H.R. No. 1495

R E S O L U T I O N

BE IT RESOLVED by the House of Representatives of the State of Texas, 89th Legislature, Regular Session, 2025, That House Rule 13, Section 9(a), be suspended in part as provided by House Rule 13, Section 9(f), to enable the conference committee appointed to resolve the differences on Senate Bill 2308 (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) to consider and take action on the following matters:

(1) House Rule 13, Section 9(a)(2), is suspended to permit the committee to omit text not in disagreement by omitting in proposed SECTION 1 of the bill added Section 491.001(2), Health and Safety Code. The omitted text reads:

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

Explanation: The change is necessary to remove a definition that no longer appears in added Chapter 491, Health and Safety Code.

(2) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding Sections 491.001(2), (3), (4), and (6), Health and

Safety Code, to read as follows:

(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.

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

Explanation: The change is necessary to define "comptroller," "drug developer," "hospital," and "institution of higher education" for purposes of added Chapter 491, Health and Safety Code.

(3) House Rule 13, Section 9(a)(2), is suspended to permit the committee to omit text not in disagreement in proposed SECTION 1 of the bill by omitting added Sections 491.002 and 491.003, Health and Safety Code. The omitted text reads:

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.

Explanation: The change is necessary to eliminate rulemaking authority and remove a grant program.

(4) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding a heading for added Subchapter B, Chapter 491, Health and Safety Code, to read as follows:

SUBCHAPTER B. DRUG DEVELOPMENT OF IBOGAINE TREATMENT

Explanation: The change is necessary for better organization of added Chapter 491, Health and Safety Code.

(5) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding Sections 491.051 and 491.052, Health and Safety Code, to read as follows:

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:

(1) opioid use disorder;

(2) co-occurring substance use disorder; and

(3) any other neurological or mental health condition for which ibogaine demonstrates efficacy.

(b) A consortium established under this section must

include one or more of each of the following entities:

(1) a drug developer;

(2) an institution of higher education; and

(3) a hospital.

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.

(b) A consortium selected by the commission under this subchapter may 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.

Explanation: The change is necessary to allow formation of a consortium for the conduct of certain drug development clinical trials, to secure United States Food and Drug Administration's approval for certain medical treatments, and to allow the consortium to select a lead institution and employ necessary personnel.

(6) House Rule 13, Section 9(a)(2), is suspended to permit the committee to omit text not in disagreement in proposed SECTION 1 of the bill by omitting the heading and Subsections (a) and (c) of added Section 491.004, Health and Safety Code. The omitted text reads:

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.

(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.

Explanation: The change is necessary to remove an application process for a removed grant program.

(7) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding a heading and Subsection (a) for Section 491.053, Health and Safety Code, to read as follows:

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.

Explanation: The change is necessary to require a consortium formed under added Chapter 491, Health and Safety Code, to submit to the Health and Human Services Commission a proposal for selection to conduct a drug development clinical trial under that chapter.

(8) House Rule 13, Sections 9(a)(1), (2), and (3), are suspended to permit the committee to change, alter, or amend text not in disagreement, omit text not in disagreement, and add text on

a matter not in disagreement in proposed SECTION 1 of the bill, by adding Section 491.053(b), Health and Safety Code, to read as follows:

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

(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 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.

Explanation: The change is necessary to specify the

information required for submission of a proposal under Section 491.053, Health and Safety Code, and selection to perform drug development clinical trials under added Chapter 491, Health and Safety Code.

(9) House Rule 13, Section 9(a)(2), is suspended to permit the committee to omit text not in disagreement in proposed SECTION 1 of the bill by omitting added Section 491.005, Health and Safety Code. The omitted text reads:

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.

Explanation: The change is necessary to remove the selection committee.

(10) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding Sections 491.054 and 491.055, Health and Safety

Code, to read as follows:

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 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.

Explanation: The change is necessary to allow the Health and Human Services Commission to select a consortium established under added Chapter 491, Health and Safety Code, for the purpose of conducting drug development clinical trials under that chapter, to require the commission to enter into an interagency contract with the consortium for the conduct of those trials, and to regulate the contract provisions and the disbursement of funds to the selected consortium.

(11) House Rule 13, Sections 9(a)(1) and (3), are suspended to permit the committee to change, alter, or amend text not in disagreement and add text on a matter not in disagreement in proposed SECTION 1 of the bill, by adding Section 491.056, Health and Safety Code, to read as follows:

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.

Explanation: The change is necessary to allow certain members of a consortium established under added Chapter 491, Health and Safety Code, to apply for an investigational new drug application with the United States Food and Drug Administration and to seek from the administration a breakthrough therapy designation for certain treatments.

(12) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding Section 491.057, Health and Safety Code, to read as follows:

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.

Explanation: The change is necessary to specify which members of a consortium established under added Chapter 491, Health and Safety Code, may serve as a drug development clinical trial site under that chapter.

(13) House Rule 13, Section 9(a)(2), is suspended to permit

the committee to omit text not in disagreement in proposed SECTION 1 of the bill by omitting added Sections 491.007 and 491.008, Health and Safety Code. The omitted text reads:

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.

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.

Explanation: The change is necessary to remove requirements relating to drug development trial sites and the conduct of a drug development trial.

(14) House Rule 13, Sections 9(a)(1), (2), and (4), are suspended to permit the committee to change, alter, or amend text

not in disagreement, omit text on a matter not in disagreement, and add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding Section 491.058, Health and Safety Code, to read as follows:

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.

(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.

Explanation: The change is necessary to clarify that matching funds provided by a consortium established under added Chapter 491, Health and Safety Code, must come from sources other than the state, and to add accountability requirements.

(15) House Rule 13, Section 9(a)(2), is suspended to permit the committee to omit text not in disagreement in proposed SECTION 1 of the bill by omitting added Section 491.009(b), Health and Safety Code. The omitted text reads:

(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.

Explanation: The change is necessary to eliminate duplicative and conflicting provisions relating to matching funds.

(16) House Rule 13, Section 9(a)(4), is suspended to permit the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 1 of the bill, by adding Sections 491.059, 491.060, and 491.061, Health and Safety Code, to read as follows:

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

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

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

(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.

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:

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

(2) the remainder to the members of the consortium in

the 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.

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.

Explanation: The change is necessary to establish reporting requirements for a consortium established under added Chapter 491, Health and Safety Code, and to clarify the allocation of revenues attributable to certain property rights under that chapter.

(17) House Rule 13, Section 9(a)(4), is suspended to permit

the committee to add text on a matter not included in either the house or senate version of the bill in proposed SECTION 2 of the bill, by adding Subsection (b) to read as follows:

(b) The Health and Human Services Commission shall 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.

Explanation: The change is necessary to require the Health and Human Services Commission to begin accepting proposals from consortiums under added Chapter 491, Health and Safety Code, by a certain date.

Harris

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Speaker of the House

I certify that H.R. No. 1495 was adopted by the House on June 1, 2025, by the following vote: Yeas 121, Nays 15, 1 present, not voting.

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Chief Clerk of the House