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SENATE FLOOR VERSION

April 6, 2015

AS AMENDED

ENGROSSED HOUSE

BILL NO. 2154

By: Echols, Grau, Montgomery,
Casey, Jordan, Cannaday,
Roberts (Sean), Perryman
and Nollan of the House

and

Crain and Standridge of the
Senate

An Act relating to public health and safety; creating
Katie's Law; amending 63 O.S. 2011, Section 2-101, as
last amended by Section 1, Chapter 154, O.S.L. 2014
(63 O.S. Supp. 2014, Section 2-101), which relates to
definitions of the Uniform Controlled Dangerous
Substances Act; modifying exception to certain
definition; defining terms; providing for the
establishment of statewide investigational new drug
applications for certain clinical trials; authorizing
physicians to serve as principal investigators for
clinical trials under certain circumstances;
providing for subinvestigators; directing
investigators and subinvestigators to adhere to
certain rules and regulations; providing guidelines
for establishing statewide investigational new drug
applications; providing exemptions from criminal or
civil penalties; providing for codification;
providing for noncodification; providing an effective
date; and declaring an emergency.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law not to be
codified in the Oklahoma Statutes reads as follows:

1 This act shall be known and may be cited as "**Katie and Cayman's**
2 Law".

3 SECTION 2. AMENDATORY 63 O.S. 2011, Section 2-101, as
4 last amended by Section 1, Chapter 154, O.S.L. 2014 (63 O.S. Supp.
5 2014, Section 2-101), is amended to read as follows:

6 Section 2-101. As used in the Uniform Controlled Dangerous
7 Substances Act:

8 1. "Administer" means the direct application of a controlled
9 dangerous substance, whether by injection, inhalation, ingestion or
10 any other means, to the body of a patient, animal or research
11 subject by:

12 a. a practitioner (or, in the presence of the
13 practitioner, by the authorized agent of the
14 practitioner), or

15 b. the patient or research subject at the direction and
16 in the presence of the practitioner;

17 2. "Agent" means a peace officer appointed by and who acts in
18 behalf of the Director of the Oklahoma State Bureau of Narcotics and
19 Dangerous Drugs Control or an authorized person who acts on behalf
20 of or at the direction of a person who manufactures, distributes,
21 dispenses, prescribes, administers or uses for scientific purposes
22 controlled dangerous substances but does not include a common or
23 contract carrier, public warehouser or employee thereof, or a person
24

1 required to register under the Uniform Controlled Dangerous
2 Substances Act;

3 3. "Board" means the Advisory Board to the Director of the
4 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;

5 4. "Bureau" means the Oklahoma State Bureau of Narcotics and
6 Dangerous Drugs Control;

7 5. "Coca leaves" includes cocaine and any compound,
8 manufacture, salt, derivative, mixture or preparation of coca
9 leaves, except derivatives of coca leaves which do not contain
10 cocaine or ecgonine;

11 6. "Commissioner" or "Director" means the Director of the
12 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control;

13 7. "Control" means to add, remove or change the placement of a
14 drug, substance or immediate precursor under the Uniform Controlled
15 Dangerous Substances Act;

16 8. "Controlled dangerous substance" means a drug, substance or
17 immediate precursor in Schedules I through V of the Uniform
18 Controlled Dangerous Substances Act or any drug, substance or
19 immediate precursor listed either temporarily or permanently as a
20 federally controlled substance. Any conflict between state and
21 federal law with regard to the particular schedule in which a
22 substance is listed shall be resolved in favor of state law;

23 9. "Counterfeit substance" means a controlled substance which,
24 or the container or labeling of which without authorization, bears

1 the trademark, trade name or other identifying marks, imprint,
2 number or device or any likeness thereof of a manufacturer,
3 distributor or dispenser other than the person who in fact
4 manufactured, distributed or dispensed the substance;

5 10. "Deliver" or "delivery" means the actual, constructive or
6 attempted transfer from one person to another of a controlled
7 dangerous substance or drug paraphernalia, whether or not there is
8 an agency relationship;

9 11. "Dispense" means to deliver a controlled dangerous
10 substance to an ultimate user or human research subject by or
11 pursuant to the lawful order of a practitioner, including the
12 prescribing, administering, packaging, labeling or compounding
13 necessary to prepare the substance for such distribution.

