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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To accelerate the development of, and access to, psychedelic drugs that could save lives and reverse the crisis of serious mental illness in the United States, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. LUTTRELL introduced the following bill; which was referred to the Committee on _____

A BILL

To accelerate the development of, and access to, psychedelic drugs that could save lives and reverse the crisis of serious mental illness in the United States, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Initiating Biomedical Outcomes to Garner Advancements into Innovative Neuroplastogen Efficacy Act'' or the ''IBOGAINE Act''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. DEFINITIONS.

Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end the following:

''(61) The term 'ibogaine' means—

''(A) all parts of the plant *Tabernanthe iboga*; and

''(B) any similar compound or analog that—

''(i) acts on neuroplasticity, opioid receptors, or serotonergic pathways that—

''(I) interrupt addiction cycles; and

''(II) restore neurological function disrupted by trauma, chronic sub-

stance use, or traumatic brain injury; and

''(ii) are distinct in mechanism from the breakthrough therapies designated under section 506 of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 4. NATIONAL HEALTH PRIORITY VOUCHER PILOT PROGRAM.

Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

''SEC. 524C. NATIONAL HEALTH PRIORITY VOUCHER PILOT PROGRAM.

''(a) DEFINITIONS.—In this section:

''(1) PRIORITY REVIEW.—The term 'priority review', with respect to a human drug application as defined in section 735(1), means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(c) of the Food and Drug Administration Amendments Act of 2007.

''(2) NATIONAL HEALTH PRIORITY REVIEW VOUCHER.—The term 'national health priority review voucher' means a voucher issued by the Secretary to the sponsor of a national health priority product application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 505(b)(1) of this Act or section 351 of the Public Health Service Act after the date of approval of the national health priority product application.

''(3) NATIONAL HEALTH PRIORITY PRODUCT.—The term 'national health priority product' means any of the following:

''(A) PUBLIC HEALTH CRISIS RESPONSE.—A product to treat or prevent an urgent or emerging threat that the Secretary has identified as having a significant impact on the population of the United States.

''(B) BREAKTHROUGH THERAPIES.—A drug that—

''(i) is designated as a breakthrough therapy under section 506(a); and

''(ii) is a transformative treatment with one or more novel mechanisms that

fundamentally change the management of one or more diseases or conditions.

''(C) LARGE UNMET MEDICAL NEEDS.—A therapy for a disease or condition for which existing treatments inadequately address patient outcomes.

''(D) ONSHORING AND SUPPLY CHAIN RESILIENCE.—A product whose development or manufacture in the United States would strengthen the Nation's domestic capacity, reduce foreign dependency, and improve national security with respect to the drug supply chain.

''(E) AFFORDABILITY.—A product that—

''(i) improves overall value through reduced costs to the health care system; or

''(ii) enhances access to important health care products.

''(F) OTHER PRODUCTS.—Any other national health priority product whose approval would—

''(i) address a health crisis in the United States;

''(ii) deliver an innovative cure;

''(iii) address an unmet public health need; and

''(iv) increase domestic drug manufacturing as a matter of national security.

''(4) NATIONAL HEALTH PRIORITY PRODUCT APPLICATION.—The term 'national health priority product application' means an application that—

''(A) is a human drug application as defined in section 735(1); and

''(B) is for a national health priority product.

''(b) PRIORITY REVIEW VOUCHER.—

''(1) IN GENERAL.—The Secretary shall award a national health priority review voucher to the sponsor of a national health priority product application upon approval by the Secretary of such application.

''(2) PROHIBITION ON TRANSFERABILITY.—The sponsor of a national health priority product that receives a national health priority review voucher may not transfer the entitlement to such voucher, except that if ownership of the sponsor is transferred to a different entity the entitlement to such voucher may be transferred to such entity as part of the change in ownership.

''(3) LIMITATIONS.—A sponsor of a national health priority product application may not—

''(A) receive more than one national health priority review voucher during any 24-month period; or

''(B) apply for an additional national health priority review voucher while in possession of such a voucher.

''(c) PRIORITY VOUCHER USER FEE.—

''(1) IN GENERAL.—The Secretary may establish a user fee program under which a sponsor of a human drug application that is the subject of a national health priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under chapter VII.

