

119TH CONGRESS
2D SESSION

H. R. 9559

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

JUNE 30, 2026

Mr. LUTTRELL (for himself, Mr. McCAUL, Mr. BERGMAN, and Mr. CORREA) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, and Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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.

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. SHORT TITLE.**

4 This Act may be cited as the “Initiating Biomedical
5 Outcomes to Garner Advancements into Innovative
6 Neuroplastogen Efficacy Act” or the “IBOGAINE Act”.

1 **SEC. 2. TABLE OF CONTENTS.**

2 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Definitions.
- Sec. 4. National Health Priority Voucher Pilot Program.
- Sec. 5. Amendment to the Federal right to try law.
- Sec. 6. Special registration requirements related to right to try.
- Sec. 7. Revising considerations for DEA quota requirements.
- Sec. 8. Federal-State collaboration.
- Sec. 9. Interagency collaboration with the private sector.
- Sec. 10. Timely rescheduling.
- Sec. 11. Designation of senior official for emerging therapeutic interventions within the Department of Veterans Affairs.
- Sec. 12. Emerging therapeutic interventions at the Department of Veterans Affairs.
- Sec. 13. Report on accelerating medical treatments for serious mental illness.

3 **SEC. 3. DEFINITIONS.**

4 Section 102 of the Controlled Substances Act (21
5 U.S.C. 802) is amended by adding at the end the fol-
6 lowing:

7 “(61) The term ‘ibogaine’ means—

8 “(A) all parts of the plant *Tabernanthe*
9 *iboga*; and

10 “(B) any similar compound or analog
11 that—

12 “(i) acts on neuroplasticity, opioid re-
13 ceptors, or serotonergic pathways that—

14 “(I) interrupt addiction cycles;
15 and

16 “(II) restore neurological func-
17 tion disrupted by trauma, chronic sub-

1 stance use, or traumatic brain injury;
 2 and
 3 “(ii) are distinct in mechanism from
 4 the breakthrough therapies designated
 5 under section 506 of the Federal Food,
 6 Drug, and Cosmetic Act.”.

7 **SEC. 4. NATIONAL HEALTH PRIORITY VOUCHER PILOT**
 8 **PROGRAM.**

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

12 **“SEC. 524C. NATIONAL HEALTH PRIORITY VOUCHER PILOT**
 13 **PROGRAM.**

14 “(a) DEFINITIONS.—In this section:

15 “(1) PRIORITY REVIEW.—The term ‘priority re-
 16 view’, with respect to a human drug application as
 17 defined in section 735(1), means review and action
 18 by the Secretary on such application not later than
 19 6 months after receipt by the Secretary of such ap-
 20 plication, as described in the Manual of Policies and
 21 Procedures of the Food and Drug Administration
 22 and goals identified in the letters described in sec-
 23 tion 101(c) of the Food and Drug Administration
 24 Amendments Act of 2007.

1 “(2) NATIONAL HEALTH PRIORITY REVIEW
2 VOUCHER.—The term ‘national health priority re-
3 view voucher’ means a voucher issued by the Sec-
4 retary to the sponsor of a national health priority
5 product application that entitles the holder of such
6 voucher to priority review of a single human drug
7 application submitted under section 505(b)(1) of
8 this Act or section 351 of the Public Health Service
9 Act after the date of approval of the national health
10 priority product application.

11 “(3) NATIONAL HEALTH PRIORITY PRODUCT.—
12 The term ‘national health priority product’ means
13 any of the following:

14 “(A) PUBLIC HEALTH CRISIS RESPONSE.—
15 A product to treat or prevent an urgent or
16 emerging threat that the Secretary has identi-
17 fied as having a significant impact on the popu-
18 lation of the United States.

19 “(B) BREAKTHROUGH THERAPIES.—A
20 drug that—

21 “(i) is designated as a breakthrough
22 therapy under section 506(a); and

23 “(ii) is a transformative treatment
24 with one or more novel mechanisms that

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

3 “(C) LARGE UNMET MEDICAL NEEDS.—A
4 therapy for a disease or condition for which ex-
5 isting treatments inadequately address patient
6 outcomes.

7 “(D) ONSHORE AND SUPPLY CHAIN RE-
8 SILIENCE.—A product whose development or
9 manufacture in the United States would
10 strengthen the Nation’s domestic capacity, re-
11 duce foreign dependency, and improve national
12 security with respect to the drug supply chain.