14 "Dispenser" is a practitioner who delivers a controlled dangerous
15 substance to an ultimate user or human research subject;

16 12. "Distribute" means to deliver other than by administering
17 or dispensing a controlled dangerous substance;

18 13. "Distributor" means a commercial entity engaged in the
19 distribution or reverse distribution of narcotics and dangerous
20 drugs and who complies with all regulations promulgated by the
21 federal Drug Enforcement Administration and the Oklahoma State
22 Bureau of Narcotics and Dangerous Drugs Control;

23 14. "Drug" means articles:
24

- 1 a. recognized in the official United States
2 Pharmacopoeia, official Homeopathic Pharmacopoeia of
3 the United States, or official National Formulary, or
4 any supplement to any of them,
5 b. intended for use in the diagnosis, cure, mitigation,
6 treatment or prevention of disease in man or other
7 animals,
8 c. other than food, intended to affect the structure or
9 any function of the body of man or other animals, and
10 d. intended for use as a component of any article
11 specified in this paragraph;

12 provided, however, the term "drug" does not include devices or their
13 components, parts or accessories;

14 15. "Drug-dependent person" means a person who is using a
15 controlled dangerous substance and who is in a state of psychic or
16 physical dependence, or both, arising from administration of that
17 controlled dangerous substance on a continuous basis. Drug
18 dependence is characterized by behavioral and other responses which
19 include a strong compulsion to take the substance on a continuous
20 basis in order to experience its psychic effects, or to avoid the
21 discomfort of its absence;

22 16. **Expanded-access clinical trial" means a process approved by**
23 **the United States Food and Drug Administration for the use of**
24

1 **investigational drugs to diagnose, monitor or otherwise treat a**
2 **patient;**

3 17. "Home care agency" means any sole proprietorship,
4 partnership, association, corporation, or other organization which
5 administers, offers, or provides home care services, for a fee or
6 pursuant to a contract for such services, to clients in their place
7 of residence;

8 ~~17.~~ 18. "Home care services" means skilled or personal care
9 services provided to clients in their place of residence for a fee;

10 ~~18.~~ 19. "Hospice" means a centrally administered, nonprofit or
11 profit, medically directed, nurse-coordinated program which provides
12 a continuum of home and inpatient care for the terminally ill
13 patient and the patient's family. Such term shall also include a
14 centrally administered, nonprofit or profit, medically directed,
15 nurse-coordinated program if such program is licensed pursuant to
16 the provisions of this act. A hospice program offers palliative and
17 supportive care to meet the special needs arising out of the
18 physical, emotional and spiritual stresses which are experienced
19 during the final stages of illness and during dying and bereavement.
20 This care is available twenty-four (24) hours a day, seven (7) days
21 a week, and is provided on the basis of need, regardless of ability
22 to pay. "Class A" Hospice refers to Medicare certified hospices.
23 "Class B" refers to all other providers of hospice services;
24

1 ~~19.~~ 20. "Imitation controlled substance" means a substance that
2 is not a controlled dangerous substance, which by dosage unit
3 appearance, color, shape, size, markings or by representations made,
4 would lead a reasonable person to believe that the substance is a
5 controlled dangerous substance. In the event the appearance of the
6 dosage unit is not reasonably sufficient to establish that the
7 substance is an "imitation controlled substance", the court or
8 authority concerned should consider, in addition to all other
9 factors, the following factors as related to "representations made"
10 in determining whether the substance is an "imitation controlled
11 substance":

- 12 a. statements made by an owner or by any other person in
13 control of the substance concerning the nature of the
14 substance, or its use or effect,
- 15 b. statements made to the recipient that the substance
16 may be resold for inordinate profit,
- 17 c. whether the substance is packaged in a manner normally
18 used for illicit controlled substances,
- 19 d. evasive tactics or actions utilized by the owner or
20 person in control of the substance to avoid detection
21 by law enforcement authorities,
- 22 e. prior convictions, if any, of an owner, or any other
23 person in control of the object, under state or
24

1 federal law related to controlled substances or fraud,
2 and

3 f. the proximity of the substances to controlled
4 dangerous substances;

