ENGROSSED SENATE AMENDMENT
TO
ENGROSSED HOUSE
BILL NO. 2154

By: Echols, Grau, Montgomery, Casey, Jordan and Cannaday of the House

and

Crain 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; and declaring an emergency.

AUTHOR: Add the following Senate Coauthors: Standridge, Sharp, Yen and Newberry

AUTHOR: Add the following House Coauthors: Roberts (Sean), Perryman and Nollan

AMENDMENT NO. 1. Page 1, strike the title, enacting clause and entire bill and insert

"An Act relating to public health and safety; creating Katie and Cayman'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; permitting Oklahoma State Bureau of Narcotics and Dangerous Drugs Control to inspect certain samples; providing guidelines for conducting clinical trials; providing exemptions from criminal or civil penalties; permitting State Commissioner of Health to perform certain acts; requiring clinical trials to comply with certain standards; providing termination date; requiring certain approval for continuation of clinical trials; requiring submission of certain report; specifying contents of report; permitting Commissioner to disclose certain data; directing promulgation of rules by certain entities; providing for codification; providing for noncodification; 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:

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

SECTION 2. AMENDATORY 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), is amended to read as follows:

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

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

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

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

2. "Agent" means a peace officer appointed by and who acts in behalf of the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or an authorized person who acts on behalf of or at the direction of a person who manufactures, distributes, dispenses, prescribes, administers or uses for scientific purposes controlled dangerous substances but does not include a common or contract carrier, public warehouser or employee thereof, or a person required to register under the Uniform Controlled Dangerous Substances Act;

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

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

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

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

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

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

9. "Counterfeit substance" means a controlled substance which, or the container or labeling of which without authorization, bears the trademark, trade name or other identifying marks, imprint, number or device or any likeness thereof of a manufacturer,

distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance;

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

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

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

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

14. "Drug" means articles:

a. recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of

the United States, or official National Formulary, or any supplement to any of them,

b. intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals,

c. other than food, intended to affect the structure or any function of the body of man or other animals, and

d. intended for use as a component of any article specified in this paragraph;

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

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

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

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

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

19. "Imitation controlled substance" means a substance that is not a controlled dangerous substance, which by dosage unit appearance, color, shape, size, markings or by representations made, would lead a reasonable person to believe that the substance is a controlled dangerous substance. In the event the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance", the court or authority concerned should consider, in addition to all other

factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

a. statements made by an owner or by any other person in control of the substance concerning the nature of the substance, or its use or effect,

b. statements made to the recipient that the substance may be resold for inordinate profit,

c. whether the substance is packaged in a manner normally used for illicit controlled substances,

d. evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities,

e. prior convictions, if any, of an owner, or any other person in control of the object, under state or federal law related to controlled substances or fraud, and

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

20. "Immediate precursor" means a substance which the Director has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used, or likely to be used, in

the manufacture of a controlled dangerous substance, the control of which is necessary to prevent, curtail or limit such manufacture;

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

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

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

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

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

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

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

e. for persons eighteen (18) years of age or younger participating in a clinical trial to administering cannabidiol for the treatment of severe forms of epilepsy pursuant to Section 4 of this act, a drug or substance approved by the federal Food and Drug Administration for use by those participants, or

f. for persons eighteen (18) years of age or younger, or the parents, legal guardians, or caretakers of the person, who have received a written certification from a physician licensed in this state that the person has been diagnosed by a physician as having Lennox-Gastaut Syndrome, Dravet Syndrome, also known as Severe Myoclonic Epilepsy of Infancy, or any other severe form of epilepsy that is not adequately treated by traditional medical therapies, the substance

cannabidiol, a nonpsychoactive cannabinoid, found in the plant Cannabis sativa L. or any other preparation thereof, that has a tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) and that is delivered to the patient in the form of a liquid, or

g. industrial hemp, from the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis which shall not be grown anywhere in the State of Oklahoma but may be shipped to Oklahoma pursuant to the provisions of subparagraph e or f of this paragraph;

