) to research psychoactive drugs to treat mental health illnesses. I commend the actions taken by the FDA to approve research on illicit psychoactive drugs—including psychedelics—that may prove beneficial in treating mental illness. I have a continued interest in the efficacy of psychoactive drugs in psychiatric treatments and request information regarding the steps your agencies are taking to prioritize research into psychedelics for treating mental illness.

Psychoactive drugs are chemical substances that alter mood, perception, or consciousness.¹ These substances include antidepressants, antipsychotics, and mood stabilizers², many of which have been approved by the FDA for treatment of various mental illnesses, including depression, schizophrenia, and anxiety disorders. Psychedelics—a class of psychoactive drugs—present a similar opportunity to provide treatment to patients while expanding psychotherapy treatment options. Studies have found the benefits of the controlled use of psychedelics in psychotherapy programs, including the benefits of lysergic acid diethylamide (LSD) to reduce anxiety for patients with life-threatening diseases,³ and the safety and efficacy of ketamine, MDMA, psilocybin, LSD, and ibogaine in clinical trials.⁴

I applaud the FDA's work to approve clinical research on various psychedelic drugs, including psilocybin and MDMA. Psilocybin may prove an effective treatment for those with depression, and MDMA may provide relief for post-traumatic stress disorder patients. As the FDA and NIH

¹ "Section 1: An Overview of Alcohol and Other Drug Issues," *Bush Book*, 2015, https://web.archive.org/web/20150328060739/http://www.nt.gov.au/health/healthdev/health_promotion/bushbook/volume2/chap1/sect1.htm. (accessed January 31, 2019).

² National Institute of Mental Health, *Mental Health Medications*, <https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml> (accessed January 31, 2019).

³ Matthias Liechti, "Modern Clinical Research on LSD," *Neuropsychopharmacology* 42, no. 11 (2017): 2114.

⁴ Eduardo Schenberg, "Psychedelic-Assisted Psychotherapy: A Paradigm Shift in Psychiatric Research and Development," *Frontiers in Pharmacology*, 2018, no. 9: 733.

consider further methods to expand research of mental health treatments, I request a brief and written response to the following inquiries and questions:

1. Please provide your research agenda for investigating the use of psychedelic drugs, including LSD, ketamine, MDMA, psilocybin, and ibogaine to treat mental health illnesses.
2. What gaps exist in our understanding of the medical potential for these psychedelic drugs?
3. What has the FDA and NIH found in terms of safety and potential for abuse for these drugs?
4. Is the FDA petitioning to reclassify any psychedelic drugs from schedule I drugs to schedule IV drugs?

I appreciate your attention to this important matter and for your efforts to research further treatment options for mental health illnesses.

Sincerely,



BRIAN SCHATZ
United States Senator