5 ~~20.~~ 21. "Immediate precursor" means a substance which the
6 Director has found to be and by regulation designates as being the
7 principal compound commonly used or produced primarily for use, and
8 which is an immediate chemical intermediary used, or likely to be
9 used, in the manufacture of a controlled dangerous substance, the
10 control of which is necessary to prevent, curtail or limit such
11 manufacture;

12 ~~21.~~ 22. "Laboratory" means a laboratory approved by the
13 Director as proper to be entrusted with the custody of controlled
14 dangerous substances and the use of controlled dangerous substances
15 for scientific and medical purposes and for purposes of instruction;

16 ~~22.~~ 23. "Manufacture" means the production, preparation,
17 propagation, compounding or processing of a controlled dangerous
18 substance, either directly or indirectly by extraction from
19 substances of natural or synthetic origin, or independently by means
20 of chemical synthesis or by a combination of extraction and chemical
21 synthesis. "Manufacturer" includes any person who packages,
22 repackages or labels any container of any controlled dangerous
23 substance, except practitioners who dispense or compound
24 prescription orders for delivery to the ultimate consumer;

1 ~~23.~~ 24. "Marihuana" means all parts of the plant Cannabis
2 sativa L., whether growing or not; the seeds thereof; the resin
3 extracted from any part of such plant; and every compound,
4 manufacture, salt, derivative, mixture or preparation of such plant,
5 its seeds or resin, but shall not include:

6 a. the mature stalks of such plant, ~~or~~ or fiber produced
7 from such stalks,

8 b. oil or cake made from the seeds of such plant,
9 including cannabidiol derived from the seeds of the
10 marihuana plant,

11 c. any other compound, manufacture, salt, derivative,
12 mixture or preparation of such mature stalks (except
13 the resin extracted therefrom), including cannabidiol
14 derived from mature stalks, fiber, oil or cake, ~~or~~

15 d. the sterilized seed of such plant which is incapable
16 of germination,

17 e. for persons eighteen (18) years of age or younger
18 participating in a clinical trial or in an expanded-
19 access **clinical trial** related to administering
20 cannabidiol for the treatment of severe forms of
21 epilepsy pursuant to Section 4 of this act, a drug or
22 substance approved by the federal Food and Drug
23 Administration for use by those participants, or
24

- 1 f. for persons eighteen (18) years of age or younger, or
2 the parents, legal guardians, or caretakers of the
3 person, who have received a written certification from
4 a physician licensed in this state that the person has
5 been diagnosed by a physician as having Lennox-Gastaut
6 Syndrome, Dravet Syndrome, also known as Severe
7 Myoclonic Epilepsy of Infancy, or any other severe
8 form of epilepsy that is not adequately treated by
9 traditional medical therapies, the substance
10 cannabidiol, a nonpsychoactive cannabinoid, found in
11 the plant Cannabis sativa L. or any other preparation
12 thereof, that has a tetrahydrocannabinol concentration
13 of not more than three-tenths of one percent (0.3%)
14 and that is delivered to the patient in the form of a
15 liquid, or
16 g. industrial hemp, from the plant Cannabis sativa L. and
17 any part of such plant, whether growing or not, with a
18 delta-9 tetrahydrocannabinol concentration of not more
19 than three-tenths of one percent (0.3%) on a dry
20 weight basis which shall not be grown anywhere in the
21 State of Oklahoma but may be shipped to Oklahoma
22 pursuant to the provisions of subparagraph e or f of
23 this paragraph;
24

1 ~~24.~~ 25. "Medical purpose" means an intention to utilize a
2 controlled dangerous substance for physical or mental treatment, for
3 diagnosis, or for the prevention of a disease condition not in
4 violation of any state or federal law and not for the purpose of
5 satisfying physiological or psychological dependence or other abuse;

6 ~~25.~~ 26. "Mid-level practitioner" means an advanced practice
7 nurse as defined and within parameters specified in Section 567.3a
8 of Title 59 of the Oklahoma Statutes, or a certified animal
9 euthanasia technician as defined in Section 698.2 of Title 59 of the
10 Oklahoma Statutes, or an animal control officer registered by the
11 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control under
12 subsection B of Section 2-301 of this title within the parameters of
13 such officer's duty under Sections 501 through 508 of Title 4 of the
14 Oklahoma Statutes;

15 ~~26.~~ 27. "Narcotic drug" means any of the following, whether
16 produced directly or indirectly by extraction from substances of
17 vegetable origin, or independently by means of chemical synthesis,
18 or by a combination of extraction and chemical synthesis:

- 19 a. opium, coca leaves and opiates,
- 20 b. a compound, manufacture, salt, derivative or
21 preparation of opium, coca leaves or opiates,
- 22 c. cocaine, its salts, optical and geometric isomers, and
23 salts of isomers,
- 24

- d. ecgonine, its derivatives, their salts, isomers and salts of isomers, and
- e. a substance, and any compound, manufacture, salt, derivative or preparation thereof, which is chemically identical with any of the substances referred to in subparagraphs a through d of this paragraph, except that the words "narcotic drug" as used in Section 2-101 et seq. of this title shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine;

~~27.~~ **28.** "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under the Uniform Controlled Dangerous Substances Act, the dextrorotatory isomer of 3-methoxy-n-methyl-morphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms;

~~28.~~ **29.** "Opium poppy" means the plant of the species *Papaver somniferum* L., except the seeds thereof;

~~29.~~ **30.** "Peace officer" means a police officer, sheriff, deputy sheriff, district attorney's investigator, investigator from the Office of the Attorney General, or any other person elected or

1 appointed by law to enforce any of the criminal laws of this state
2 or of the United States;

3 ~~30.~~ 31. "Person" means an individual, corporation, government
4 or governmental subdivision or agency, business trust, estate,
5 trust, partnership or association, or any other legal entity;

6 ~~31.~~ 32. "Poppy straw" means all parts, except the seeds, of the
7 opium poppy, after mowing;

8 ~~32.~~ 33. "Practitioner" means:

- 9 a. (1) a medical doctor or osteopathic physician,
10 (2) a dentist,
11 (3) a podiatrist,
12 (4) an optometrist,
13 (5) a veterinarian,
14 (6) a physician assistant under the supervision of a
15 licensed medical doctor or osteopathic physician,
16 (7) a scientific investigator, or
17 (8) any other person,
18 licensed, registered or otherwise permitted to
19 prescribe, distribute, dispense, conduct research with
20 respect to, use for scientific purposes or administer
21 a controlled dangerous substance in the course of
22 professional practice or research in this state, or
23 b. a pharmacy, hospital, laboratory or other institution
24 licensed, registered or otherwise permitted to

1 distribute, dispense, conduct research with respect
2 to, use for scientific purposes or administer a
3 controlled dangerous substance in the course of
4 professional practice or research in this state;

5 ~~33.~~ 34. "Production" includes the manufacture, planting,
6 cultivation, growing or harvesting of a controlled dangerous
7 substance;

8 ~~34.~~ 35. "State" means the State of Oklahoma or any other state
9 of the United States;

10 ~~35.~~ 36. "Ultimate user" means a person who lawfully possesses a
11 controlled dangerous substance for the person's own use or for the
12 use of a member of the person's household or for administration to
13 an animal owned by the person or by a member of the person's
14 household;

15 ~~36.~~ 37. "Drug paraphernalia" means all equipment, products and
16 materials of any kind which are used, intended for use, or fashioned
17 specifically for use in planting, propagating, cultivating, growing,
18 harvesting, manufacturing, compounding, converting, producing,
19 processing, preparing, testing, analyzing, packaging, repackaging,
20 storing, containing, concealing, injecting, ingesting, inhaling or
21 otherwise introducing into the human body, a controlled dangerous
22 substance in violation of the Uniform Controlled Dangerous
23 Substances Act including, but not limited to:

- 1 a. kits used, intended for use, or fashioned specifically
2 for use in planting, propagating, cultivating, growing
3 or harvesting of any species of plant which is a
4 controlled dangerous substance or from which a
5 controlled dangerous substance can be derived,
- 6 b. kits used, intended for use, or fashioned specifically
7 for use in manufacturing, compounding, converting,
8 producing, processing or preparing controlled
9 dangerous substances,
- 10 c. isomerization devices used, intended for use, or
11 fashioned specifically for use in increasing the
12 potency of any species of plant which is a controlled
13 dangerous substance,
- 14 d. testing equipment used, intended for use, or fashioned
15 specifically for use in identifying, or in analyzing
16 the strength, effectiveness or purity of controlled
17 dangerous substances,
- 18 e. scales and balances used, intended for use, or
19 fashioned specifically for use in weighing or
20 measuring controlled dangerous substances,
- 21 f. diluents and adulterants, such as quinine
22 hydrochloride, mannitol, mannite, dextrose and
23 lactose, used, intended for use, or fashioned
24