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

25. "Mid-level practitioner" means an advanced practice nurse as defined and within parameters specified in Section 567.3a of Title 59 of the Oklahoma Statutes, or a certified animal euthanasia technician as defined in Section 698.2 of Title 59 of the Oklahoma Statutes, or an animal control officer registered by the Oklahoma

State Bureau of Narcotics and Dangerous Drugs Control under subsection B of Section 2-301 of this title within the parameters of such officer's duty under Sections 501 through 508 of Title 4 of the Oklahoma Statutes;

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

a. opium, coca leaves and opiates,

b. a compound, manufacture, salt, derivative or preparation of opium, coca leaves or opiates,

c. cocaine, its salts, optical and geometric isomers, and salts of isomers,

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

29. "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 appointed by law to enforce any of the criminal laws of this state or of the United States;

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

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

32. "Practitioner" means:

a. (1) a medical doctor or osteopathic physician,

(2) a dentist,

(3) a podiatrist,

(4) an optometrist,

(5) a veterinarian,

(6) a physician assistant under the supervision of a licensed medical doctor or osteopathic physician,

(7) a scientific investigator, or

(8) any other person,

licensed, registered or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, use for scientific purposes or administer a controlled dangerous substance in the course of professional practice or research in this state, or

b. a pharmacy, hospital, laboratory or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, use for scientific purposes or administer a controlled dangerous substance in the course of professional practice or research in this state;

33. "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled dangerous substance;

34. "State" means the State of Oklahoma or any other state of the United States;

35. "Ultimate user" means a person who lawfully possesses a controlled dangerous substance for the person's own use or for the

use of a member of the person's household or for administration to an animal owned by the person or by a member of the person's household;

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

a. kits used, intended for use, or fashioned specifically for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled dangerous substance or from which a controlled dangerous substance can be derived,

b. kits used, intended for use, or fashioned specifically for use in manufacturing, compounding, converting, producing, processing or preparing controlled dangerous substances,

c. isomerization devices used, intended for use, or fashioned specifically for use in increasing the

potency of any species of plant which is a controlled dangerous substance,

d. testing equipment used, intended for use, or fashioned specifically for use in identifying, or in analyzing the strength, effectiveness or purity of controlled dangerous substances,

e. scales and balances used, intended for use, or fashioned specifically for use in weighing or measuring controlled dangerous substances,

f. diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used, intended for use, or fashioned 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 substance as defined in this section or any other substances not legal for possession or use;

provided, however, the term "drug paraphernalia" shall not include separation gins intended for use in preparing tea or spice, clamps used for constructing electrical equipment, water pipes designed for ornamentation in which no detectable amount of an illegal substance is found or pipes designed and used solely for smoking tobacco, traditional pipes of an American Indian tribal religious ceremony, or antique pipes that are thirty (30) years of age or older;

37. a. "Synthetic controlled substance" means a substance:

(1) the chemical structure of which is substantially similar to the chemical structure of a controlled dangerous substance in Schedule I or II,

(2) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled dangerous substance in Schedule I or II, or

(3) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled dangerous substance in Schedule I or II.

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

c. "Synthetic controlled substance" does not include:

(1) a controlled dangerous substance,

(2) any substance for which there is an approved new drug application,

(3) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person under the provisions of Section 505 of the Federal Food, Drug and Cosmetic Act, Title 21 of the United States Code, Section 355, to the extent conduct with respect to such substance is pursuant to such exemption, or

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

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

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

As used in this act:

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

a. operate a medical residency program for physicians, and

b. conduct research that is overseen by the federal Department of Health and Human Services and involves human subjects;

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

a. has been manufactured and tested in a facility approved or certified by the United States Food and Drug Administration or similar national regulatory agency in another country which has been approved by the United States Food and Drug Administration, and

b. has been tested on animals to demonstrate preliminary effectiveness and to ensure that it is safe to administer to humans;