''(2) FEE AMOUNT.—The amount of the user fee under paragraph (1) shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

''(3) ANNUAL FEE SETTING.—The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2026, for that fiscal year, the amount of the user fee under paragraph (1).

''(4) OFFSETTING COLLECTIONS.—Fees collected pursuant to this subsection for any fiscal year—

''(A) shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

''(B) shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

''(d) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing in this section precludes a sponsor who seeks a national health priority review voucher from participating in any other incentive program, including under this Act, except that no sponsor of a national priority health product application may receive more than one national health priority review voucher with respect to the drug for which the application is made.

''(e) RELATION TO OTHER PROVISIONS.—The provisions of this section shall supplement, not supplant, any other provisions of this Act or the Public Health Service Act that encourage the development of drugs for tropical diseases, rare pediatric diseases, or national health priority products.

''(f) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a national health priority product application for which the sponsor seeks a voucher under this section to enable the sponsor—

''(1) to plan a development program to obtain the necessary data for approval of the national health priority product that is the subject of such application; and

''(2) to conduct any additional studies that would be required for approval of such product for use in a broader population.

''(g) GAO STUDY AND REPORT.—

''(1) STUDY.—

''(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study of the effectiveness of awarding national health priority review vouchers in the development of human drug products.

''(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

''(i) With respect to each national health priority review voucher awarded:

''(I) Whether, and to what extent, an unmet need related to the treatment or prevention of a disease or condition was met through the approval of a national health priority product.

''(II) Identification of each drug for which the voucher was used.

''(III) The length of the period of time between the date on which the voucher was awarded and the date on which it was used.

''(ii) Whether the pathway under this section has helped to provide safe and effective treatments for patients.

''(iii) Whether a similar voucher program would be appropriate for other categories of drugs.

''(2) REPORT.—Not later than 1 year after the date of enactment of this section, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report containing the results of the study under paragraph (1).

''(h) TERMINATION OF AUTHORITY.—The Secretary may not award a voucher under this section after September 30, 2029.''.

SEC. 5. AMENDMENT TO THE FEDERAL RIGHT TO TRY LAW.

Section 561B(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a(b)) is amended by inserting ''any provision of the Controlled Substances Act (21 U.S.C. 801 et seq.) that prohibits the unauthorized use, possession, distribution, dispensation, or transportation of an eligible investigational drug,'' before ''and parts''.

SEC. 6. SPECIAL REGISTRATION REQUIREMENTS RELATED TO RIGHT TO TRY.

(a) AMENDMENT.—Section 303 of the Controlled Substances Act (21 U.S.C. 823) is amended by adding at the end the following:

''(p) SPECIAL REGISTRATION FOR SCHEDULE I ELIGIBLE INVESTIGATIONAL DRUGS UNDER RIGHT TO TRY.—

''(1) DEFINITIONS.—In this subsection, the terms 'eligible investigational drug' and 'eligible patient' have the meanings given those terms in section 561B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a).

''(2) SPECIAL REGISTRATION PROCESS.—The Attorney General shall register physicians to directly

administer eligible investigational drugs in schedule I to eligible patients under section 561B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a) in accordance with paragraphs (3) through (6) of this subsection.

''(3) REQUIREMENTS.—

''(A) APPLICATION.—A physician desiring a registration to directly administer an eligible investigational drug as described in paragraph (2) shall submit to the Attorney General an application containing—

''(i) evidence of a valid registration to dispense or administer controlled substances in schedules II through V;

''(ii) evidence of compliance with section 561B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0a), including—

''(I) documentation from the manufacturer or sponsor verifying the investigational drug in schedule I is an eligible investigational drug;

''(II) an agreement from the manufacturer or sponsor to supply the eligible investigational drug, along

with guidance on its administration, to the requesting physician for the treatment of eligible patients; and

''(III) an affirmation that the physician will only directly administer the eligible investigational drug to treat eligible patients in a manner consistent with the guidance provided by the manufacturer or sponsor;

''(iii) the quantity of the eligible investigational drug to be supplied by the manufacturer or sponsor to the physician to treat eligible patients;

''(iv) evidence that the physician is allowed to treat patients under the laws of the State in which the treatment will take place;

''(v) a description of the site at which the physician intends to store and administer the eligible investigational drug; and

''(vi) any additional information the Attorney General determines necessary to prevent diversion.

