EXECUTIVE ORDER
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ACCELERATING MEDICAL TREATMENTS FOR SERIOUS MENTAL ILLNESS

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose and Policy. Policymakers and the medical field have long struggled to address the burden of suicide and serious mental illness rates in America. Today, over 14 million American adults have a serious mental illness, defined as having a diagnosable mental, behavioral, or emotional disorder that substantially interferes with a person's life and ability to function, and about 8 million are on prescription medication for these conditions. Suicide rates tragically increased by 37 percent from 2000 to 2018. During my first term, we made historic progress in helping those struggling with some of the most insidious mental illnesses, and suicide rates decreased by 5 percent from 2018 to 2020. The COVID-19 pandemic and the Biden Administration's prolonged shutdown stunted this progress and suicide rates rebounded upwards again to their peak rate in 2022. Critically, veterans often suffer in greater measure from this tragedy. For over 20 years, there have been more than 6,000 veteran suicides per year, and the current veteran suicide rate is more than twice as much as the non-veteran adult population.

Individuals suffering from major depressive disorder and substance abuse disorder, among other serious mental illnesses, can relapse or not fully respond to standard medical and psychiatric therapies. Despite massive Federal investment into researching potential advancements in mental health care and

treatment, our medical research system has yet to produce approved therapies that promote enduring improvements in the mental health condition of these most complex patients. Innovative methods are needed to find long-term solutions for these Americans beyond existing prescription medications.

Psychedelic drugs, including ibogaine compounds, show potential in clinical studies to address serious mental illnesses for patients whose conditions persist after completing standard therapy. Indeed, the Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to specific psychedelic drugs, and there are numerous products currently in the clinical trial pipeline for review of safety and efficacy. It is the policy of my Administration to accelerate innovative research models and appropriate drug approvals to increase access to psychedelic drugs that could save lives and reverse the crisis of serious mental illness in America.

Sec. 2. FDA Review Prioritization and Right to Try. (a) The Commissioner of Food and Drugs shall provide Commissioner's National Priority Vouchers to appropriate psychedelic drugs that have received a Breakthrough Therapy designation and are in accordance with the criteria of the National Priority Voucher Program.

(b) The FDA and Drug Enforcement Administration shall facilitate and establish a pathway for eligible patients to access psychedelic drugs, including ibogaine compounds, under the Right to Try Act (21 U.S.C. 360bbb-0a), including any necessary Schedule I handling authorizations for treating physicians and researchers, consistent with 21 U.S.C. 823, and any applicable waiver authority under the Controlled Substances Act.

Sec. 3. Department of Health and Human Services Funding for Federal-State Collaboration. The Secretary of Health and Human Services shall, through the Advanced Research Projects Agency for Health, allocate at least $50 million from existing funds to support and partner with State governments that have enacted or are developing programs to advance psychedelic drugs for serious mental illnesses, including through Federal funding, technical assistance, and data sharing as appropriate and consistent with applicable law.

Sec. 4. Department of Health and Human Services and FDA Collaboration with the Department of Veterans Affairs and the Private Sector. The Department of Health and Human Services (HHS) and FDA shall collaborate with the Department of Veterans Affairs (VA) and, as appropriate and consistent with applicable law, including any privacy restrictions from the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act of 1996, with the private sector, to increase clinical trial participation, data sharing, and real-world evidence generation regarding psychedelic drugs, and shall prioritize drugs that have received a Breakthrough Therapy designation. The HHS, FDA, and VA are directed to sign data-sharing memoranda as appropriate to ensure that data from relevant clinical studies conducted by other executive departments and agencies is made available to FDA to facilitate the timely evaluation and approval of drugs that meet standards for approval under section 505 of the Federal Food, Drug, and Cosmetic Act.

Sec. 5. Timely Rescheduling. The Attorney General shall, in consultation with HHS, initiate and complete review of any product containing a Schedule I substance that has successfully completed Phase 3 clinical trials for a serious mental health disorder, so that rescheduling, if appropriate under 21 U.S.C.

811, may proceed as quickly as practicable for such specific products that are ultimately approved under section 505 of the Federal Food, Drug, and Cosmetic Act.

Sec. 6. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The costs for publication of this order shall be borne by the Department of Health and Human Services.

THE WHITE HOUSE,

April 18, 2026.

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