13 “(E) AFFORDABILITY.—A product that—

14 “(i) improves overall value through re-
15 duced costs to the health care system; or

16 “(ii) enhances access to important
17 health care products.

18 “(F) OTHER PRODUCTS.—Any other na-
19 tional health priority product whose approval
20 would—

21 “(i) address a health crisis in the
22 United States;

23 “(ii) deliver an innovative cure;

24 “(iii) address an unmet public health
25 need; and

1 “(iv) increase domestic drug manufac-
2 turing as a matter of national security.

3 “(4) NATIONAL HEALTH PRIORITY PRODUCT
4 APPLICATION.—The term ‘national health priority
5 product application’ means an application that—

6 “(A) is a human drug application as de-
7 fined in section 735(1); and

8 “(B) is for a national health priority prod-
9 uct.

10 “(b) PRIORITY REVIEW VOUCHER.—

11 “(1) IN GENERAL.—The Secretary shall award
12 a national health priority review voucher to the
13 sponsor of a national health priority product applica-
14 tion upon approval by the Secretary of such applica-
15 tion.

16 “(2) PROHIBITION ON TRANSFERABILITY.—The
17 sponsor of a national health priority product that re-
18 ceives a national health priority review voucher may
19 not transfer the entitlement to such voucher, except
20 that if ownership of the sponsor is transferred to a
21 different entity the entitlement to such voucher may
22 be transferred to such entity as part of the change
23 in ownership.

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

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

4 “(B) apply for an additional national
5 health priority review voucher while in posses-
6 sion of such a voucher.

7 “(c) PRIORITY VOUCHER USER FEE.—

8 “(1) IN GENERAL.—The Secretary may estab-
9 lish a user fee program under which a sponsor of a
10 human drug application that is the subject of a na-
11 tional health priority review voucher shall pay to the
12 Secretary a fee determined under paragraph (2).
13 Such fee shall be in addition to any fee required to
14 be submitted by the sponsor under chapter VII.

15 “(2) FEE AMOUNT.—The amount of the user
16 fee under paragraph (1) shall be determined each
17 fiscal year by the Secretary and based on the aver-
18 age cost incurred by the agency in the review of a
19 human drug application subject to priority review in
20 the previous fiscal year.

21 “(3) ANNUAL FEE SETTING.—The Secretary
22 shall establish, before the beginning of each fiscal
23 year beginning after September 30, 2026, for that
24 fiscal year, the amount of the user fee under para-
25 graph (1).

1 “(4) OFFSETTING COLLECTIONS.—Fees col-
2 lected pursuant to this subsection for any fiscal
3 year—

4 “(A) shall be deposited and credited as off-
5 setting collections to the account providing ap-
6 propriations to the Food and Drug Administra-
7 tion; and

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

11 “(d) ELIGIBILITY FOR OTHER PROGRAMS.—Nothing
12 in this section precludes a sponsor who seeks a national
13 health priority review voucher from participating in any
14 other incentive program, including under this Act, except
15 that no sponsor of a national priority health product appli-
16 cation may receive more than one national health priority
17 review voucher with respect to the drug for which the ap-
18 plication is made.

19 “(e) RELATION TO OTHER PROVISIONS.—The provi-
20 sions of this section shall supplement, not supplant, any
21 other provisions of this Act or the Public Health Service
22 Act that encourage the development of drugs for tropical
23 diseases, rare pediatric diseases, or national health pri-
24 ority products.

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

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

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

12 “(g) GAO STUDY AND REPORT.—

13 “(1) STUDY.—

14 “(A) IN GENERAL.—The Comptroller Gen-
15 eral of the United States shall conduct a study
16 of the effectiveness of awarding national health
17 priority review vouchers in the development of
18 human drug products.

19 “(B) CONTENTS OF STUDY.—In con-
20 ducting the study under subparagraph (A), the
21 Comptroller General shall examine the fol-
22 lowing:

23 “(i) With respect to each national
24 health priority review voucher awarded:

1 “(I) Whether, and to what ex-
2 tent, an unmet need related to the
3 treatment or prevention of a disease
4 or condition was met through the ap-
5 proval of a national health priority
6 product.

7 “(II) Identification of each drug
8 for which the voucher was used.

9 “(III) The length of the period of
10 time between the date on which the
11 voucher was awarded and the date on
12 which it was used.

13 “(ii) Whether the pathway under this
14 section has helped to provide safe and ef-
15 fective treatments for patients.