3. "Cannabidiol" means a nonpsychoactive cannabinoid found in the plant Cannabis sativa L. or any other preparation thereof, that has a tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) and that is delivered to the patient in the form of a liquid;

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

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

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

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

B. Any physician licensed by the State Board of Medical Licensure and Supervision or the State Board of Osteopathic Examiners, practicing in this state, and treating patients with severe forms of epilepsy may serve as the principal investigator for such clinical trials if such physician:

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

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

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

C. Such physician, acting as principal investigator, may include subinvestigators who are also board certified, practice in an academic medical center in this state, and treat patients with severe forms of epilepsy. Such subinvestigators shall be required

to comply with the licensing requirement provided in paragraphs 2 and 3 of subsection B of this section.

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

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

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

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

A. Clinical trials conducted pursuant to a statewide investigational new drug application established pursuant to the provisions of this act shall only utilize cannabidiol which is:

1. From an approved source; and

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

B. The principal investigator and any subinvestigator may receive cannabidiol directly from an approved source or authorized distributor for an approved source for use in the clinical trials.

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

A person acting in compliance with the provisions of this act shall not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the use, prescription, administration, possession, manufacture, or distribution of medical cannabidiol.

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

A. The State Commissioner of Health shall have the authority to approve physicians conducting clinical trials performed pursuant to the provisions of this act. In the event of a substantial violation of this act, the Commissioner shall provide written notice to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and the Governor. The Governor, upon receipt of a notice from the

Commissioner, shall have the authority to terminate the operations of a clinical trial found to be in violation of any provision of this act.

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

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

D. The State Commissioner of Health shall submit a report to the Chair and Vice Chair of the Senate Health and Human Services Committee, the Chair and Vice Chair of the House Alcohol, Tobacco and Dangerous Drugs Committee, and the Chair and Vice Chair of the House Public Health Committee on or before December 31, 2017. Such report shall include a summary of findings from clinical trials authorized by this act. The Commissioner shall, upon request by the Chair and Vice Chair of the Committees specified in this subsection, make available any data, excluding individual health records, relating to clinical trials authorized by this act.

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

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

Passed the Senate the 15th day of April, 2015.

_____
Presiding Officer of the Senate

Passed the House of Representatives the ____ day of _____, 2015.

_____
Presiding Officer of the House of Representatives

ENGROSSED HOUSE
BILL NO. 2154

By: Echols, Grau, Montgomery, Casey, Jordan and Cannaday of the House

and

Crain 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; and declaring an emergency.

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

SECTION 8. NEW LAW A new section of law not to be codified in the Oklahoma Statutes reads as follows:

This act shall be known and may be cited as "Katie's Law".

SECTION 9. AMENDATORY 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), is amended to read as follows:

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

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

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

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

2. "Agent" means a peace officer appointed by and who acts in behalf of the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or an authorized person who acts on behalf of or at the direction of a person who manufactures, distributes, dispenses, prescribes, administers or uses for scientific purposes controlled dangerous substances but does not include a common or contract carrier, public warehouser or employee thereof, or a person required to register under the Uniform Controlled Dangerous Substances Act;

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

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

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

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

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

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

9. "Counterfeit substance" means a controlled substance which, or the container or labeling of which without authorization, bears the trademark, trade name or other identifying marks, imprint, number or device or any likeness thereof of a manufacturer,

distributor or dispenser other than the person who in fact manufactured, distributed or dispensed the substance;

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

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

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

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

14. "Drug" means articles:

a. recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of

the United States, or official National Formulary, or any supplement to any of them,

b. intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals,

c. other than food, intended to affect the structure or any function of the body of man or other animals, and

d. intended for use as a component of any article specified in this paragraph;

