**BILL ANALYSIS**

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| Senate Research Center | S.B. 2308 |
| 89R15836 CJD-D | By: Parker |
|  | Health & Human Services |
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**AUTHOR'S / SPONSOR'S STATEMENT OF INTENT**

Clinically, ibogaine has shown promise in rapidly interrupting opioid and other substance dependencies. A single administration, in controlled settings, has been associated with the abrupt cessation of withdrawal symptoms and long-term reduction in cravings. Patients frequently report transformative psychological experiences that catalyze sustained behavioral change. Preliminary reports also suggest benefits in cognitive function, mood regulation, and sleep among individuals with TBI and PTSD—conditions prevalent among U.S. veterans.

Prominent advocates, including Navy SEAL Marcus Luttrell and former SEAL Bryan Hubbard, have described ibogaine's life-saving effects and are part of a growing veteran movement seeking alternatives to conventional treatments. With 1.8 million veterans living in Texas, ensuring access to innovative therapies like ibogaine is both a public health priority and a moral imperative.

Despite its potential, ibogaine remains a Schedule I substance and is not FDA-approved. However, it qualifies for Breakthrough Therapy designation, a pathway to accelerate the development of treatments for serious conditions. Safety concerns, particularly related to cardiac health, demand rigorous clinical protocols and administration in advanced care settings.

A successful ibogaine development initiative could unlock a new paradigm in the treatment of addiction and neuropsychiatric disorders, while securing Texas' role in shaping the future of transformative mental health therapies.

S.B. 2308 would establish a public-private grant program under the Health and Human Services Commission (HHSC) to support FDA Investigational New Drug (IND) trials for ibogaine. The program will fund Texas-based clinical research through gifts, grants, or donations and require dollar-for-dollar matching by recipients.

Eligible applicants must demonstrate the ability to:

* Conduct and finance FDA-compliant clinical trials;
* Assemble expert teams in pharmacology, psychiatry, cardiology, and data integrity;
* Provide detailed protocols for safety, aftercare, and data management;
* Maintain a commercial presence in Texas with intellectual property protections;
* Plan for broad access, including insurance reimbursement and care for uninsured populations; and
* Train medical providers in ibogaine therapy.

A multidisciplinary selection committee will review applications and recommend grantees to HHSC. An Institutional Review Board (IRB) based in Texas will ensure FDA standards are met.

Once IND approval is secured, HHSC and awardees will launch clinical trials at Texas facilities equipped for cardiac-intensive monitoring. All treatment will be physician-supervised in licensed healthcare settings. Applicants must pursue Breakthrough Therapy designation upon demonstration of clinical efficacy.

By advancing ibogaine research, Texas has the opportunity to lead in neuroscience innovation, address urgent veteran health needs, and shape the future of mental health treatment nationwide.

As proposed, S.B. 2308 amends current law 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.

**RULEMAKING AUTHORITY**

Rulemaking authority is expressly granted to the executive commissioner of the Health and Human Services Commission in SECTION 1 (Section 491.002, Health and Safety Code) of this bill.

**SECTION BY SECTION ANALYSIS**

SECTION 1. Amends Subtitle C, Title 6, Health and Safety Code, by adding Chapter 491, as follows:

CHAPTER 491. IBOGAINE TREATMENT

SUBCHAPTER A. GRANT PROGRAM FOR DRUG DEVELOPMENT OF IBOGAINE TREATMENT

Sec. 491.001. DEFINITIONS. Defines "commission" and "executive commissioner."

Sec. 491.002. RULES. Requires the executive commissioner of the Health and Human Services Commission (executive commissioner) to adopt rules necessary to administer this chapter.

Sec. 491.003. ESTABLISHMENT OF GRANT PROGRAM. Requires the Health and Human Services Commission (HHSC) to establish and administer a grant program to fund a public-private partnership program that will pay for the costs of the United States Food and Drug Administration's drug development trials with ibogaine to secure 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.

Sec. 491.004. APPLICATION. (a) Requires HHSC to prepare and issue a notice of funding opportunity to solicit applications for the grant program established under this subchapter.

(b) Authorizes an applicant to apply to HHSC in the form and manner prescribed by HHSC for a grant under this subchapter. Requires an applicant, to be eligible for a grant, to:

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

(A) conduct the United States Food and Drug Administration's drug development trials with ibogaine to secure 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;

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

(C) conduct future drug development trials of ibogaine 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

(2) provide certain information.

(c) Requires HHSC to make available the application required under this section and announce a period of not less than 90 days during which applicants may submit an application under this subchapter.

Sec. 491.005. SELECTION COMMITTEE. (a) Requires HHSC to create a selection committee and select the number of members. Requires the committee to be composed of subject matter experts, philanthropic partners, and legislative designees.

(b) Requires the selection committee to review applications, communicate supplemental inquiries to applicants, and recommend to HHSC the best applicants to conduct the drug development trials.

(c) Requires HHSC to consider the recommendations of the selection committee in selecting the applicant to conduct the ibogaine drug development trial.

Sec. 491.006. INVESTIGATIONAL NEW DRUG APPLICATION. Requires the applicant, on notification from HHSC that the applicant was selected to conduct the ibogaine drug development trial, as soon as practicable, to submit an investigational new drug (IND) application with the United States Food and Drug Administration in accordance with 21 C.F.R. Part 312 and seek a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. Section 356.

Sec. 491.007. ESTABLISHMENT OF DRUG DEVELOPMENT TRIAL SITES. Requires HHSC, on approval of the applicant's investigational new drug application by the United States Food and Drug Administration, in consultation with the applicant, to establish drug development trial sites that are required to be equipped and staffed to provide cardiac intensive care services to patients.

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

(b) Requires HHSC, in consultation with the selection committee under Section 491.005, to select an institutional review board with a presence in this state to oversee and verify the drug development trial research activity for scientific validation and authentication under the requirements of the United States Food and Drug Administration.

(c) Requires the applicant to request the designation under 21 U.S.C. Section 356 during the drug development trial if the ibogaine treatment is demonstrating efficacy.

Sec. 491.009. FUNDING. (a) Authorizes HHSC to use money received as a gift, grant, or donation to pay for a grant under this subchapter. Authorizes HHSC to solicit and accept gifts, grants, and donations of any kind and from any source for purposes of this section.

(b) Requires an applicant selected to perform a drug development trial under this subchapter to contribute toward the cost of developing the ibogaine treatment an amount of money that is at least equal to the amount of money that the applicant received in the form of a grant from HHSC.

SUBCHAPTER B. IBOGAINE TREATMENT ADMINISTRATION

Sec. 491.051. APPLICABILITY. Provides that this subchapter applies only if ibogaine is approved by the United States Food and Drug Administration to treat a medical condition.

Sec. 491.052. MEDICAL SUPERVISION. Requires a physician licensed under Subtitle B (Physicians), Title 3 (Health Professions), Occupations Code, who has prescribed ibogaine for a patient to supervise the administration of ibogaine at a hospital or other licensed health care facility to ensure the patient's safety while the patient is under the influence of ibogaine.

Sec. 491.053. ADMINISTRATION UNDER FEDERAL LAW PERMITTED. Provides that this subchapter does not preclude a physician from otherwise administering ibogaine according to federal law.

SECTION 2. Requires a state agency, if necessary for implementation of a provision of this Act, to request a waiver or authorization from a federal agency, and authorizes a delay of implementation until such a waiver or authorization is granted.

SECTION 3. Effective date: upon passage or September 1, 2025.