

By: Parker, et al.

S.B. No. 2308

A BILL TO BE ENTITLED

AN ACT

relating to the establishment of a grant program to fund the United States Food and Drug Administration's drug development trials with ibogaine for the purpose of securing the administration's approval as a medication for treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health conditions for which ibogaine demonstrates efficacy and the administration of that treatment.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 491 to read as follows:

CHAPTER 491. IBOGAINE TREATMENT

SUBCHAPTER A. GRANT PROGRAM FOR DRUG DEVELOPMENT OF IBOGAINE

TREATMENT

Sec. 491.001. DEFINITIONS. In this chapter:

(1) "Commission" means the Health and Human Services Commission.

(2) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

Sec. 491.002. RULES. The executive commissioner shall adopt rules necessary to administer this chapter.

Sec. 491.003. ESTABLISHMENT OF GRANT PROGRAM. The commission shall establish and administer a grant program to fund a public-private partnership program that will pay for the costs of

1 the United States Food and Drug Administration's drug development  
2 trials with ibogaine to secure the administration's approval as a  
3 medication for treatment of opioid use disorder, co-occurring  
4 substance use disorder, and any other neurological or mental health  
5 conditions for which ibogaine demonstrates efficacy.

6 Sec. 491.004. APPLICATION. (a) The commission shall  
7 prepare and issue a notice of funding opportunity to solicit  
8 applications for the grant program established under this  
9 subchapter.

10 (b) An applicant may apply to the commission in the form and  
11 manner prescribed by the commission for a grant under this  
12 subchapter. To be eligible for a grant, an applicant must:

13 (1) be a for-profit, nonprofit, or public benefit  
14 corporate entity that has the requisite organizational and  
15 financial capacity to:

16 (A) conduct the United States Food and Drug  
17 Administration's drug development trials with ibogaine to secure  
18 the administration's approval as a medication for treatment of  
19 opioid use disorder, co-occurring substance use disorder, and any  
20 other neurological or mental health conditions for which ibogaine  
21 demonstrates efficacy;

22 (B) as a result of the data obtained from the drug  
23 development trial described by Paragraph (A), seek United States  
24 Food and Drug Administration approval of ibogaine; and

25 (C) conduct future drug development trials of  
26 ibogaine as a medication for treatment of opioid use disorder,  
27 co-occurring substance use disorder, and any other neurological or

mental health conditions for which ibogaine demonstrates efficacy;  
and

(2) provide:

(A) a detailed description of the planned  
strategy for obtaining approval for the drug development trial from  
the United States Food and Drug Administration;

(B) a detailed drug development trial design that  
includes:

(i) a description of the composition of the  
applicant's drug development trial team and the expertise of the  
team members;

(ii) a drug development trial participant  
recruitment plan;

(iii) detailed patient screening criteria  
and cardiac safety protocols;

(iv) administration protocols;

(v) an aftercare and post-acute treatment  
support plan; and

(vi) a data integrity plan;

(C) a proposal to recognize this state's  
commercial interest in all patentable intellectual property that  
may be generated over the course of the drug development trials,  
including:

(i) the treatment that is the subject of the  
trials;

(ii) administration protocols;

(iii) treatment models or techniques; and

1                   (iv) technology used in the trials;

2                   (D) a plan to establish a corporate presence in  
3 this state and to promote and maintain ibogaine-related biomedical  
4 research, development, treatment, manufacturing, and distribution  
5 in this state;

6                   (E) a plan to secure third-party payor approval  
7 for ibogaine treatment following approval by the United States Food  
8 and Drug Administration through:

9                   (i) private insurers;

10                  (ii) Medicare;

11                  (iii) Medicaid; and

12                  (iv) the TRICARE program of the United  
13 States Department of Defense;

14                  (F) a plan to ensure ibogaine treatment access to  
15 uninsured individuals following approval by the United States Food  
16 and Drug Administration;

17                  (G) a plan to train and credential medical  
18 providers to administer ibogaine treatment according to developed  
19 clinical standards; and

20                  (H) financial disclosures that verify the  
21 applicant's capacity to fully match state funding.

22                  (c) The commission shall:

23                   (1) make available the application required under this  
24 section; and

25                   (2) announce a period of not less than 90 days during  
26 which applicants may submit an application under this subchapter.

