

AMENDMENT TO
RULES COMMITTEE PRINT 119-33
OFFERED BY MR. LUTTRELL OF TEXAS

At the end of title XVII, add the following new subtitle:

1 **Subtitle C—Initiating Biomedical**
2 **Outcomes to Garner Advance-**
3 **ments Into Innovative Efficacy**

4 **SEC. 17___. DEFINITIONS.**

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

8 “(61) The term ‘ibogaine’ means—

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

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

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

15 “(I) interrupt addiction cycles;
16 and

17 “(II) restore neurological func-
18 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. 17___ . 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. 17___. AMENDMENT TO THE FEDERAL RIGHT TO TRY**
5 **LAW.**

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

12 **SEC. 17___. SPECIAL REGISTRATION REQUIREMENTS RE-**
13 **LATED TO RIGHT TO TRY.**

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

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

20 “(1) **DEFINITIONS.**—In this subsection, the
21 terms ‘eligible investigational drug’ and ‘eligible pa-
22 tient’ have the meanings given those terms in section
23 561B of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 360bbb–0a).

1 “(2) SPECIAL REGISTRATION PROCESS.—The
2 Attorney General shall register physicians to directly
3 administer eligible investigational drugs in schedule
4 I to eligible patients under section 561B of the Fed-
5 eral Food, Drug, and Cosmetic Act (21 U.S.C.
6 360bbb–0a) in accordance with paragraphs (3)
7 through (6) of this subsection.

8 “(3) REQUIREMENTS.—

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

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

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

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

1 “(II) an agreement from the
2 manufacturer or sponsor to supply the
3 eligible investigational drug, along
4 with guidance on its administration,
5 to the requesting physician for the
6 treatment of eligible patients; and

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

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

17 “(iv) evidence that the physician is al-
18 lowed to treat eligible patients with the eli-
19 gible investigational drug under the laws of
20 the State in which the treatment will take
21 place;

22 “(v) evidence of training, credentials,
23 or experience relevant to treating patients
24 with the eligible investigational drug;

1 “(vi) a description of the site at which
2 the physician intends to store and admin-
3 ister the eligible investigational drug; and

4 “(vii) any additional information the
5 Attorney General determines necessary to
6 prevent diversion.

7 “(B) APPROVAL.—Not later than 45 days
8 after receiving an application containing the in-
9 formation required under subparagraph (A), the
10 Attorney General shall—

11 “(i) register the applicant; or

12 “(ii) serve an order to show cause
13 upon the applicant in accordance with sec-
14 tion 304(c).

15 “(4) ELECTRONIC SUBMISSIONS.—The Attorney
16 General shall provide a means for a physician to
17 submit an application under paragraph (3)(A) elec-
18 tronically.

19 “(5) LIMITATION ON AMOUNTS.—A physician
20 treating eligible patients with an eligible investiga-
21 tional drug in schedule I under this subsection may
22 only possess the amounts of the eligible investiga-
23 tional drug identified in—

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

1 “(B) a supplemental notification that the
2 physician may submit to the Attorney General
3 if the physician needs additional amounts of the
4 eligible investigational drug for the treatment of
5 eligible patients, which supplemental notifica-
6 tion—

7 “(i) shall include—

8 “(I) the name of the physician;

9 “(II) the additional quantity of
10 the eligible investigational drug need-
11 ed; and

12 “(III) an attestation that the
13 treatment with the eligible investiga-
14 tional drug is consistent with the
15 scope of treatment that was the sub-
16 ject of the application under para-
17 graph (3)(A); and

18 “(ii) shall be deemed approved on the
19 date that is 30 days after the date on
20 which the physician submits the supple-
21 mental notification to the Attorney Gen-
22 eral, unless the Attorney General serves an
23 order to show cause upon the applicant in
24 accordance with section 304(c).

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

6 “(A) the treatment occurs exclusively on
7 sites all of which are—

8 “(i) within the same city or county;
9 and

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

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

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

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

4 (2) the storage and security of an eligible inves-
5 tigational drug;

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

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

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

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

18 **SEC. 17 ____. REVISING CONSIDERATIONS FOR DEA QUOTA**

19 **REQUIREMENTS.**

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

22 (1) in subsection (a)—

23 (A) in paragraph (1)—

24 (i) by striking “total”;

1 (ii) by inserting “clinical,” after “re-
2 search,”; and

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

5 (B) in paragraph (2), by inserting “, in
6 consultation with the Secretary of Health and
7 Human Services,” after “if the Attorney Gen-
8 eral determines”; and

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

10 “(3) The Attorney General shall revise the annually
11 established production quotas within 90 days for any basic
12 class of controlled substance in schedule I, and within 60
13 days for any basic class of controlled substance in schedule
14 II, if any of the following triggering events occurs during
15 the calendar year:

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

19 “(B) A controlled substance in schedule I or II
20 is approved or cleared by the Food and Drug Ad-
21 ministration in accordance with the Federal Food,
22 Drug, and Cosmetic Act.

