

CONFERENCE COMMITTEE REPORT FORM

Austin, Texas

May 25, 2025
Date

Honorable Dan Patrick
President of the Senate

Honorable Dustin Burrows
Speaker of the House of Representatives

Sirs:

We, Your Conference Committee, appointed to adjust the differences between the Senate and the House of Representatives on _____ have had the same under consideration, and beg to report it back with the recommendation that it do pass in the form and text hereto attached.

<u>Tom Parker</u>	<u>[Signature]</u>
<u>C. J. Blum</u>	<u>Erin [Signature]</u>
<u>Brenda Light</u>	<u>Dale [Signature]</u>
<u>Phil King</u>	<u>Tom [Signature]</u>
<u>[Signature]</u>	<u>[Signature]</u>
On the part of the Senate	On the part of the House

Note to Conference Committee Clerk:

Please type the names of the members of the Conference Committee under the lines provided for signature. Those members desiring to sign the report should sign each of the six copies. Attach a copy of the Conference Committee Report and a Section by Section side by side comparison to each of the six reporting forms. The original and two copies are filed in house of origin of the bill, and three copies in the other house.

CONFERENCE COMMITTEE REPORT

3rd Printing

S.B. No. 2308

A BILL TO BE ENTITLED

AN ACT

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.

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. GENERAL PROVISIONS

Sec. 491.001. DEFINITIONS. In this chapter:

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

(2) "Comptroller" means the comptroller of public accounts.

(3) "Drug developer" means a pharmaceutical company, biotechnology company, or contract development and manufacturing organization engaged in drug development and manufacturing.

(4) "Hospital" has the meaning assigned by Section 241.003.

(5) "Ibogaine" means ibogaine and ibogaine-based

1 therapeutics, including ibogaine analogs.

2 (6) "Institution of higher education" has the meaning
3 assigned by Section 61.003, Education Code.

4 SUBCHAPTER B. DRUG DEVELOPMENT OF IBOGAINE TREATMENT

5 Sec. 491.051. ESTABLISHMENT OF CONSORTIUM. (a) A
6 consortium may be established under this section and apply for
7 commission selection under this subchapter to conduct drug
8 development clinical trials with ibogaine and secure the United
9 States Food and Drug Administration's approval of ibogaine as a
10 medication for the treatment of:

- 11 (1) opioid use disorder;
12 (2) co-occurring substance use disorder; and
13 (3) any other neurological or mental health condition
14 for which ibogaine demonstrates efficacy.

15 (b) A consortium established under this section must
16 include one or more of each of the following entities:

- 17 (1) a drug developer;
18 (2) an institution of higher education; and
19 (3) a hospital.

20 Sec. 491.052. LEAD INSTITUTION; ADMINISTRATION; PERSONNEL.

21 (a) A consortium established under this subchapter shall select a
22 lead institution of higher education from among the consortium's
23 members to represent the consortium and perform administrative
24 functions under this subchapter, including contracting with and
25 reporting to the commission as required by this subchapter.

26 (b) A consortium selected by the commission under this
27 subchapter may employ personnel, including clinical,

1 administrative, and data management personnel, necessary to
2 support any consortium member's activities related to drug
3 development clinical trials conducted under this subchapter.

4 Sec. 491.053. CONSORTIUM PROPOSAL. (a) The lead
5 institution of higher education of a consortium shall submit to the
6 commission a proposal and request for funding on behalf of the
7 consortium for purposes of conducting ibogaine drug development
8 clinical trials in accordance with this subchapter.

