BILL ANALYSIS

Senate Research Center

S.B. 2308
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Enrolled

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.

S.B. 2308 amends current law relating to the establishment of a consortium to conduct United States Food and Drug Administration's drug development clinical trials with ibogaine to secure the administration's approval of the medication's use 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 to the administration of that treatment.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

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. GENERAL PROVISIONS

Sec. 491.001. DEFINITIONS. Defines "commission," "comptroller," "drug developer," "hospital," "ibogaine," and "institution of higher education."

Sec. 491.051. ESTABLISHMENT OF CONSORTIUM. (a) Authorizes a consortium to be established under this section and apply for Health and Human Services Commission (HHSC) selection under this subchapter to conduct drug development clinical trials with ibogaine and secure the United States Food and Drug Administration's approval of ibogaine as a medication for the treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health condition for which ibogaine demonstrates efficacy.

(b) Requires a consortium established under this section to include one or more of each of one of the following entities: a drug developer, an institution of higher education, and a hospital.

Sec. 491.052. LEAD INSTITUTION; ADMINISTRATION; PERSONNEL. (a) Requires a consortium established under this subchapter to select a lead institution of higher education from among the consortium's members to represent the consortium and perform administrative functions under this subchapter, including contracting with and reporting to HHSC as required by this subchapter.

(b) Authorizes a consortium selected by HHSC under this subchapter to employ personnel, including clinical, administrative, and data management personnel, necessary to support any consortium member's activities related to drug development clinical trials conducted under this subchapter.

Sec. 491.053. CONSORTIUM PROPOSAL. (a) Requires the lead institution of higher education of a consortium to submit to HHSC a proposal and request for funding on behalf of the consortium for purposes of conducting ibogaine drug development clinical trials in accordance with this subchapter.

(b) Requires that a proposal submitted under Subsection (a) provide:

(1) the identity of all consortium members;

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

(3) a detailed drug development clinical trial design that includes certain components;

(4) a detailed plan to seek a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. Section 356;

(5) a proposal to recognize this state's commercial interest in all intellectual property that may be generated over the course of the drug development clinical trials, including the treatment that is the subject of the trials, administration protocols, treatment models or techniques, and technology used in the trials;

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

(7) a plan to secure third-party payor approval for ibogaine treatment following approval by the United States Food and Drug Administration through private insurers, Medicare, Medicaid, and the TRICARE program of the United States Department of Defense;

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

(9) a plan to train and credential medical providers to administer ibogaine treatment according to developed clinical standards; and

(10) financial disclosures that verify the consortium's capacity to fully match state funding with funds received from non-state sources.

Sec. 491.054. COMMISSION SELECTION. Requires HHSC, in HHSC's sole discretion, to select a consortium established in accordance with Section 491.051 for the purpose of conducting ibogaine drug development clinical trials under this subchapter.

Sec. 491.055. CONTRACT WITH LEAD INSTITUTION. (a) Requires HHSC, as soon as practicable after selecting a consortium to conduct ibogaine drug development clinical trials under Section 491.054, to enter into an interagency contract, as provided by Chapter 771 (Interagency Cooperation Act), Government Code, with the lead institution of higher education of the selected consortium to provide funding to implement the consortium's proposed ibogaine drug development clinical trials.

(b) Requires that the interagency contract described by Subsection (a) specify certain information.

(c) Requires HHSC, as soon as practicable after entering into an interagency contract under Subsection (a), to report the existence of the contract to the legislature.

(d) Prohibits HHSC from disbursing funds to or for a selected consortium under the interagency contract described by Subsection (a) until the consortium receives and HHSC verifies the receipt of matching funds from sources other than the state.

Sec. 491.056. INVESTIGATIONAL NEW DRUG APPLICATION. Requires a drug developer or hospital member of the selected consortium or the lead institution of higher education of the consortium, as specified by written agreement of the consortium members, on HHSC's notification that a consortium is selected to conduct the drug development clinical trials under this subchapter, as soon as practicable, to submit an investigational new drug (IND) application to 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. 491.057. DRUG DEVELOPMENT CLINICAL TRIAL SITES. Provides that, for purposes of conducting a drug development clinical trial under this subchapter, only an institution of higher education or a hospital is authorized to serve as a trial site.

Sec. 491.058. FUNDING; DISBURSEMENT BY COMMISSION. (a) Authorizes HHSC and consortium members to solicit and accept gifts, grants, and donations of any kind received from sources other than the state for purposes of funding drug development clinical trials under this subchapter.

(b) Authorizes disbursements of funds by HHSC to be made incrementally based on the completion of clearly defined objectives as negotiated in the contract described by Section 491.055, including verifiable documentation demonstrating the efficient expenditure of both state and matching funds.

Sec. 491.059. REPORTING REQUIREMENTS. (a) Requires a consortium selected to conduct ibogaine drug development clinical trials to quarterly prepare and submit to HHSC a report on the progress of the drug development clinical trials conducted under this subchapter and a financial status report, including information to verify expenditures of state funds and required matching funds.

(b) Requires HHSC to submit a report to the legislature on the progress of the drug development clinical trials conducted under this subchapter not later than December 1 of each year.

Sec. 491.060. ALLOCATION OF REVENUE ATTRIBUTABLE TO INTELLECTUAL PROPERTY AND OTHER RIGHTS. (a) Requires that the revenue attributable to all intellectual property rights and other commercial rights arising from drug development clinical trials conducted by a consortium under this subchapter during the period for which the trials are funded and any following period of commercialization be allocated as follows: not less than 20 percent to the state as specified in the contract under Section 491.055 and the remainder to the members of the consortium in the amounts specified by written agreement of the members.

(b) Provides that, for purposes of this section, intellectual property rights and other commercial rights arising from the drug development clinical trials conducted under this subchapter include any of certain components as related to the trials.

Sec. 491.061. USE OF STATE REVENUE. (a) Requires the Comptroller of Public Accounts of the State of Texas (comptroller) to deposit the revenue received under Section 491.060 to the credit of the general revenue fund.

(b) Provides that, of the amount deposited under Subsection (a), 25 percent is authorized to be appropriated only to programs that assist veterans in this state.

(c) Requires the comptroller to develop accounting procedures for the purpose of implementing this section.

SUBCHAPTER C. IBOGAINE TREATMENT ADMINISTRATION

Sec. 491.101. 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. 491.102. 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. 491.103. ADMINISTRATION UNDER FEDERAL LAW. Provides that this subchapter does not preclude a physician from administering ibogaine in accordance with federal law.

SECTION 2. (a) 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.

(b) Requires HHSC to begin accepting proposals from consortiums under Chapter 491, Health and Safety Code, as added by this Act, not later than the 60th day after the effective date of this Act.

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