specifically for use in cutting controlled dangerous substances,

g. separation gins and sifters used, intended for use, or fashioned specifically for use in removing twigs and seeds from, or in otherwise cleaning or refining, marihuana,

h. blenders, bowls, containers, spoons and mixing devices used, intended for use, or fashioned specifically for use in compounding controlled dangerous substances,

i. capsules, balloons, envelopes and other containers used, intended for use, or fashioned specifically for use in packaging small quantities of controlled dangerous substances,

j. containers and other objects used, intended for use, or fashioned specifically for use in parenterally injecting controlled dangerous substances into the human body,

k. hypodermic syringes, needles and other objects used, intended for use, or fashioned specifically for use in parenterally injecting controlled dangerous substances into the human body,

l. objects used, intended for use, or fashioned specifically for use in ingesting, inhaling or

otherwise introducing marihuana, cocaine, hashish or hashish oil into the human body, such as:

- (1) metal, wooden, acrylic, glass, stone, plastic or ceramic pipes with or without screens, permanent screens, hashish heads or punctured metal bowls,
- (2) water pipes,
- (3) carburetion tubes and devices,
- (4) smoking and carburetion masks,
- (5) roach clips, meaning objects used to hold burning material, such as a marihuana cigarette, that has become too small or too short to be held in the hand,
- (6) miniature cocaine spoons and cocaine vials,
- (7) chamber pipes,
- (8) carburetor pipes,
- (9) electric pipes,
- (10) air-driven pipes,
- (11) chillums,
- (12) bongs, or
- (13) ice pipes or chillers,

m. all hidden or novelty pipes, and

n. any pipe that has a tobacco bowl or chamber of less than one-half (1/2) inch in diameter in which there is any detectable residue of any controlled dangerous

1 substance as defined in this section or any other
2 substances not legal for possession or use;
3 provided, however, the term "drug paraphernalia" shall not include
4 separation gins intended for use in preparing tea or spice, clamps
5 used for constructing electrical equipment, water pipes designed for
6 ornamentation in which no detectable amount of an illegal substance
7 is found or pipes designed and used solely for smoking tobacco,
8 traditional pipes of an American Indian tribal religious ceremony,
9 or antique pipes that are thirty (30) years of age or older;

10 ~~37.~~

11 **38.** a. "Synthetic controlled substance" means a substance:

- 12 (1) the chemical structure of which is substantially
13 similar to the chemical structure of a controlled
14 dangerous substance in Schedule I or II,
15 (2) which has a stimulant, depressant, or
16 hallucinogenic effect on the central nervous
17 system that is substantially similar to or
18 greater than the stimulant, depressant or
19 hallucinogenic effect on the central nervous
20 system of a controlled dangerous substance in
21 Schedule I or II, or
22 (3) with respect to a particular person, which such
23 person represents or intends to have a stimulant,
24 depressant, or hallucinogenic effect on the

1 central nervous system that is substantially
2 similar to or greater than the stimulant,
3 depressant, or hallucinogenic effect on the
4 central nervous system of a controlled dangerous
5 substance in Schedule I or II.

6 b. The designation of gamma butyrolactone or any other
7 chemical as a precursor, pursuant to Section 2-322 of
8 this title, does not preclude a finding pursuant to
9 subparagraph a of this paragraph that the chemical is
10 a synthetic controlled substance.

11 c. "Synthetic controlled substance" does not include:
12 (1) a controlled dangerous substance,
13 (2) any substance for which there is an approved new
14 drug application,
15 (3) with respect to a particular person any
16 substance, if an exemption is in effect for
17 investigational use, for that person under the
18 provisions of Section 505 of the Federal Food,
19 Drug and Cosmetic Act, Title 21 of the United
20 States Code, Section 355, to the extent conduct
21 with respect to such substance is pursuant to
22 such exemption, or
23
24

(4) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

d. Prima facie evidence that a substance containing salvia divinorum has been enhanced, concentrated or chemically or physically altered shall give rise to a rebuttable presumption that the substance is a synthetic controlled substance;