9 (b) A proposal submitted under Subsection (a) must provide:

10 (1) the identity of all consortium members;

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

14 (3) a detailed drug development clinical trial design
15 that includes:

16 (A) a description of the composition of the
17 consortium's drug development clinical trial team and the expertise
18 of the team members;

19 (B) a drug development clinical trial
20 participant recruitment plan;

21 (C) patient screening criteria and cardiac
22 safety protocols;

23 (D) administration protocols;

24 (E) an aftercare and post-acute treatment
25 support plan; and

26 (F) a data integrity plan;

27 (4) a detailed plan to seek a breakthrough therapy

1 designation for ibogaine from the United States Food and Drug
2 Administration under 21 U.S.C. Section 356;

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

6 (A) the treatment that is the subject of the
7 trials;

8 (B) administration protocols;

9 (C) treatment models or techniques; and

10 (D) technology used in the trials;

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

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

18 (A) private insurers;

19 (B) Medicare;

20 (C) Medicaid; and

21 (D) the TRICARE program of the United States
22 Department of Defense;

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

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

1 standards; and

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

5 Sec. 491.054. COMMISSION SELECTION. The commission, in the
6 commission's sole discretion, shall select a consortium
7 established in accordance with Section 491.051 for the purpose of
8 conducting ibogaine drug development clinical trials under this
9 subchapter.

10 Sec. 491.055. CONTRACT WITH LEAD INSTITUTION. (a) As soon
11 as practicable after selecting a consortium to conduct ibogaine
12 drug development clinical trials under Section 491.054, the
13 commission shall enter into an interagency contract, as provided by
14 Chapter 771, Government Code, with the lead institution of higher
15 education of the selected consortium to provide funding to
16 implement the consortium's proposed ibogaine drug development
17 clinical trials.

18 (b) The interagency contract described by Subsection (a)
19 must specify:

20 (1) the goals and objectives of the proposed ibogaine
21 drug development clinical trials;

22 (2) the proposed budget;

23 (3) the timeline for completing the proposed
24 objectives;

25 (4) the for-profit, nonprofit, or public benefit
26 corporate entities collaborating with the consortium in the drug
27 development clinical trials under this subchapter;

1 (5) the percentage of the revenue arising from the
2 drug development clinical trials to be paid to the state; and
3 (6) any other information required by the commission.

4 (c) As soon as practicable after entering into an
5 interagency contract under Subsection (a), the commission shall
6 report the existence of the contract to the legislature.

7 (d) The commission may not disburse funds to or for a
8 selected consortium under the interagency contract described by
9 Subsection (a) until the consortium receives and the commission
10 verifies the receipt of matching funds from sources other than the
11 state.

12 Sec. 491.056. INVESTIGATIONAL NEW DRUG APPLICATION. On the
13 commission's notification that a consortium is selected to conduct
14 the drug development clinical trials under this subchapter, a drug
15 developer or hospital member of the selected consortium or the lead
16 institution of higher education of the consortium, as specified by
17 written agreement of the consortium members, shall, as soon as
18 practicable:

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

22 (2) seek a breakthrough therapy designation for
23 ibogaine from the United States Food and Drug Administration under
24 21 U.S.C. Section 356.

25 Sec. 491.057. DRUG DEVELOPMENT CLINICAL TRIAL SITES. For
26 purposes of conducting a drug development clinical trial under this
27 subchapter, only an institution of higher education or a hospital

1 may serve as a trial site.

2 Sec. 491.058. FUNDING; DISBURSEMENT BY COMMISSION. (a)
3 The commission and consortium members may solicit and accept gifts,
4 grants, and donations of any kind received from sources other than
5 the state for purposes of funding drug development clinical trials
6 under this subchapter.

7 (b) Disbursements of funds by the commission may be made
8 incrementally based on the completion of clearly defined objectives
9 as negotiated in the contract described by Section 491.055,
10 including verifiable documentation demonstrating the efficient
11 expenditure of both state and matching funds.

12 Sec. 491.059. REPORTING REQUIREMENTS. (a) A consortium
13 selected to conduct ibogaine drug development clinical trials shall
14 quarterly prepare and submit to the commission:

15 (1) a report on the progress of the drug development
16 clinical trials conducted under this subchapter; and

17 (2) a financial status report, including information
18 to verify expenditures of state funds and required matching funds.