''(B) APPROVAL.—Not later than 45 days after receiving an application containing the in-

formation required under subparagraph (A), the Attorney General shall—

''(i) register the applicant; or

''(ii) serve an order to show cause upon the applicant in accordance with section 304(c).

''(4) ELECTRONIC SUBMISSIONS.—The Attorney General shall provide a means for a physician to submit an application under paragraph (3)(A) electronically.

''(5) LIMITATION ON AMOUNTS.—A physician treating eligible patients with an eligible investigational drug in schedule I under this subsection may only possess the amounts of the eligible investigational drug identified in—

''(A) the application submitted to the Attorney General under paragraph (3)(A); or

''(B) a supplemental notification that the physician may submit to the Attorney General if the physician needs additional amounts of the eligible investigational drug for the treatment of eligible patients, which supplemental notification—

''(i) shall include—

''(I) the name of the physician;

''(II) the additional quantity of the eligible investigational drug needed; and

''(III) an attestation that the treatment with the eligible investigational drug is consistent with the scope of treatment that was the subject of the application under paragraph (3)(A); and

''(ii) shall be deemed approved on the date that is 30 days after the date on which the physician submits the supplemental notification to the Attorney General, unless the Attorney General serves an order to show cause upon the applicant in accordance with section 304(c).

''(6) SINGLE REGISTRATION FOR RELATED TREATMENT SITES.—A physician may treat eligible patients with an eligible investigational drug in schedule I under a single registration under this subsection if—

''(A) the treatment occurs exclusively on sites all of which are—

''(i) within the same city or county; and

"(ii) under the control of the same institution, organization, or agency; and

"(B) before commencing the treatment, the physician notifies the Attorney General of each site where the eligible investigational drug will be stored or administered in accordance with paragraph (3)(A)(vi).".

(b) RULEMAKING.—Notwithstanding the requirements of section 553 of title 5, United States Code, not later than 240 days after the date of enactment of this Act, the Attorney General shall issue an interim final rule to implement subsection (p) (as added by this section) of section 303 of the Controlled Substances Act (21 U.S.C. 823), including with respect to—

(1) the manner in which an eligible investigational drug may be delivered to an approved registrant;

(2) the storage and security of an eligible investigational drug;

(3) the maintenance of records for an approved registrant;

(4) the process for renewal, suspension, or revocation of a registration; and

(5) any other matters necessary to ensure effective controls against diversion.

(c) FINAL RULE.—Not later than 2 years after issuing an interim final rule under subsection (b), the Attorney General shall issue a final rule to implement subsection (p) (as added by this section) of section 303 of the Controlled Substances Act (21 U.S.C. 823) in accordance with section 553 of title 5, United States Code.

SEC. 7. REVISING CONSIDERATIONS FOR DEA QUOTA REQUIREMENTS.

(a) IN GENERAL.—Section 306 of the Controlled Substances Act (21 U.S.C. 826) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking ''total'';

(ii) by inserting ''clinical,'' after ''research,''; and

(iii) by inserting ''and paragraph (3)'' after ''(2)'';

(B) in paragraph (2), by inserting '', in consultation with the Secretary of Health and Human Services,'' after ''if the Attorney General determines''; and

(C) by adding at the end the following:

''(3) The Attorney General shall revise the annually established production quotas within 90 days for any basic class of controlled substance in schedule I, and within 60

days for any basic class of controlled substance in schedule II, if any of the following triggering events occurs during the calendar year:

''(A) A controlled substance in schedule I or II is transferred or placed into another class of controlled substances in accordance with applicable law.

''(B) A controlled substance in schedule I or II is approved or cleared by the Food and Drug Administration in accordance with the Federal Food, Drug, and Cosmetic Act.

''(C) A controlled substance in schedule I or II is designated as a breakthrough therapy under section 506 of such Act.

''(D) An exemption for investigational use is granted for a drug in schedule I or II investigational use under section 505(i) of such Act.