16 “(iii) Whether a similar voucher pro-
17 gram would be appropriate for other cat-
18 egories of drugs.

19 “(2) REPORT.—Not later than 1 year after the
20 date of enactment of this section, the Comptroller
21 General shall submit to the Committee on Energy
22 and Commerce of the House of Representatives and
23 the Committee on Health, Education, Labor, and
24 Pensions of the Senate, a report containing the re-
25 sults of the study under paragraph (1).

1 “(h) TERMINATION OF AUTHORITY.—The Secretary
2 may not award a voucher under this section after Sep-
3 tember 30, 2029.”.

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

5 Section 561B(b) of the Federal Food, Drug, and Cos-
6 metic Act (21 U.S.C. 360bbb–0a(b)) is amended by insert-
7 ing “any provision of the Controlled Substances Act (21
8 U.S.C. 801 et seq.) that prohibits the unauthorized use,
9 possession, distribution, dispensation, or transportation of
10 an eligible investigational drug,” before “and parts”.

11 **SEC. 6. SPECIAL REGISTRATION REQUIREMENTS RELATED**
12 **TO RIGHT TO TRY.**

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

16 “(p) SPECIAL REGISTRATION FOR SCHEDULE I ELI-
17 GIBLE INVESTIGATIONAL DRUGS UNDER RIGHT TO
18 TRY.—

19 “(1) DEFINITIONS.—In this subsection, the
20 terms ‘eligible investigational drug’ and ‘eligible pa-
21 tient’ have the meanings given those terms in section
22 561B of the Federal Food, Drug, and Cosmetic Act
23 (21 U.S.C. 360bbb–0a).

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

1 administer eligible investigational drugs in schedule
2 I to eligible patients under section 561B of the Fed-
3 eral Food, Drug, and Cosmetic Act (21 U.S.C.
4 360bbb-0a) in accordance with paragraphs (3)
5 through (6) of this subsection.

6 “(3) REQUIREMENTS.—

7 “(A) APPLICATION.—A physician desiring
8 a registration to directly administer an eligible
9 investigational drug as described in paragraph
10 (2) shall submit to the Attorney General an ap-
11 plication containing—

12 “(i) evidence of a valid registration to
13 dispense or administer controlled sub-
14 stances in schedules II through V;

15 “(ii) evidence of compliance with sec-
16 tion 561B of the Federal Food, Drug, and
17 Cosmetic Act (21 U.S.C. 360bbb-0a), in-
18 cluding—

19 “(I) documentation from the
20 manufacturer or sponsor verifying the
21 investigational drug in schedule I is
22 an eligible investigational drug;

23 “(II) an agreement from the
24 manufacturer or sponsor to supply the
25 eligible investigational drug, along

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

4 “(III) an affirmation that the
5 physician will only directly administer
6 the eligible investigational drug to
7 treat eligible patients in a manner
8 consistent with the guidance provided
9 by the manufacturer or sponsor;

10 “(iii) the quantity of the eligible inves-
11 tigational drug to be supplied by the man-
12 ufacturer or sponsor to the physician to
13 treat eligible patients;

14 “(iv) evidence that the physician is al-
15 lowed to treat patients under the laws of
16 the State in which the treatment will take
17 place;

18 “(v) a description of the site at which
19 the physician intends to store and admin-
20 ister the eligible investigational drug; and

21 “(vi) any additional information the
22 Attorney General determines necessary to
23 prevent diversion.

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

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

3 “(i) register the applicant; or

4 “(ii) serve an order to show cause
5 upon the applicant in accordance with sec-
6 tion 304(c).

7 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
8 General shall provide a means for a physician to
9 submit an application under paragraph (3)(A) elec-
10 tronically.

11 “(5) LIMITATION ON AMOUNTS.—A physician
12 treating eligible patients with an eligible investiga-
13 tional drug in schedule I under this subsection may
14 only possess the amounts of the eligible investiga-
15 tional drug identified in—

16 “(A) the application submitted to the At-
17 torney General under paragraph (3)(A); or

18 “(B) a supplemental notification that the
19 physician may submit to the Attorney General
20 if the physician needs additional amounts of the
21 eligible investigational drug for the treatment of
22 eligible patients, which supplemental notifica-
23 tion—

24 “(i) shall include—

25 “(I) the name of the physician;

1 “(II) the additional quantity of
2 the eligible investigational drug need-
3 ed; and

4 “(III) an attestation that the
5 treatment with the eligible investiga-
6 tional drug is consistent with the
7 scope of treatment that was the sub-
8 ject of the application under para-
9 graph (3)(A); and

10 “(ii) shall be deemed approved on the
11 date that is 30 days after the date on
12 which the physician submits the supple-
13 mental notification to the Attorney Gen-
14 eral, unless the Attorney General serves an
15 order to show cause upon the applicant in
16 accordance with section 304(c).