19 (b) The commission shall submit a report to the legislature
20 on the progress of the drug development clinical trials conducted
21 under this subchapter not later than December 1 of each year.

22 Sec. 491.060. ALLOCATION OF REVENUE ATTRIBUTABLE TO
23 INTELLECTUAL PROPERTY AND OTHER RIGHTS. (a) The revenue
24 attributable to all intellectual property rights and other
25 commercial rights arising from drug development clinical trials
26 conducted by a consortium under this subchapter during the period
27 for which the trials are funded and any following period of

1 commercialization shall be allocated as follows:

2 (1) not less than 20 percent to the state as specified
3 in the contract under Section 491.055; and

4 (2) the remainder to the members of the consortium in
5 the amounts specified by written agreement of the members.

6 (b) For purposes of this section, intellectual property
7 rights and other commercial rights arising from the drug
8 development clinical trials conducted under this subchapter
9 include any of the following as related to the trials:

10 (1) intellectual property, technology, and
11 inventions;

12 (2) patents, trademarks, and licenses;

13 (3) proprietary and confidential information;

14 (4) trade secrets, data, and databases;

15 (5) tools, methods, and processes;

16 (6) treatment models or techniques;

17 (7) administration protocols; and

18 (8) works of authorship.

19 Sec. 491.061. USE OF STATE REVENUE. (a) The comptroller
20 shall deposit the revenue received under Section 491.060 to the
21 credit of the general revenue fund.

22 (b) Of the amount deposited under Subsection (a), 25 percent
23 may be appropriated only to programs that assist veterans in this
24 state.

25 (c) The comptroller shall develop accounting procedures for
26 the purpose of implementing this section.

1 SUBCHAPTER C. IBOGAINES TREATMENT ADMINISTRATION

2 Sec. 491.101. APPLICABILITY. This subchapter applies only
3 if ibogaine is approved by the United States Food and Drug
4 Administration to treat a medical condition.

5 Sec. 491.102. MEDICAL SUPERVISION. A physician licensed
6 under Subtitle B, Title 3, Occupations Code, who has prescribed
7 ibogaine for a patient shall supervise the administration of
8 ibogaine at a hospital or other licensed health care facility to
9 ensure the patient's safety while the patient is under the
10 influence of ibogaine.

11 Sec. 491.103. ADMINISTRATION UNDER FEDERAL LAW. This
12 subchapter does not preclude a physician from administering
13 ibogaine in accordance with federal law.

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

20 (b) The Health and Human Services Commission shall begin
21 accepting proposals from consortiums under Chapter 491, Health and
22 Safety Code, as added by this Act, not later than the 60th day after
23 the effective date of this Act.

24 SECTION 3. This Act takes effect immediately if it receives
25 a vote of two-thirds of all the members elected to each house, as
26 provided by Section 39, Article III, Texas Constitution. If this
27 Act does not receive the vote necessary for immediate effect, this

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1 Act takes effect September 1, 2025.

Senate Bill 2308
Conference Committee Report
Section-by-Section Analysis

SENATE VERSION

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

CHAPTER 491. IBOGAIN TREATMENT

SUBCHAPTER A. GRANT PROGRAM FOR DRUG DEVELOPMENT OF IBOGAIN 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 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.

HOUSE VERSION (IE)

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

CHAPTER 491. GRANT PROGRAM FOR DRUG DEVELOPMENT OF IBOGAIN TREATMENT

No equivalent provision.

Sec. 491.001. Same as Senate version except also defines "ibogaine."

Sec. 491.002. Same as Senate version.

Sec. 491.003. Same as Senate version.

CONFERENCE

[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

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

CHAPTER 491. IBOGAIN TREATMENT

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 491.001. Same as House version except does not define "executive commissioner" and adds definitions for "comptroller," "drug developer," "hospital," and "institution of higher education."

No equivalent provision.

No equivalent provision.