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

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

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

7 (2) in subsection (c), by adding at the end the
8 following: “Upon the occurrence of a triggering
9 event listed in subsection (a)(3) with respect to a
10 controlled substance, a registered manufacturer may
11 apply for an expedited mid-year adjustment of the
12 manufacturing quota determined for such manufac-
13 turer under this subsection with respect to such con-
14 trolled substance.”; and

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

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

21 **SEC. 17 ___. FEDERAL-STATE COLLABORATION.**

22 (a) IN GENERAL.—Using funds allocated pursuant to
23 subsection (c), the Secretary of Health and Human Serv-
24 ices (in this section referred to as the “Secretary”), acting
25 through the Director of the Advanced Research Projects

1 Agency—Health, the Director of the National Institutes
2 of Health, and the Assistant Secretary for Mental Health
3 and Substance Use, may partner with States, territories,
4 and Indian Tribes to implement programs to advance re-
5 search on, and development of, psychedelic drugs, includ-
6 ing ibogaine, for treating serious mental illnesses.

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

- 9 (1) the award of Federal funds;
- 10 (2) the provision of technical assistance; and
- 11 (3) subject to applicable privacy and other law,
12 sharing data.

13 (c) FUNDING.—Subject to the availability of appro-
14 priations, the Secretary, to carry out this section, shall
15 allocate \$250,000,000 from funds otherwise made avail-
16 able to the Advanced Research Projects Agency—Health,
17 the National Institutes of Health, and the Substance
18 Abuse and Mental Health Services Administration. No ad-
19 ditional funds are authorized to be appropriated to carry
20 out this section.

21 **SEC. 17 ____. INTERAGENCY COLLABORATION WITH THE**
22 **PRIVATE SECTOR.**

23 (a) PROGRAM.—The Secretary of Health and Human
24 Services (in this section referred to as the “Secretary”),
25 in collaboration with the Secretary of Veterans Affairs,

1 shall carry out a program to collaborate with the private
2 sector to increase clinical trial participation, data sharing,
3 and real-world evidence generation regarding psychedelic
4 drugs.

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

11 (c) **PROVISION OF HHS AND VA DATA FROM CLIN-**
12 **ICAL STUDIES TO FDA.**—

13 (1) **INTERAGENCY AGREEMENT.**—Subject to
14 paragraph (2), the Secretary of Health and Human
15 Services, the Secretary of Veterans Affairs, and the
16 heads of other Federal departments and agencies,
17 shall enter into agreements to provide data from fed-
18 erally conducted or supported clinical trials to the
19 Food and Drug Administration to facilitate the
20 timely evaluation and approval or licensure (as ap-
21 plicable) of drugs (including biological products)
22 under section 505 of the Federal Food, Drug, and
23 Cosmetic Act (21 U.S.C. 351) or section 351 of the
24 Public Health Service Act (42 U.S.C. 351).

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

7 **SEC. 17___ . TIMELY RESCHEDULING.**

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

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

18 “(2) The Attorney General shall complete pro-
19 ceedings under subsection (a) for a drug as quickly as
20 practicable.

21 “(3) In this subsection, the term ‘phase 3 clinical
22 trial’ means phase 3 clinical investigations conducted pur-
23 suant to an exemption for investigational use under sec-
24 tion 505(i) of the Federal Food, Drug, and Cosmetic Act
25 or section 351(a)(3) of the Public Health Service Act.”.

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

10 **SEC. 17___ . DESIGNATION OF SENIOR OFFICIAL FOR**
11 **EMERGING THERAPEUTIC INTERVENTIONS**
12 **WITHIN THE DEPARTMENT OF VETERANS AF-**
13 **FAIRS.**

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

20 (b) ROLE, RESPONSIBILITY, AND AUTHORITY.—The
21 Under Secretary for Health, in consultation with the Sec-
22 retary of Veterans Affairs, shall prescribe the roles, re-
23 sponsibilities, and authorities of the official designated
24 under subsection (a), including—

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

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

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

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

22 (1) the status of the designation of the official
23 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. 17___ . 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. 17___ . REPORT ON ACCELERATING MEDICAL TREAT-**
18 **MENTS FOR SERIOUS MENTAL ILLNESS.**

19 Not later than 180 days after the date of enactment
20 of this Act, the Secretary of Veterans Affairs shall provide
21 a report to the Committees on Veterans' Affairs of the
22 House of Representatives and Senate on the implementa-
23 tion of Executive Order 14401, titled "Accelerating Med-

1 ical Treatments for Serious Mental Illness” (April 18,
2 2026).

