

SENATE BILL NO. 43

BY SENATORS MCMATH, BARTHELEMY, BASS, BOUDREAUX, CARTER, CLOUD, CONNICK, DUPLESSIS, EDMONDS, FESI, HARRIS, HENRY, HENSGENS, JACKSON-ANDREWS, JENKINS, KLEINPETER, LUNEAU, MIGUEZ, MILLER, MIZELL, MYERS, OWEN, PRICE, SEABAUGH, SELDERS, STINE, TALBOT, WHEAT AND WOMACK AND REPRESENTATIVES ADAMS, BAYHAM, BERAULT, BILLINGS, BOYD, BOYER, BRASS, BROUSSARD, BRYANT, CARPENTER, CARVER, CHASSION, CHENEVERT, COATES, COX, CREWS, DESHOTEL, DEWITT, DICKERSON, DOMANGUE, ECHOLS, EGAN, FISHER, FREEMAN, FREIBERG, GLORIOSO, HEBERT, CHANCE HENRY, HILFERTY, HORTON, JACKSON, MIKE JOHNSON, KERNER, KNOX, LAFLEUR, JACOB LANDRY, LYONS, MACK, MCMAKIN, MELERINE, MILLER, MOORE, MURRAY, RISER, SAWYER, SCHAMERHORN, SPELL, ST. BLANC, STAGNI, TAYLOR, VENTRELLA, WALTERS, WRIGHT AND WYBLE

1 AN ACT

2 To enact Part IX of Chapter 1 of Title 28 of the Louisiana Revised Statutes of 1950, to be
3 comprised of R.S. 28:211 and 212, relative to psychedelic-assisted therapy; to
4 establish the Psychedelic-Assisted Therapy Initiative within the Louisiana
5 Department of Health; to provide for clinical studies; to provide for clinical trial-
6 enabling studies; to provide for drug development clinical trials; to provide for
7 patient eligibility; to provide for funding; to provide for reporting; and to provide for
8 related matters.

9 Be it enacted by the Legislature of Louisiana:

10 Section 1. Part IX of Chapter 1 of Title 28 of the Louisiana Revised Statutes of 1950,
11 comprised of R.S. 28:211 and 212, is hereby enacted to read as follows:

12 **PART IX. ALTERNATIVE THERAPIES**

13 **§211. Psychedelic-assisted therapy; clinical studies**

14 **A. For purposes of this Part, the following definitions shall apply:**

15 **(1) "Academic health center" means an organization that has a medical**
16 **school, one or more other health professional schools or programs, and one or**
17 **more affiliated teaching hospitals.**

18 **(2) "Drug developer" means a pharmaceutical company, biotechnology**
19 **company, or contract development and manufacturing organization engaged in**
20 **drug development and manufacturing.**

1 (3) "Ibogaine" means ibogaine and ibogaine-based therapeutics,
2 including ibogaine analogs.

3 (4) "Psychedelic medication" means ibogaine, ibogaine-based
4 therapeutics, ibogaine analogs, MDMA, psilocybin, psilocybin-based
5 therapeutics, and mechanistically-similar analogs.

6 (5) "Psychedelic-assisted therapy" means an intervention that includes
7 the administration of a psychedelic medication to an individual in a controlled
8 clinical setting and manualized, trauma-informed preparatory and integrative
9 psychotherapy delivered by a qualified therapist to the individual before and
10 after administration of the psychedelic medication.

11 B. There is hereby established within the Louisiana Department of
12 Health, office of behavioral health, the Psychedelic-Assisted Therapy Initiative.
13 The purpose of the initiative shall be all of the following:

14 (1) To identify academic health centers that are conducting clinical
15 studies and clinical trial-enabling studies for the use of psychedelic-assisted
16 therapy for the treatment of opioid use disorders, co-occurring substance use
17 disorders, and treatment-resistant neurological or mental health conditions.

18 (2) To utilize the human service districts and authorities to identify
19 eligible patients to participate in the program.

20 (3) To provide information to parishes on utilizing opioid settlement
21 funds to enroll eligible patients residing in the parish to participate in the
22 studies or to support clinical trial-enabling studies that allow for the initiation
23 of clinical trials that may enroll patients who reside in the parish.

24 (4) To designate a state point of contact to coordinate with federal
25 agencies and other states with regard to psychedelic-assisted therapy and
26 related drug development.

27 C. The Louisiana Department of Health shall maintain a record of all
28 academic health centers participating in the program.

29 D. Each participating academic health center shall maintain
30 documentation ensuring compliance with state and federal regulations,

1 including all of the following:

2 (1) Ensuring that the clinical study will be conducted in accordance with
3 a United States Food and Drug Administration investigational new drug
4 application, expanded access program, or other federally authorized pathway.

5 (2) Ensuring that any study will be conducted on-site in a hospital, clinic,
6 or research unit affiliated with the academic center, with confirmation of
7 appropriate trial liability insurance coverage.

8 (3) Maintaining a United States Drug Enforcement Agency Schedule I
9 research registration and any required state controlled substance registration.

10 (4) Obtaining Institutional Review Board approval for the clinical study.