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Section-by-Section Analysis

SENATE VERSION	HOUSE VERSION (IE)	CONFERENCE
		<i>[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]</i>
<i>No equivalent provision.</i>	Same as Senate version.	<u>SUBCHAPTER B. DRUG DEVELOPMENT OF IBOGAIN TREATMENT</u>
<i>No equivalent provision.</i>	Same as Senate version.	<u>Sec. 491.051. ESTABLISHMENT OF CONSORTIUM. (a) A consortium may be established under this section and apply for commission 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:</u> <u>(1) opioid use disorder;</u> <u>(2) co-occurring substance use disorder; and</u> <u>(3) any other neurological or mental health condition for which ibogaine demonstrates efficacy.</u> <u>(b) A consortium established under this section must include one or more of each of the following entities:</u> <u>(1) a drug developer;</u> <u>(2) an institution of higher education; and</u> <u>(3) a hospital.</u>
<i>No equivalent provision.</i>	Same as Senate version.	<u>Sec. 491.052. LEAD INSTITUTION; ADMINISTRATION; PERSONNEL. (a) A consortium established under this subchapter shall 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 the commission as required by this subchapter.</u> <u>(b) A consortium selected by the commission under this subchapter may employ personnel, including clinical, administrative, and data management personnel, necessary to</u>

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HOUSE VERSION (IE)

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[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

support any consortium member's activities related to drug development clinical trials conducted under this subchapter.

No equivalent provision.

No equivalent provision.

Sec. 491.053. CONSORTIUM PROPOSAL.

(a) The lead institution of higher education of a consortium shall submit to the commission 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) A proposal submitted under Subsection (a) must provide:
(1) the identity of all consortium members;

Sec. 491.004. APPLICATION.

(a) The commission shall prepare and issue a notice of funding opportunity to solicit applications for the grant program established under this subchapter.

No equivalent provision.

No equivalent provision.

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

Sec. 491.004. APPLICATION.

(a) Substantially the same as Senate version.

Same as Senate version.

Same as Senate version.

(b) Substantially the same as Senate version.

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CONFERENCE

[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

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:

(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;

(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:

(A) a description of the composition of the **consortium's** drug development **clinical** trial team and the expertise of the team members;

(B) a drug development **clinical** trial participant recruitment plan;

(C) patient screening criteria and cardiac safety protocols;

(D) administration protocols;

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

(F) a data integrity plan;

(4) a detailed plan to seek a breakthrough therapy designation for ibogaine from the United States Food and

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(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
- (iv) technology used in the trials;

(D) 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;

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

- (i) private insurers;
- (ii) Medicare;
- (iii) Medicaid; and
- (iv) the TRICARE program of the United States Department of Defense;

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

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

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

HOUSE VERSION (IE)

CONFERENCE

[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

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:

- (A) the treatment that is the subject of the trials;
- (B) administration protocols;
- (C) treatment models or techniques; and
- (D) 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:

- (A) private insurers;
- (B) Medicare;
- (C) Medicaid; and
- (D) 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.**

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(c) The commission shall:
(1) make available the application required under this section;
and
(2) 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) The
commission shall create a selection committee and select the
number of members. The committee must be composed of:
(1) subject matter experts;
(2) philanthropic partners; and
(3) legislative designees.
(b) The selection committee shall review applications,
communicate supplemental inquiries to applicants, and
recommend to the commission the best applicants to conduct
the drug development trials.
(c) The commission shall consider the recommendations of
the selection committee in selecting the applicant to conduct
the ibogaine drug development trial.

No equivalent provision.

No equivalent provision.

HOUSE VERSION (IE)

(c) Substantially the same as Senate version.

Sec. 491.005. Same as Senate version.

Same as Senate version.

Same as Senate version.

CONFERENCE

*[The conference committee may have exceeded the limitations imposed
on its jurisdiction, but only the presiding officer can make the final
determination on this issue.]*

No equivalent provision.