~~38.~~ 39. "Tetrahydrocannabinols" means all substances that have been chemically synthesized to emulate the tetrahydrocannabinols of marihuana;

~~39.~~ 40. "Isomer" means the optical isomer, except as used in subsections C and F of Section 2-204 of this title and paragraph 4 of subsection A of Section 2-206 of this title. As used in subsections C and F of Section 2-204 of this title, "isomer" means the optical, positional or geometric isomer. As used in paragraph 4 of subsection A of Section 2-206 of this title, the term "isomer" means the optical or geometric isomer;

~~40.~~ 41. "Hazardous materials" means materials, whether solid, liquid or gas, which are toxic to human, animal, aquatic or plant life, and the disposal of which materials is controlled by state or federal guidelines; and

~~41.~~ 42. "Anhydrous ammonia" means any substance that exhibits cryogenic evaporative behavior and tests positive for ammonia.

1 SECTION 3. NEW LAW A new section of law to be codified
2 in the Oklahoma Statutes as Section 2-801 of Title 63, unless there
3 is created a duplication in numbering, reads as follows:

4 As used in this act:

5 1. "Academic medical center" means a medical school and its
6 affiliated teaching hospitals and clinics **in this state** that:

- 7 a. operate a medical residency program for physicians,
8 and
9 b. conduct research that is overseen by the federal
10 Department of Health and Human Services and involves
11 human subjects;

12 2. "Approved source" means a provider approved by the United
13 States Food and Drug Administration which produces cannabidiol that:

- 14 a. has been manufactured and tested in a facility
15 approved or certified by the United States Food and
16 Drug Administration or similar national regulatory
17 agency in another country which has been approved by
18 the United States Food and Drug Administration, and
19 b. has been tested on animals to demonstrate preliminary
20 effectiveness and to ensure that it is safe to
21 administer to humans;

22 3. "Cannabidiol" means a nonpsychoactive cannabinoid found in
23 the plant Cannabis sativa L. or any other preparation thereof, that
24 has a tetrahydrocannabinol concentration of not more than three-

1 tenths of one percent (0.3%) and that is delivered to the patient in
2 the form of a liquid;

3 4. "Physician" means a doctor of medicine or doctor of
4 osteopathic medicine licensed by the **State Board of Medical**
5 **Licensure and Supervision or the State Board of Osteopathic**
6 **Examiners;** and

7 5. "Qualifying patient" means any person eighteen (18) years of
8 age or younger who suffers from Lennox-Gastaut Syndrome, Dravet
9 Syndrome, also known as Severe Myoclonic Epilepsy of Infancy, or any
10 other form of refractory epilepsy that is not adequately treated by
11 traditional medical therapies.

12 SECTION 4. NEW LAW A new section of law to be codified
13 in the Oklahoma Statutes as Section 2-802 of Title 63, unless there
14 is created a duplication in numbering, reads as follows:

15 A. A statewide investigational new drug application may be
16 established in this state, if approved by the United States Food and
17 Drug Administration, to conduct expanded-access clinical trials
18 using cannabidiol on qualifying patients with severe forms of
19 epilepsy.

20 B. Any physician **licensed by the State Board of Medical**
21 **Licensure and Supervision or the State Board of Osteopathic**
22 **Examiners,** practicing in an academic medical center in this state,
23 and treating patients with severe forms of epilepsy may serve as the
24 principal investigator for such clinical trials if such physician:

1 1. Applies to and is approved by the United States Food and
2 Drug Administration as the principal investigator in a statewide
3 investigational new drug application;

4 2. Receives a license from the United States Drug Enforcement
5 Administration; **and**

6 **3. Receives a registration from the Oklahoma State Bureau of**
7 **Narcotics and Dangerous Drugs Control.**

8 C. Such physician, acting as principal investigator, may
9 include subinvestigators who are also board certified, practice in
10 an academic medical center in this state, and treat patients with
11 severe forms of epilepsy. Such subinvestigators shall be required
12 to comply with the licensing requirement provided in paragraphs 2
13 **and 3** of subsection B of this section.

14 D. The principal investigator and all subinvestigators shall
15 adhere to the rules and regulations established by the relevant
16 institutional review board for each participating academic medical
17 center and by the United States Food and Drug Administration, the
18 United States Drug Enforcement Administration, **the Oklahoma State**
19 **Bureau of Narcotics and Dangerous Drugs Control**, and the National
20 Institute on Drug Abuse.