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

22 “(A) the treatment occurs exclusively on
23 sites all of which are—

24 “(i) within the same city or county;
25 and

1 “(ii) under the control of the same in-
2 stitution, organization, or agency; and

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

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

15 (1) the manner in which an eligible investiga-
16 tional drug may be delivered to an approved reg-
17 istrant;

18 (2) the storage and security of an eligible inves-
19 tigational drug;

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

22 (4) the process for renewal, suspension, or rev-
23 ocation of a registration; and

24 (5) any other matters necessary to ensure effec-
25 tive controls against diversion.

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

7 **SEC. 7. REVISING CONSIDERATIONS FOR DEA QUOTA RE-**
 8 **QUIREMENTS.**

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

11 (1) in subsection (a)—

12 (A) in paragraph (1)—

13 (i) by striking “total”;

14 (ii) by inserting “clinical,” after “re-
 15 search,”; and

16 (iii) by inserting “and paragraph (3)”
 17 after “(2)”;

18 (B) in paragraph (2), by inserting “, in
 19 consultation with the Secretary of Health and
 20 Human Services,” after “if the Attorney Gen-
 21 eral determines”; and

22 (C) by adding at the end the following:

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

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

4 “(A) A controlled substance in schedule I or II
5 is transferred or placed into another class of con-
6 trolled substances in accordance with applicable law.

7 “(B) A controlled substance in schedule I or II
8 is approved or cleared by the Food and Drug Ad-
9 ministration in accordance with the Federal Food,
10 Drug, and Cosmetic Act.

11 “(C) A controlled substance in schedule I or II
12 is designated as a breakthrough therapy under sec-
13 tion 506 of such Act.

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

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

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

1 turer under this subsection with respect to such con-
2 trolled substance.”; and

3 (3) by adding at the end the following:

4 “(j) The Attorney General shall establish annual suf-
5 ficiency standards for each established production quota
6 at levels necessary to meet the legitimate medical, sci-
7 entific, research, clinical, and industrial needs of the
8 United States.”.

9 **SEC. 8. FEDERAL-STATE COLLABORATION.**

10 (a) IN GENERAL.—Using funds allocated pursuant to
11 subsection (c), the Secretary of Health and Human Serv-
12 ices (in this section referred to as the “Secretary”), acting
13 through the Director of the Advanced Research Projects
14 Agency—Health, the Director of the National Institutes
15 of Health, and the Assistant Secretary for Mental Health
16 and Substance Use, may partner with States, territories,
17 and Indian Tribes to implement programs to advance re-
18 search on, and development of, psychedelic drugs, includ-
19 ing ibogaine, for treating serious mental illnesses.

20 (b) PARTNERSHIPS.—A partnership under subsection

21 (a) may include—

22 (1) the award of Federal funds;

23 (2) the provision of technical assistance; and

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

1 **SEC. 9. INTERAGENCY COLLABORATION WITH THE PRI-**
2 **VATE SECTOR.**

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

10 (b) PRIORITIZING BREAKTHROUGH THERAPIES.—In
11 carrying out the program under subsection (a), the Sec-
12 retary shall prioritize collaboration regarding psychedelic
13 drugs that are designated as a breakthrough therapy
14 under section 506(a) of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 356(a)).

16 (c) PROVISION OF HHS AND VA DATA FROM CLIN-
17 ICAL STUDIES TO FDA.—

18 (1) INTERAGENCY AGREEMENT.—Subject to
19 paragraph (2), the Secretary of Health and Human
20 Services, the Secretary of Veterans Affairs, and the
21 heads of other Federal departments and agencies,
22 shall enter into agreements to provide data from fed-
23 erally conducted or supported clinical trials to the
24 Food and Drug Administration to facilitate the
25 timely evaluation and approval or licensure (as ap-
26 plicable) of drugs (including biological products)

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

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

10 **SEC. 10. TIMELY RESCHEDULING.**

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

14 “(k)(1) Upon successful completion of phase 3 clin-
15 ical trials for a drug in schedule I intended to treat a seri-
16 ous mental health disorder, the Attorney General, in con-
17 sultation with the Secretary of Health and Human Serv-
18 ices, shall initiate and complete proceedings under sub-
19 section (a) to determine whether to place such drug in an-
20 other schedule.