No equivalent provision.

Sec. 491.054. COMMISSION SELECTION. The
commission, in the commission's sole discretion, shall 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) As soon as practicable after selecting a consortium to

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[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

conduct ibogaine drug development clinical trials under Section 491.054, the commission shall enter into an interagency contract, as provided by Chapter 771, 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) The interagency contract described by Subsection (a) must specify:

(1) the goals and objectives of the proposed ibogaine drug development clinical trials;

(2) the proposed budget;

(3) the timeline for completing the proposed objectives;

(4) the for-profit, nonprofit, or public benefit corporate entities collaborating with the consortium in the drug development clinical trials under this subchapter;

(5) the percentage of the revenue arising from the drug development clinical trials to be paid to the state; and

(6) any other information required by the commission.

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

(d) The commission may not disburse funds to or for a selected consortium under the interagency contract described by Subsection (a) until the consortium receives and the commission verifies the receipt of matching funds from sources other than the state.

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

- (1) 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
- (2) seek a breakthrough therapy designation for ibogaine from the United States Food and Drug Administration under 21 U.S.C. Section 356.

No equivalent provision.

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

HOUSE VERSION (IE)

Sec. 491.006. Same as Senate version.

Same as Senate version.

Sec. 491.007. Same as Senate version.

CONFERENCE

[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

Sec. 491.056. INVESTIGATIONAL NEW DRUG APPLICATION. *On the commission's notification that a consortium is* selected to conduct the drug development *clinical trials under this subchapter, 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,* shall, as soon as practicable:

- (1) 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
- (2) 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. For purposes of conducting a drug development clinical trial under this subchapter, only an institution of higher education or a hospital may serve as a trial site.

No equivalent provision.

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

(b) The commission, in consultation with the selection committee under Section 491.005, shall 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) The applicant shall 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) *The commission may use money received as a gift, grant, or donation to pay for a grant under this subchapter. The commission may solicit and accept gifts, grants, and donations of any kind and from any source for purposes of this section.*

(b) An applicant selected to perform a drug development trial under this subchapter shall 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 the commission.

HOUSE VERSION (IE)

Sec. 491.008. Same as Senate version.

Sec. 491.009. FUNDING.

(a) *The commission may use money appropriated to the commission and money received as a gift, grant, or donation to pay for a grant under this chapter. The commission may solicit and accept gifts, grants, and donations of any kind and from any source for purposes of this section.*

(b) Substantially the same as Senate version.

CONFERENCE

[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]

No equivalent provision.

Sec. 491.058. FUNDING; ***DISBURSEMENT BY COMMISSION.***

(a) The commission *and consortium members* may 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.*

No equivalent provision.

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SENATE VERSION	HOUSE VERSION (IE)	CONFERENCE
		<i>[The conference committee may have exceeded the limitations imposed on its jurisdiction, but only the presiding officer can make the final determination on this issue.]</i>
<i>No equivalent provision.</i>	Same as Senate version.	<u>(b) Disbursements of funds by the commission may 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.</u>
<i>No equivalent provision.</i>	Same as Senate version.	<u>Sec. 491.059. REPORTING REQUIREMENTS. (a) A consortium selected to conduct ibogaine drug development clinical trials shall quarterly prepare and submit to the commission:</u> <u>(1) a report on the progress of the drug development clinical trials conducted under this subchapter; and</u> <u>(2) a financial status report, including information to verify expenditures of state funds and required matching funds.</u> <u>(b) The commission shall 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.</u>
<i>No equivalent provision.</i>	Same as Senate version.	<u>Sec. 491.060. ALLOCATION OF REVENUE ATTRIBUTABLE TO INTELLECTUAL PROPERTY AND OTHER RIGHTS. (a) 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 shall be allocated as follows:</u> <u>(1) not less than 20 percent to the state as specified in the contract under Section 491.055; and</u> <u>(2) the remainder to the members of the consortium in the</u>

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SENATE VERSION

HOUSE VERSION (IE)

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amounts specified by written agreement of the members.
(b) 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 the following as related to the trials:
(1) intellectual property, technology, and inventions;
(2) patents, trademarks, and licenses;
(3) proprietary and confidential information;
(4) trade secrets, data, and databases;
(5) tools, methods, and processes;
(6) treatment models or techniques;
(7) administration protocols; and
(8) works of authorship.

