

1 AN ACT relating to ibogaine research in the Commonwealth, making an
2 appropriation therefor, and declaring an emergency.

3 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

4 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
5 READ AS FOLLOWS:

6 *As used in Sections 1 to 5 of this Act:*

7 *(1) "Department" means the Department of Agriculture;*

8 *(2) "Drug developer" means a for-profit, nonprofit, or public benefit corporation*
9 *engaged in drug development and manufacturing that has established an*
10 *ibogaine drug development agreement with at least one (1) additional state with a*
11 *plan to conduct drug development clinical trials to obtain United States Food and*
12 *Drug Administration approval for use of ibogaine; and*

13 *(3) "Ibogaine":*

14 *(a) Means a crystalline alkaloid psychogenic compound obtained from the*
15 *Tabernanthe iboga plant; and*

16 *(b) Includes any of its derivatives or analogs in any form, whether existing or*
17 *as-yet to be developed.*

18 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
19 READ AS FOLLOWS:

20 *(1) There is hereby established in the State Treasury a trust and agency fund entitled*
21 *the ibogaine research and intellectual property fund, to be administered by the*
22 *department for the purpose of allowing the department to enter into a public-*
23 *private partnership with a drug developer to conduct a clinical drug development*
24 *trial or trials related to the use of ibogaine for the treatment of opioid use*
25 *disorder, co-occurring substance use disorder, or any other neurological or*
26 *mental health condition for which ibogaine demonstrates efficacy.*

27 *(2) The fund may receive state appropriations, gifts, grants, federal funds, and any*

1 other funds, both public and private. Moneys deposited in the fund are hereby
2 appropriated for the purposes set out in Sections 1 to 5 of this Act.

3 (3) Notwithstanding KRS 45.229, any unallocated or unencumbered balances in the
4 fund shall be invested as provided in KRS 42.500(9), and any interest or other
5 income earned from the investments, along with the unallotted or unencumbered
6 balances in the fund, shall not lapse but shall be carried forward into the next
7 fiscal year.

8 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
9 READ AS FOLLOWS:

10 (1) Before the department may contract with a drug developer, the drug developer
11 shall provide the department with:

12 (a) A detailed description of the drug developer's strategy for obtaining
13 approval for the drug development clinical trials from the United States
14 Food and Drug Administration and a detailed drug development clinical
15 trial design, including a description of the composition of the consortium's
16 drug development clinical trial team and the expertise of the team members;

17 (b) Protocols for clinical trial participant recruitment, patient screening
18 criteria, administration, after-care, and post-acute treatment support;

19 (c) A plan to seek a breakthrough therapy designation for ibogaine from the
20 United States Food and Drug Administration under 21 U.S.C. sec. 356;

21 (d) Financial disclosures necessary to verify that the drug developer is prepared
22 to meet its full obligations under this section; and

23 (e) Certification of an existing ibogaine drug development agreement with one
24 (1) or more other states or state-sponsored consortiums.

25 (2) Before the department may contract with a drug developer, the department shall
26 negotiate a contract requiring the drug developer to substantially agree to:

27 (a) Match the Commonwealth's investment in drug development clinical trials

1 with ibogaine with an equal amount of additional funding and to devote this
2 total amount in drug development clinical trials conducted within the
3 Commonwealth. These trials shall exclusively use in-state clinicians,
4 facilities, and study participants;

5 (b) Provide reports as specified under Section 4 of this act;

6 (c) Establish a plan to ensure broad and accessible ibogaine treatment access to
7 patients within the Commonwealth following approval of ibogaine by the
8 United States Food and Drug Administration by diverse means, including
9 but not limited to:

10 1. Providing priority access to ibogaine treatment to residents of the
11 Commonwealth;

12 2. Seeking third-party payor approval for ibogaine treatment within the
13 Commonwealth;

14 3. Developing means of access to ibogaine treatment within the
15 Commonwealth for uninsured and low-income individuals; and

16 4. Training and credentialing medical providers within the
17 Commonwealth to administer ibogaine treatment; and

18 (d) Provide a plan to recognize the Commonwealth's economic interest in the
19 intellectual property generated over the course of the multistate drug
20 development clinical trials with ibogaine, consisting of a share of the
21 proceeds from said intellectual property which is proportional to the
22 Commonwealth's contribution to the total cost of the multistate drug
23 development trials, and to deposit the state's share of those proceeds in the
24 ibogaine research and intellectual property fund established in Section 2 of
25 this Act at agreed-upon intervals during the period for which the drug
26 development clinical trials are funded and during any subsequent period of
27 commercialization.

1 (3) In negotiating a contract with the drug developer, the department may agree to
2 additional terms and make reasonable deviations from the requirements of this
3 section as long as the resulting contract is fair and creates substantially
4 equivalent value for the Commonwealth.

5 (4) For purposes of this section, intellectual property rights and other commercial
6 rights arising from multistate drug development clinical trials with ibogaine
7 include any of the following as related to these trials:

8 (a) Intellectual property, technology, and inventions;

9 (b) Patents, trademarks, and licenses;

10 (c) Proprietary and confidential information;

11 (d) Trade secrets, data, and databases;

12 (e) Tools, methods, and processes;

13 (f) Treatment models or techniques;

14 (g) Administration protocols; and

15 (h) Works of authorship.

16 ➔SECTION 4. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO
17 READ AS FOLLOWS:

18 (1) The drug developer shall quarterly prepare and submit to the department a:

19 (a) Report on the progress of any multistate drug development clinical trials
20 with ibogaine conducted pursuant to Sections 1 to 5 of this Act; and

21 (b) Financial status report, including information to verify expenditures of
22 Commonwealth funds and required matching funds.

23 (2) The department shall submit an annual report by December 1 each year to the
24 Legislative Research Commission for referral to the Interim Joint Committee on
25 Health Services on the progress of the drug development clinical trials and their
26 related financial status until the clinical trials are concluded.

27 ➔SECTION 5. A NEW SECTION OF KRS CHAPTER 218A IS CREATED TO

1 READ AS FOLLOWS:

2 All receipts from the proceeds from the commercialization of intellectual property
3 created through the public-private partnership created under Sections 1 to 5 of this Act
4 shall be deposited into the ibogaine research and intellectual property fund established
5 in Section 2 of this act and these moneys in the fund shall be expended only after all
6 funds appropriated in the 2026-2028 fiscal biennium have been expended.
7 Expenditures from the fund shall be used only for programs or research benefitting at-
8 risk populations that suffer from conditions treatable with ibogaine, including but not
9 limited to opioid use disorder, co-occurring substance use disorder, post-traumatic
10 stress disorder, traumatic brain injury, and other neurological or mental health
11 disorders.

12 ➔Section 6. There is hereby transferred moneys from the opioid abatement trust
13 fund established in KRS 15.293 in the amount of \$21,000,000 in each fiscal year of the
14 2026-2028 fiscal biennium to the ibogaine research and intellectual property fund
15 established in Section 2 of this Act. These funds are hereby appropriated for the purposes
16 set forth in Sections 1 to 5 of this Act.

17 ➔Section 7. Whereas it is essential that the General Assembly promptly provide
18 access to research and development of new drugs and medicines in the Commonwealth in
19 order to provide for the health and safety of citizens, an emergency is declared to exist,
20 and this Act takes effect upon its passage and approval by the Governor or upon its
21 otherwise becoming a law.