1	ENGROSSED SENATE AMENDMENT TO
2	ENGROSSED HOUSE
3	BILL NO. 2154 By: Echols, Grau, Montgomery, Casey, Jordan and Cannaday
4	of the House
5	and
6	Crain of the Senate
0 7	
/	
8	An Act relating to public health and safety; creating Katie's Law; amending 63 O.S. 2011, Section 2-101, as
9	last amended by Section 1, Chapter 154, O.S.L. 2014 (63 O.S. Supp. 2014, Section 2-101), which relates to
10	definitions of the Uniform Controlled Dangerous Substances Act; modifying exception to certain
11	definition; defining terms; providing for the establishment of statewide investigational new drug
12	applications for certain clinical trials; authorizing
13	physicians to serve as principal investigators for clinical trials under certain circumstances;
14	providing for subinvestigators; directing investigators and subinvestigators to adhere to
15	certain rules and regulations; providing guidelines for establishing statewide investigational new drug
16	applications; providing exemptions from criminal or civil penalties; providing for codification;
	providing for noncodification; and declaring an
17	emergency.
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20	AUTHOR: Add the following Senate Coauthors: Standridge, Sharp, Yen and Newberry
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22	AUTHOR: Add the following House Coauthors: Roberts (Sean), Perryman and Nollan
23	AMENDMENT NO. 1. Page 1, strike the title, enacting clause and
24	entire bill and insert

1	"An Act relating to public health and safety;
	creating Katie and Cayman's Law; amending 63 O.S.
2	2011, Section 2-101, as last amended by Section 1,
	Chapter 154, O.S.L. 2014 (63 O.S. Supp. 2014, Section
3	2-101), which relates to definitions of the Uniform
	Controlled Dangerous Substances Act; modifying
4	exception to certain definition; defining terms;
	providing for the establishment of statewide
5	investigational new drug applications for certain
	clinical trials; authorizing physicians to serve as
6	principal investigators for clinical trials under
	certain circumstances; providing for
7	subinvestigators; directing investigators and
	subinvestigators to adhere to certain rules and
8	regulations; permitting Oklahoma State Bureau of
	Narcotics and Dangerous Drugs Control to inspect
9	certain samples; providing guidelines for conducting
	clinical trials; providing exemptions from criminal
10	or civil penalties; permitting State Commissioner of
	Health to perform certain acts; requiring clinical
11	trials to comply with certain standards; providing
	termination date; requiring certain approval for
12	continuation of clinical trials; requiring submission
	of certain report; specifying contents of report;
13	permitting Commissioner to disclose certain data;
	directing promulgation of rules by certain entities;
14	providing for codification; providing for
	noncodification; and declaring an emergency.
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	BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:
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	SECTION 1. NEW LAW A new section of law not to be
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10	codified in the Oklahoma Statutes reads as follows:
20	courried in the oktanoma statutes reads as rorrows.
20	This act shall be known and may be cited as "Katie and Cayman's
21	THIS act shall be known and may be cited as hatte and cayman s
<u> </u>	Law".
22	Law .
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1 SECTION 2. AMENDATORY 63 O.S. 2011, Section 2-101, as 2 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: 3 4 Section 2-101. As used in the Uniform Controlled Dangerous 5 Substances Act: 6 1. "Administer" means the direct application of a controlled 7 dangerous substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient, animal or research 8 9 subject by: 10 a practitioner (or, in the presence of the a. 11 practitioner, by the authorized agent of the 12 practitioner), or 13 b. the patient or research subject at the direction and 14 in the presence of the practitioner; 15 "Agent" means a peace officer appointed by and who acts in 2. 16 behalf of the Director of the Oklahoma State Bureau of Narcotics and 17 Dangerous Drugs Control or an authorized person who acts on behalf 18 of or at the direction of a person who manufactures, distributes, 19 dispenses, prescribes, administers or uses for scientific purposes 20 controlled dangerous substances but does not include a common or 21 contract carrier, public warehouser or employee thereof, or a person 22 required to register under the Uniform Controlled Dangerous 23 Substances Act;