No equivalent provision.

Same as Senate version.

Sec. 491.061. USE OF STATE REVENUE. (a) The comptroller shall deposit the revenue received under Section 491.060 to the credit of the general revenue fund.
(b) Of the amount deposited under Subsection (a), 25 percent may be appropriated only to programs that assist veterans in this state.
(c) The comptroller shall develop accounting procedures for the purpose of implementing this section.

SUBCHAPTER B. IBOGAINE TREATMENT ADMINISTRATION
Sec. 491.051. APPLICABILITY. This subchapter applies only if ibogaine is approved by the United States Food and

No equivalent provision.

SUBCHAPTER C (Secs. 491.101-491.103). Substantially the same as Senate version.

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Drug Administration to treat a medical condition.
Sec. 491.052. MEDICAL SUPERVISION. A physician licensed under Subtitle B, Title 3, Occupations Code, who has prescribed ibogaine for a patient shall 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. This subchapter does not preclude a physician from otherwise administering ibogaine according to federal law.

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

SECTION 3. Effective date.

SECTION 2. Same as Senate version.

SECTION 3. Same as Senate version.

SECTION 2. Same as Senate version except also includes a requirement for the Health and Human Services Commission to begin accepting proposals from consortiums under the bill's provisions not later than the 60th day after the bill's effective date.

SECTION 3. Same as Senate version.

LEGISLATIVE BUDGET BOARD

Austin, Texas

FISCAL NOTE, 89TH LEGISLATIVE REGULAR SESSION

May 30, 2025

TO: Honorable Dan Patrick, Lieutenant Governor, Senate
Honorable Dustin Burrows, Speaker of the House, House of Representatives

FROM: Jerry McGinty, Director, Legislative Budget Board

IN RE: SB2308 by Parker (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.), **Conference Committee Report**

The fiscal implications of the bill cannot be determined due to the unknown cost related to the funding needs required to conduct the drug development trials.

The bill would establish a consortium to apply for Health and Human Services Commission (HHSC) selection to conduct drug development trials with ibogaine to secure the United States Food and Drug Administration's (USDA) approval of ibogaine as a medication for treatment of opioid use disorder, co-occurring substance use disorder, and any other neurological or mental health condition for which ibogaine demonstrates efficacy. The consortium would be required to select a lead institution of higher education from the consortium's members to represent the consortium and perform administrative functions. The lead institution of higher education selected would also be required submit a proposal and request for funding to HHSC to conduct the ibogaine drug development clinical trials. The proposal must verify that the consortium has capacity to contribute toward the cost of developing ibogaine treatment at an amount of funding to fully match state funding with funds received from non-state sources. HHSC would be required to select a consortium to conduct the clinical trials and enter into an interagency contract to provide funding to implement the clinical trials. The bill would allocate revenue attributable to all intellectual property rights and other commercial rights arising from the drug development trials at an amount of not less than 20.0 percent to the state and the remainder to the consortium members.

HHSC would require appropriations to fund the consortium's clinical trials, but the cost of such funding is unknown at this time. It is also unknown what the cost would be at the selected institution of higher education related to employing administrative, clinical, and data management personnel.

Revenue received from intellectual property rights that would be allocated to the state is indeterminate and would be dependent on the drug development trials.

Local Government Impact

No significant fiscal implication to units of local government is anticipated.

Source Agencies: 529 Health and Human Services Commission

LBB Staff: JMc, CMA, ER, SB, NPe, SD, NV