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

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

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

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

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

19. "Imitation controlled substance" means a substance that is not a controlled dangerous substance, which by dosage unit appearance, color, shape, size, markings or by representations made, would lead a reasonable person to believe that the substance is a controlled dangerous substance. In the event the appearance of the dosage unit is not reasonably sufficient to establish that the substance is an "imitation controlled substance", the court or authority concerned should consider, in addition to all other

factors, the following factors as related to "representations made" in determining whether the substance is an "imitation controlled substance":

a. statements made by an owner or by any other person in control of the substance concerning the nature of the substance, or its use or effect,

b. statements made to the recipient that the substance may be resold for inordinate profit,

c. whether the substance is packaged in a manner normally used for illicit controlled substances,

d. evasive tactics or actions utilized by the owner or person in control of the substance to avoid detection by law enforcement authorities,

e. prior convictions, if any, of an owner, or any other person in control of the object, under state or federal law related to controlled substances or fraud, and

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

20. "Immediate precursor" means a substance which the Director has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used, or likely to be used, in

the manufacture of a controlled dangerous substance, the control of which is necessary to prevent, curtail or limit such manufacture;

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

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

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

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

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

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

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

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

f. for persons eighteen (18) years of age or younger, or the parents, legal guardians, or caretakers of the person, who have received a written certification from a physician licensed in this state that the person has been diagnosed by a physician as having Lennox-Gastaut Syndrome, Dravet Syndrome, also known as Severe Myoclonic Epilepsy of Infancy, or any other severe form of epilepsy that is not adequately treated by

traditional medical therapies, the substance cannabidiol, a nonpsychoactive cannabinoid, found in the plant Cannabis sativa L. or any other preparation thereof, that has a tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) and that is delivered to the patient in the form of a liquid, or

g. industrial hemp, from the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis which shall not be grown anywhere in the State of Oklahoma but may be shipped to Oklahoma pursuant to the provisions of subparagraph e or f of this paragraph;

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

25. "Mid-level practitioner" means an advanced practice nurse as defined and within parameters specified in Section 567.3a of Title 59 of the Oklahoma Statutes, or a certified animal euthanasia technician as defined in Section 698.2 of Title 59 of the Oklahoma

Statutes, or an animal control officer registered by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control under subsection B of Section 2-301 of this title within the parameters of such officer's duty under Sections 501 through 508 of Title 4 of the Oklahoma Statutes;

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

a. opium, coca leaves and opiates,

b. a compound, manufacture, salt, derivative or preparation of opium, coca leaves or opiates,

c. cocaine, its salts, optical and geometric isomers, and salts of isomers,

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

29. "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 appointed by law to enforce any of the criminal laws of this state or of the United States;

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

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

32. "Practitioner" means:

a. (1) a medical doctor or osteopathic physician,

(2) a dentist,

(3) a podiatrist,

(4) an optometrist,

(5) a veterinarian,

(6) a physician assistant under the supervision of a licensed medical doctor or osteopathic physician,

(7) a scientific investigator, or

(8) any other person,

licensed, registered or otherwise permitted to prescribe, distribute, dispense, conduct research with respect to, use for scientific purposes or administer a controlled dangerous substance in the course of professional practice or research in this state, or

b. a pharmacy, hospital, laboratory or other institution licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to, use for scientific purposes or administer a controlled dangerous substance in the course of professional practice or research in this state;

33. "Production" includes the manufacture, planting, cultivation, growing or harvesting of a controlled dangerous substance;

34. "State" means the State of Oklahoma or any other state of the United States;

35. "Ultimate user" means a person who lawfully possesses a controlled dangerous substance for the person's own use or for the

use of a member of the person's household or for administration to an animal owned by the person or by a member of the person's household;