21 E. Nothing in this section shall be construed to prohibit a
22 physician licensed in Oklahoma from applying for Investigational New
23 Drug authorization from the United States Food and Drug
24 Administration.

1 **F. The Oklahoma State Bureau of Narcotics and Dangerous Drugs**
2 **Control shall have the authority to inspect and test samples of**
3 **cannabidiol used in this state pursuant to the provisions of this**
4 **act.**

5 SECTION 5. NEW LAW A new section of law to be codified
6 in the Oklahoma Statutes as Section 2-803 of Title 63, unless there
7 is created a duplication in numbering, reads as follows:

8 A. Expanded-access clinical trials conducted pursuant to a
9 statewide investigational new drug application established pursuant
10 to the provisions of this act shall only utilize cannabidiol which
11 is:

12 1. From an approved source; and

13 2. Approved by the United States Food and Drug Administration
14 to be used for treatment of a condition specified in an
15 investigational new drug application.

16 B. The principal investigator and any subinvestigator may
17 receive cannabidiol directly from an approved source or authorized
18 distributor for an approved source for use in the expanded-access
19 clinical trials.

20 SECTION 6. NEW LAW A new section of law to be codified
21 in the Oklahoma Statutes as Section 2-804 of Title 63, unless there
22 is created a duplication in numbering, reads as follows:

23 A person acting in compliance with the provisions of this act
24 shall not be subject to arrest, prosecution, or any civil or

1 administrative penalty, including a civil penalty or disciplinary
2 action by a professional licensing board, or be denied any right or
3 privilege, for the use, prescription, administration, possession,
4 manufacture, or distribution of medical cannabidiol.

5 **SECTION 7. NEW LAW A new section of law to be codified**
6 **in the Oklahoma Statutes as Section 2-805 of Title 63, unless there**
7 **is created a duplication in numbering, reads as follows:**

8 **A. The State Commissioner of Health shall have the authority to**
9 **approve all academic medical centers and physicians conducting**
10 **clinical trials performed pursuant to the provisions of this act.**
11 **In the event of a substantial violation of this act, the**
12 **Commissioner shall provide written notice to the Oklahoma State**
13 **Bureau of Narcotics and Dangerous Drugs Control and the Governor.**
14 **The Governor, upon receipt of a notice from the Commissioner, shall**
15 **have the authority to terminate the operations of a clinical trial**
16 **found to be in violation of any provision of this act.**

17 **B. The clinical trials and related research authorized by this**
18 **act shall adhere to the highest standards of academic research**
19 **including, but not limited to, peer review of research conducted**
20 **pursuant to this act.**

21 **C. Clinical trials and related research authorized by this act**
22 **shall conclude no later than December 31, 2017. Nothing in this act**
23 **shall be construed as to permit the continuation of clinical trials**
24 **after December 31, 2017, without approval by a concurrent resolution**

1 approved by the Legislature expressing approval of such
2 continuation.

3 D. The State Commissioner of Health shall submit a report to
4 the Chair and Vice Chair of the Senate Health and Human Services
5 Committee, the Chair and Vice Chair of the House Alcohol, Tobacco
6 and Dangerous Drugs Committee, and the Chair and Vice Chair of the
7 House Public Health Committee on or before December 31, 2017. Such
8 report shall include a summary of findings from expanded-access
9 clinical trials authorized by this act. The Commissioner shall,
10 upon request by the Chair and Vice Chair of the Committees specified
11 in this subsection, make available any data relating to expanded-
12 access clinical trials authorized by this act.

13 E. The Oklahoma State Bureau of Narcotics and Dangerous Drugs
14 Control, the State Board of Health, and the Oklahoma State Regents
15 for Higher Education shall promulgate rules to implement the
16 provisions of this act.

17 SECTION 8. This act shall become effective July 1, 2015.

18 SECTION 7. It being immediately necessary for the preservation
19 of the public peace, health and safety, an emergency is hereby
20 declared to exist, by reason whereof this act shall take effect and
21 be in full force from and after its passage and approval.

22 COMMITTEE REPORT BY: COMMITTEE ON HEALTH AND HUMAN SERVICES
23 April 6, 2015 - DO PASS AS AMENDED
24