''(E) A drug in schedule I or II is approved by the Food and Drug Administration for use in a phase 3 clinical trial.'';

(2) in subsection (c), by adding at th end the following: ''Upon the occurrence of a triggering event listed in subsection (a)(3) with respect to a controlled substance, a registered manufacturer may apply for an expedited mid-year adjustment of the manufacturing quota determined for such manufac-

turer under this subsection with respect to such controlled substance.''; and

(3) by adding at the end the following:

''(j) The Attorney General shall establish annual sufficiency standards for each established production quota at levels necessary to meet the legitimate medical, scientific, research, clinical, and industrial needs of the United States.''.

SEC. 8. FEDERAL-STATE COLLABORATION.

(a) IN GENERAL.—Using funds allocated pursuant to subsection (c), the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Director of the Advanced Research Projects Agency—Health, the Director of the National Institutes of Health, and the Assistant Secretary for Mental Health and Substance Use, may partner with States, territories, and Indian Tribes to implement programs to advance research on, and development of, psychedelic drugs, including ibogaine, for treating serious mental illnesses.

(b) PARTNERSHIPS.—A partnership under subsection (a) may include—

(1) the award of Federal funds;

(2) the provision of technical assistance; and

(3) subject to applicable privacy and other law, sharing data.

SEC. 9. INTERAGENCY COLLABORATION WITH THE PRIVATE SECTOR.

(a) PROGRAM.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary''), in collaboration with the Secretary of Veterans Affairs, shall carry out a program to collaborate with the private sector to increase clinical trial participation, data sharing, and real-world evidence generation regarding psychedelic drugs.

(b) PRIORITIZING BREAKTHROUGH THERAPIES.—In carrying out the program under subsection (a), the Secretary shall prioritize collaboration regarding psychedelic drugs that are designated as a breakthrough therapy under section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)).

(c) PROVISION OF HHS AND VA DATA FROM CLINICAL STUDIES TO FDA.—

(1) INTERAGENCY AGREEMENT.—Subject to paragraph (2), the Secretary of Health and Human Services, the Secretary of Veterans Affairs, and the heads of other Federal departments and agencies, shall enter into agreements to provide data from federally conducted or supported clinical trials to the Food and Drug Administration to facilitate the timely evaluation and approval or licensure (as applicable) of drugs (including biological products)

under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) or section 351 of the Public Health Service Act (42 U.S.C. 351).

(2) APPLICABLE PROVISIONS.—The provision of data under paragraph (1) shall be subject to other applicable law, including any privacy restrictions under the Privacy Act of 1974 (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191).

SEC. 10. TIMELY RESCHEDULING.

(a) IN GENERAL.—Section 201 of the Controlled Substances Act (21 U.S.C. 811) is amended by adding at the end the following:

''(k)(1) Upon successful completion of phase 3 clinical trials for a drug in schedule I intended to treat a serious mental health disorder, the Attorney General, in consultation with the Secretary of Health and Human Services, shall initiate and complete proceedings under subsection (a) to determine whether to place such drug in another schedule.

''(2) The Attorney General shall complete proceedings under subsection (a) for a drug as quickly as practicable.

''(3) In this subsection, the term 'phase 3 clinical trial' means phase 3 clinical investigations conducted pur-

suant to an exemption for investigational use under section 505(i) of the Federal Food, Drug, and Cosmetic Act or section 351(a)(3) of the Public Health Service Act.''.

(b) NECESSARY STEPS FOR RESCHEDULING DETERMINATION.—Notwithstanding section 201 and subsections (a) and (b) of section 202 of the Controlled Substances Act (21 U.S.C. 811, 812) respecting the scheduling of controlled substances, the Attorney General shall, by order, not later than 60 days after the date of enactment of this Act, take all necessary steps to determine whether to transfer ibogaine and ibogaine compounds from schedule I of such Act to schedule II of such Act.

SEC. 11. DESIGNATION OF SENIOR OFFICIAL FOR EMERGING THERAPEUTIC INTERVENTIONS WITHIN THE DEPARTMENT OF VETERANS AFFAIRS.

(a) DESIGNATION.—Not later than 90 days after the date of enactment of this Act, the Under Secretary for Health of the Department of Veterans Affairs shall designate a senior official of the Department to oversee policy, programs, and other activities related to emerging therapeutic interventions.