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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,
6 manufacture, salt, derivative, mixture or preparation of coca
7 leaves, except derivatives of coca leaves which do not contain
8 cocaine or ecgonine;

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

11 7. "Control" means to add, remove or change the placement of a 12 drug, substance or immediate precursor under the Uniform Controlled 13 Dangerous Substances Act;

14 8. "Controlled dangerous substance" means a drug, substance or 15 immediate precursor in Schedules I through V of the Uniform 16 Controlled Dangerous Substances Act or any drug, substance or 17 immediate precursor listed either temporarily or permanently as a 18 federally controlled substance. Any conflict between state and 19 federal law with regard to the particular schedule in which a 20 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,

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

3 10. "Deliver" or "delivery" means the actual, constructive or 4 attempted transfer from one person to another of a controlled 5 dangerous substance or drug paraphernalia, whether or not there is 6 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;

14 12. "Distribute" means to deliver other than by administering 15 or dispensing a controlled dangerous substance;

16 13. "Distributor" means a commercial entity engaged in the 17 distribution or reverse distribution of narcotics and dangerous 18 drugs and who complies with all regulations promulgated by the 19 federal Drug Enforcement Administration and the Oklahoma State 20 Bureau of Narcotics and Dangerous Drugs Control;

21 14. "Drug" means articles:

a. recognized in the official United States
 Pharmacopoeia, official Homeopathic Pharmacopoeia of
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- 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
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specified in this paragraph;

10 provided, however, the term "drug" does not include devices or their 11 components, parts or accessories;

15. "Drug-dependent person" means a person who is using a 12 13 controlled dangerous substance and who is in a state of psychic or 14 physical dependence, or both, arising from administration of that 15 controlled dangerous substance on a continuous basis. Drug 16 dependence is characterized by behavioral and other responses which 17 include a strong compulsion to take the substance on a continuous 18 basis in order to experience its psychic effects, or to avoid the 19 discomfort of its absence;

20 16. "Home care agency" means any sole proprietorship, 21 partnership, association, corporation, or other organization which 22 administers, offers, or provides home care services, for a fee or 23 pursuant to a contract for such services, to clients in their place 24 of residence;

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"Home care services" means skilled or personal care 1 17. 2 services provided to clients in their place of residence for a fee; "Hospice" means a centrally administered, nonprofit or 3 18. 4 profit, medically directed, nurse-coordinated program which provides 5 a continuum of home and inpatient care for the terminally ill patient and the patient's family. Such term shall also include a 6 7 centrally administered, nonprofit or profit, medically directed, nurse-coordinated program if such program is licensed pursuant to 8 9 the provisions of this act. A hospice program offers palliative and 10 supportive care to meet the special needs arising out of the 11 physical, emotional and spiritual stresses which are experienced 12 during the final stages of illness and during dying and bereavement. 13 This care is available twenty-four (24) hours a day, seven (7) days 14 a week, and is provided on the basis of need, regardless of ability 15 to pay. "Class A" Hospice refers to Medicare certified hospices. 16 "Class B" refers to all other providers of hospice services; 17 19. "Imitation controlled substance" means a substance that is 18 not a controlled dangerous substance, which by dosage unit 19 appearance, color, shape, size, markings or by representations made, 20 would lead a reasonable person to believe that the substance is a

21 controlled dangerous substance. In the event the appearance of the 22 dosage unit is not reasonably sufficient to establish that the 23 substance is an "imitation controlled substance", the court or 24 authority concerned should consider, in addition to all other

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1 factors, the following factors as related to "representations made" 2 in determining whether the substance is an "imitation controlled 3 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,
- 9 c. whether the substance is packaged in a manner normally
 10 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
- 18 f. the proximity of the substances to controlled
 19 dangerous substances;