21 “(2) The Attorney General shall complete pro-
22 ceedings under subsection (a) for a drug as quickly as
23 practicable.

24 “(3) In this subsection, the term ‘phase 3 clinical
25 trial’ means phase 3 clinical investigations conducted pur-

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

4 (b) NECESSARY STEPS FOR RESCHEDULING DETER-
5 MINATION.—Notwithstanding section 201 and subsections
6 (a) and (b) of section 202 of the Controlled Substances
7 Act (21 U.S.C. 811, 812) respecting the scheduling of con-
8 trolled substances, the Attorney General shall, by order,
9 not later than 60 days after the date of enactment of this
10 Act, take all necessary steps to determine whether to
11 transfer ibogaine and ibogaine compounds from schedule
12 I of such Act to schedule II of such Act.

13 **SEC. 11. DESIGNATION OF SENIOR OFFICIAL FOR EMERG-**
14 **ING THERAPEUTIC INTERVENTIONS WITHIN**
15 **THE DEPARTMENT OF VETERANS AFFAIRS.**

16 (a) DESIGNATION.—Not later than 90 days after the
17 date of enactment of this Act, the Under Secretary for
18 Health of the Department of Veterans Affairs shall des-
19 ignate a senior official of the Department to oversee pol-
20 icy, programs, and other activities related to emerging
21 therapeutic interventions.

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

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

3 (1) assisting the Secretary of Veterans Affairs,
4 the Deputy Secretary of Veterans Affairs, and the
5 Under Secretary for Health with policies, operations,
6 programs, and activities relating to emerging thera-
7 peutic interventions;

8 (2) working in coordination with the Secretary
9 of Health and Human Services, the Commissioner of
10 Food and Drugs, the Secretary of Defense, and the
11 Attorney General to improve the efficiency and effec-
12 tiveness of all activities related to emerging thera-
13 peutic interventions within the Department of Vet-
14 erans Affairs; and

15 (3) working with Federal agencies, State and
16 local governments, and nongovernmental organiza-
17 tions to improve the delivery of, and access to,
18 emerging therapeutic interventions.

19 (c) BRIEFING ON DESIGNATION AND IMPLEMENTA-
20 TION.—Not later than 90 days after the date of enactment
21 of this Act, the Secretary of Veterans Affairs shall provide
22 a briefing to the Committees on Veterans’ Affairs of the
23 House of Representatives and Senate on—

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

1 (2) the implementation of the roles, responsibil-
2 ities, and the authorities of the official under sub-
3 section (b).

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

6 (a) REPORT.—

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

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

19 (A) a summary of research activities, in-
20 cluding a list of active and planned clinical
21 trials, of the Department relating to emerging
22 therapeutic interventions;

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

1 made during clinical trials conducted or sup-
2 ported by the Department;

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

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

10 (E) recommendations to improve the deliv-
11 ery of innovative therapies to veterans, includ-
12 ing psychedelic-assisted therapies; and

13 (F) recommendations for legislative or ad-
14 ministrative actions relating to emerging thera-
15 peutic interventions.

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

21 (1) conducting a workforce-readiness assess-
22 ment to identify clinicians and peer support special-
23 ists with prior training or certification relevant to
24 emerging therapeutic interventions and gaps in
25 training, supervision, and clinical capacity necessary

1 to support safe and effective implementation of such
2 interventions;

3 (2) developing a standardized, competency-
4 based training framework for clinicians and peer
5 support specialists participating in emerging thera-
6 peutic interventions, including safety monitoring, su-
7 pervision standards, competent care, interdiscipli-
8 nary collaboration, and other areas where appro-
9 priate; and

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

17 **SEC. 13. REPORT ON ACCELERATING MEDICAL TREAT-**
18 **MENTS FOR SERIOUS MENTAL ILLNESS.**

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

1 tive Order 14401 (91 Fed. Reg. 21709, relating to accel-
2 erating medical treatments for serious mental illness).

3 (b) APPROPRIATE COMMITTEES OF CONGRESS.—In
4 this section, the term “appropriate committees of Con-
5 gress” means—

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

8 (2) the Committee on Veterans’ Affairs of the
9 House of Representatives;

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

12 (4) the Committee on Veterans’ Affairs of the
13 Senate.

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