(b) ROLE, RESPONSIBILITY, AND AUTHORITY.—The Under Secretary for Health, in consultation with the Secretary of Veterans Affairs, shall prescribe the roles, re-

sponsibilities, and authorities of the official designated under subsection (a), including—

(1) assisting the Secretary of Veterans Affairs, the Deputy Secretary of Veterans Affairs, and the Under Secretary for Health with policies, operations, programs, and activities relating to emerging therapeutic interventions;

(2) working in coordination with the Secretary of Health and Human Services, the Commissioner of Food and Drugs, the Secretary of Defense, and the Attorney General to improve the efficiency and effectiveness of all activities related to emerging therapeutic interventions within the Department of Veterans Affairs; and

(3) working with Federal agencies, State and local governments, and nongovernmental organizations to improve the delivery of, and access to, emerging therapeutic interventions.

(c) BRIEFING ON DESIGNATION AND IMPLEMENTATION.—Not later than 90 days after the date of enactment of this Act, the Secretary of Veterans Affairs shall provide a briefing to the Committees on Veterans' Affairs of the House of Representatives and Senate on—

(1) the status of the designation of the official under subsection (a); and

(2) the implementation of the roles, responsibilities, and the authorities of the official under subsection (b).

SEC. 12. EMERGING THERAPEUTIC INTERVENTIONS AT THE DEPARTMENT OF VETERANS AFFAIRS.

(a) REPORT.—

(1) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, and biannually thereafter, the Under Secretary for Health of the Department of Veterans Affairs shall submit to the Committees on Veterans' Affairs of the House of Representatives and Senate a report on the activities of the Department with respect to emerging therapeutic interventions, including psychedelic-assisted therapies.

(2) CONTENTS.—At a minimum, each report under paragraph (1) shall, with respect to emerging therapeutic interventions, include—

(A) a summary of research activities, including a list of active and planned clinical trials, of the Department relating to emerging therapeutic interventions;

(B) an identification of key findings from clinical outcomes and patient-reported outcomes

made during clinical trials conducted or supported by the Department;

(C) the number of veterans enrolled in treatment programs and clinical trials related to emerging therapeutic interventions;

(D) interagency coordination efforts of the Department, including with the Food and Drug Administration, the Drug Enforcement Agency, and other relevant government agencies;

(E) recommendations to improve the delivery of innovative therapies to veterans, including psychedelic-assisted therapies; and

(F) recommendations for legislative or administrative actions relating to emerging therapeutic interventions.

(b) WORKFORCE READINESS.—The Under Secretary for Health of the Department of Veterans Affairs shall develop a workforce implementation-readiness plan for emerging therapeutic interventions (including psychedelic-assisted therapies), including—

(1) conducting a workforce-readiness assessment to identify clinicians and peer support specialists with prior training or certification relevant to emerging therapeutic interventions and gaps in training, supervision, and clinical capacity necessary

to support safe and effective implementation of such interventions;

(2) developing a standardized, competency-based training framework for clinicians and peer support specialists participating in emerging therapeutic interventions, including safety monitoring, supervision standards, competent care, interdisciplinary collaboration, and other areas where appropriate; and

(3) developing and implementing a plan to ensure training, using such framework, is conducted, and credentialing standards are applied, with respect to the appropriate clinicians and medical centers of the Department, including any centers of excellence, in a manner designed to ensure access across each Veterans Integrated Service Network.

SEC. 13. REPORT ON ACCELERATING MEDICAL TREATMENTS FOR SERIOUS MENTAL ILLNESS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Veterans Affairs, in collaboration with the Commissioner of Food and Drugs and the Administrator of the Drug Enforcement Agency, shall provide a report to the appropriate committees of Congress on the implementation of Execu-

tive Order 14401 (91 Fed. Reg. 21709, relating to accelerating medical treatments for serious mental illness).

(b) APPROPRIATE COMMITTEES OF CONGRESS.—In this section, the term ''appropriate committees of Congress'' means—

(1) the Committee on Energy and Commerce of the House of Representatives;

(2) the Committee on Veterans' Affairs of the House of Representatives;

(3) the Committee on Health, Education, Labor, and Pensions of the Senate; and

(4) the Committee on Veterans' Affairs of the Senate.