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

a. kits used, intended for use, or fashioned specifically for use in planting, propagating, cultivating, growing or harvesting of any species of plant which is a controlled dangerous substance or from which a controlled dangerous substance can be derived,

b. kits used, intended for use, or fashioned specifically for use in manufacturing, compounding, converting, producing, processing or preparing controlled dangerous substances,

c. isomerization devices used, intended for use, or fashioned specifically for use in increasing the

potency of any species of plant which is a controlled dangerous substance,

d. testing equipment used, intended for use, or fashioned specifically for use in identifying, or in analyzing the strength, effectiveness or purity of controlled dangerous substances,

e. scales and balances used, intended for use, or fashioned specifically for use in weighing or measuring controlled dangerous substances,

f. diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose and lactose, used, intended for use, or fashioned 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 substance as defined in this section or any other substances not legal for possession or use;

provided, however, the term "drug paraphernalia" shall not include separation gins intended for use in preparing tea or spice, clamps used for constructing electrical equipment, water pipes designed for ornamentation in which no detectable amount of an illegal substance is found or pipes designed and used solely for smoking tobacco, traditional pipes of an American Indian tribal religious ceremony, or antique pipes that are thirty (30) years of age or older;

37. a. "Synthetic controlled substance" means a substance:

(1) the chemical structure of which is substantially similar to the chemical structure of a controlled dangerous substance in Schedule I or II,

(2) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant or hallucinogenic effect on the central nervous system of a controlled dangerous substance in Schedule I or II, or

(3) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled dangerous substance in Schedule I or II.

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

c. "Synthetic controlled substance" does not include:

(1) a controlled dangerous substance,

(2) any substance for which there is an approved new drug application,

(3) with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person under the provisions of Section 505 of the Federal Food, Drug and Cosmetic Act, Title 21 of the United States Code, Section 355, to the extent conduct with respect to such substance is pursuant to such exemption, or

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

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

SECTION 10. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-801 of Title 63, unless there is created a duplication in numbering, reads as follows:

As used in this act:

1. "Academic medical center" means a medical school and its affiliated teaching hospitals and clinics that:

a. operate a medical residency program for physicians, and

b. conduct research that is overseen by the federal Department of Health and Human Services and involves human subjects;

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

a. has been manufactured and tested in a facility approved or certified by the United States Food and Drug Administration or similar national regulatory agency in another country which has been approved by the United States Food and Drug Administration, and

b. has been tested on animals to demonstrate preliminary effectiveness and to ensure that it is safe to administer to humans;

3. "Cannabidiol" means a nonpsychoactive cannabinoid found in the plant Cannabis sativa L. or any other preparation thereof, that has a tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) and that is delivered to the patient in the form of a liquid;

4. "Physician" means a doctor of medicine or doctor of osteopathic medicine licensed by the Oklahoma Board of Medical Examiners; and

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

SECTION 11. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-802 of Title 63, unless there is created a duplication in numbering, reads as follows:

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

B. Any physician who is board certified, practicing in an academic medical center in this state, and treating patients with severe forms of epilepsy may serve as the principal investigator for such clinical trials if such physician:

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

2. Receives a license from the United States Drug Enforcement Administration.

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

D. The principal investigator and all subinvestigators shall adhere to the rules and regulations established by the relevant institutional review board for each participating academic medical center and by the United States Food and Drug Administration, the

United States Drug Enforcement Administration and the National Institute on Drug Abuse.

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

SECTION 12. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-803 of Title 63, unless there is created a duplication in numbering, reads as follows:

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

1. From an approved source; and

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

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

SECTION 13. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 2-804 of Title 63, unless there is created a duplication in numbering, reads as follows:

A person acting in compliance with the provisions of this act shall not be subject to arrest, prosecution, or any civil or administrative penalty, including a civil penalty or disciplinary action by a professional licensing board, or be denied any right or privilege, for the use, prescription, administration, possession, manufacture, or distribution of medical cannabidiol.

SECTION 14. It being immediately necessary for the preservation of the public peace, health and safety, an emergency is hereby declared to exist, by reason whereof this act shall take effect and be in full force from and after its passage and approval.

Passed the House of Representatives the 11th day of February, 2015.

_____
Presiding Officer of the House of Representatives

Passed the Senate the ___ day of _____, 2015.

_____
Presiding Officer of the Senate