27                  Sec. 491.005. SELECTION COMMITTEE. (a) The commission

1 shall create a selection committee and select the number of  
2 members. The committee must be composed of:

- 3 (1) subject matter experts;  
4 (2) philanthropic partners; and  
5 (3) legislative designees.

6 (b) The selection committee shall review applications,  
7 communicate supplemental inquiries to applicants, and recommend to  
8 the commission the best applicants to conduct the drug development  
9 trials.

10 (c) The commission shall consider the recommendations of  
11 the selection committee in selecting the applicant to conduct the  
12 ibogaine drug development trial.

13 Sec. 491.006. INVESTIGATIONAL NEW DRUG APPLICATION. On  
14 notification from the commission that the applicant was selected to  
15 conduct the ibogaine drug development trial, the applicant shall,  
16 as soon as practicable:

17 (1) submit an investigational new drug (IND)  
18 application with the United States Food and Drug Administration in  
19 accordance with 21 C.F.R. Part 312; and

20 (2) seek a breakthrough therapy designation for  
21 ibogaine from the United States Food and Drug Administration under  
22 21 U.S.C. Section 356.

23 Sec. 491.007. ESTABLISHMENT OF DRUG DEVELOPMENT TRIAL  
24 SITES. On approval of the applicant's investigational new drug  
25 application by the United States Food and Drug Administration, the  
26 commission shall, in consultation with the applicant, establish  
27 drug development trial sites that must be equipped and staffed to

1 provide cardiac intensive care services to patients.

2 Sec. 491.008. CONDUCTING DRUG DEVELOPMENT TRIAL. (a) As  
3 soon as practicable after drug development trial sites are  
4 established under Section 491.007, the applicant shall begin a drug  
5 development trial to administer treatment with ibogaine.

6 (b) The commission, in consultation with the selection  
7 committee under Section 491.005, shall select an institutional  
8 review board with a presence in this state to oversee and verify the  
9 drug development trial research activity for scientific validation  
10 and authentication under the requirements of the United States Food  
11 and Drug Administration.

12 (c) The applicant shall request the designation under 21  
13 U.S.C. Section 356 during the drug development trial if the  
14 ibogaine treatment is demonstrating efficacy.

15 Sec. 491.009. FUNDING. (a) The commission may use money  
16 received as a gift, grant, or donation to pay for a grant under this  
17 subchapter. The commission may solicit and accept gifts, grants,  
18 and donations of any kind and from any source for purposes of this  
19 section.

20 (b) An applicant selected to perform a drug development  
21 trial under this subchapter shall contribute toward the cost of  
22 developing the ibogaine treatment an amount of money that is at  
23 least equal to the amount of money that the applicant received in  
24 the form of a grant from the commission.

25 SUBCHAPTER B. IBOGAINE TREATMENT ADMINISTRATION

26 Sec. 491.051. APPLICABILITY. This subchapter applies only  
27 if ibogaine is approved by the United States Food and Drug

1 Administration to treat a medical condition.

2 Sec. 491.052. MEDICAL SUPERVISION. A physician licensed  
3 under Subtitle B, Title 3, Occupations Code, who has prescribed  
4 ibogaine for a patient shall supervise the administration of  
5 ibogaine at a hospital or other licensed health care facility to  
6 ensure the patient's safety while the patient is under the  
7 influence of ibogaine.

8 Sec. 491.053. ADMINISTRATION UNDER FEDERAL LAW PERMITTED.  
9 This subchapter does not preclude a physician from otherwise  
10 administering ibogaine according to federal law.

11 SECTION 2. If before implementing any provision of this Act  
12 a state agency determines that a waiver or authorization from a  
13 federal agency is necessary for implementation of that provision,  
14 the agency affected by the provision shall request the waiver or  
15 authorization and may delay implementing that provision until the  
16 waiver or authorization is granted.

17 SECTION 3. This Act takes effect immediately if it receives  
18 a vote of two-thirds of all the members elected to each house, as  
19 provided by Section 39, Article III, Texas Constitution. If this  
20 Act does not receive the vote necessary for immediate effect, this  
21 Act takes effect September 1, 2025.