11 (5) A clinical study protocol that includes all of the following:

12 (a) The study design, inclusion and exclusion criteria, objectives and
13 endpoints, eligible patient visit schedule, and schedule of follow-up assessments.

14 (b) Informed consent procedures and participant safeguards.

15 (c) Data security and privacy protections, including for personal
16 information.

17 (6) A drug administration plan for the clinical study that includes all of
18 the following:

19 (a) The investigational drug product description, source, formulation,
20 route of administration, and dosing regimen.

21 (b) A clinical staffing model and monitoring procedures for the
22 administration of the investigational drug.

23 (c) Discharge criteria and transportation procedures for participants
24 after psychedelic-assisted therapy.

25 (d) Procedures for the storage, handling, chain of custody, and disposal
26 of controlled substances, and an accountability plan for violations of the
27 procedures.

28 (7) A safety monitoring and risk management plan for the clinical study
29 that includes all of the following:

30 (a) Medical and psychiatric screening procedures.

1 (b) On-site emergency response procedures.

2 (c) Adverse event and serious adverse event capture and reporting
3 timelines.

4 (d) Predefined rules for pausing or stopping the clinical study.

5 (8) A fidelity plan for the clinical study that includes all of the following:

6 (a) Clinician licensure and qualification requirements.

7 (b) A training, supervision, and fidelity monitoring plan.

8 (c) Ethical safeguards and a participant complaint and grievance
9 process.

10 E. Each academic health center may utilize the human service districts
11 and authorities to identify eligible participants for the clinical studies. Eligible
12 participants include individuals with opioid use disorders, co-occurring
13 substance use disorders, and treatment-resistant neurological or mental health
14 conditions.

15 F.(1) The academic health centers shall coordinate with parishes to
16 utilize opioid settlement funds to enroll eligible patients residing in the parish
17 to participate in the studies.

18 (2) In addition to utilization of opioid settlement funds, the department
19 may seek and receive voluntary monies from any sources, including federal
20 funds, gifts, grants, and donations, which shall be expended for the purposes
21 provided for in this Section.

22 (3) To the extent feasible, the Louisiana Department of Health shall
23 support and encourage the use of opioid settlement funds and other related
24 monies as matching funds for federal or other external funding opportunities
25 in support of Louisiana trial and trial-enabling studies.

26 G. No later than January first of each year, each academic health center
27 participating in the program shall submit a progress report to the Louisiana
28 Department of Health on clinical studies conducted by the academic health
29 center. The Louisiana Department of Health shall determine the data required
30 for inclusion in the report. The Louisiana Department of Health shall prepare

1 a compiled report of the data received from participating academic health
2 centers and submit the report to the legislature by March first of each year.

3 H. To the extent feasible, participating academic health centers shall
4 coordinate with other states that are conducting clinical trials for use of
5 psychedelic-assisted therapy.

6 §212. Drug development of ibogaine and psychedelic medication treatments

7 A. An academic health center may enter into an agreement with a drug
8 developer to establish a consortium for the purpose of conducting drug
9 development clinical trials with ibogaine and psychedelic medication treatments
10 and securing the United States Food and Drug Administration's approval of
11 such treatments for the treatment of opioid use disorder, co-occurring
12 substance use disorder, and any other neurological or mental health condition
13 for which the treatments demonstrate efficacy.

14 B. A consortium seeking to conduct a drug development clinical trial
15 may do all of the following:

16 (1) Submit an investigational new drug application to the United States
17 Food and Drug Administration in accordance with 21 CFR Part 312.

18 (2) Seek a breakthrough therapy designation from the United States
19 Food and Drug Administration in accordance with 21 U.S.C. 356.

20 (3) Enter into an agreement with a consortium established by the
21 government of another state, whether acting through an agent or joint venture,
22 that has taken both of the following actions:

23 (a) Has submitted an investigational new drug application to the United
24 States Food and Drug Administration in accordance with 21 CFR Part 312.

25 (b) Has requested a breakthrough therapy designation for ibogaine from
26 the United States Food and Drug Administration in accordance with 21 U.S.C.
27 356.

28 (4) Work with the United States Food and Drug Administration to
29 coordinate the drug development trial in Louisiana with drug development
30 trials that are being conducted in other states.

1 C.(1) Any revenue attributable to newly developed intellectual property
2 and other commercial rights arising from trial-enabling and drug development
3 clinical trial activity conducted by a consortium pursuant to this Section, during
4 the period for which the trials are funded, and any following period of
5 commercialization shall be allocated as follows:

6 (a) Not less than a two and one-half percent of net sales running royalty
7 to the state.

8 (b) The remainder to the members of the consortium in the amounts
9 specified by written agreement of the members.

10 (2) Intellectual property and other commercial rights arising from the
11 drug development clinical trials conducted pursuant to this Section shall include
12 any of the following as related to the trials:

13 (a) Intellectual property, technology, and inventions.

14 (b) Patents, trademarks, and licenses.

15 (c) Proprietary and confidential information.

16 (d) Trade secrets, data, and databases.

17 (e) Tools, methods, and processes.

18 (f) Treatment models or techniques.

19 (g) Administration protocols.

20 (h) Works of authorship.

PRESIDENT OF THE SENATE

SPEAKER OF THE HOUSE OF REPRESENTATIVES

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____