20 20. "Immediate precursor" means a substance which the Director 21 has found to be and by regulation designates as being the principal 22 compound commonly used or produced primarily for use, and which is 23 an immediate chemical intermediary used, or likely to be used, in

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1 the manufacture of a controlled dangerous substance, the control of 2 which is necessary to prevent, curtail or limit such manufacture; 3 21. "Laboratory" means a laboratory approved by the Director as 4 proper to be entrusted with the custody of controlled dangerous 5 substances and the use of controlled dangerous substances for scientific and medical purposes and for purposes of instruction; 6 7 22. "Manufacture" means the production, preparation, propagation, compounding or processing of a controlled dangerous 8 9 substance, either directly or indirectly by extraction from 10 substances of natural or synthetic origin, or independently by means 11 of chemical synthesis or by a combination of extraction and chemical 12 synthesis. "Manufacturer" includes any person who packages, 13 repackages or labels any container of any controlled dangerous 14 substance, except practitioners who dispense or compound prescription orders for delivery to the ultimate consumer; 15 16 "Marihuana" means all parts of the plant Cannabis sativa 23. 17 L., whether growing or not; the seeds thereof; the resin extracted

18 from any part of such plant; and every compound, manufacture, salt, 19 derivative, mixture or preparation of such plant, its seeds or 20 resin, but shall not include:

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the mature stalks of such plant τ or fiber produced from such stalks,

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a.

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 oil or cake made from the seeds of such plant,

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 including cannabidiol derived from the seeds of the

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 marihuana plant,
- 4c.any other compound, manufacture, salt, derivative,5mixture or preparation of such mature stalks (except6the resin extracted therefrom), including cannabidiol7derived from mature stalks, fiber, oil or cake, or
 - <u>d.</u> the sterilized seed of such plant which is incapable of germination<u>,</u>
- 10e.for persons eighteen (18) years of age or younger11participating in a clinical trial to administering12cannabidiol for the treatment of severe forms of13epilepsy pursuant to Section 4 of this act, a drug or14substance approved by the federal Food and Drug15Administration for use by those participants, or
- 16 f. for persons eighteen (18) years of age or younger, or 17 the parents, legal guardians, or caretakers of the 18 person, who have received a written certification from 19 a physician licensed in this state that the person has 20 been diagnosed by a physician as having Lennox-Gastaut 21 Syndrome, Dravet Syndrome, also known as Severe 22 Myoclonic Epilepsy of Infancy, or any other severe 23 form of epilepsy that is not adequately treated by 24 traditional medical therapies, the substance

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- 1cannabidiol, a nonpsychoactive cannabinoid, found in2the plant Cannabis sativa L. or any other preparation3thereof, that has a tetrahydrocannabinol concentration4of not more than three-tenths of one percent (0.3%)5and that is delivered to the patient in the form of a6liquid, or
- 7 industrial hemp, from the plant Cannabis sativa L. and g. any part of such plant, whether growing or not, with a 8 9 delta-9 tetrahydrocannabinol concentration of not more 10 than three-tenths of one percent (0.3%) on a dry 11 weight basis which shall not be grown anywhere in the 12 State of Oklahoma but may be shipped to Oklahoma 13 pursuant to the provisions of subparagraph e or f of 14 this paragraph;

15 "Medical purpose" means an intention to utilize a 24. 16 controlled dangerous substance for physical or mental treatment, for 17 diagnosis, or for the prevention of a disease condition not in 18 violation of any state or federal law and not for the purpose of 19 satisfying physiological or psychological dependence or other abuse; "Mid-level practitioner" means an advanced practice nurse 20 25. 21 as defined and within parameters specified in Section 567.3a of 22 Title 59 of the Oklahoma Statutes, or a certified animal euthanasia 23 technician as defined in Section 698.2 of Title 59 of the Oklahoma 24 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:

9 a. opium, coca leaves and opiates,

10b. a compound, manufacture, salt, derivative or11preparation 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

16 a substance, and any compound, manufacture, salt, e. 17 derivative or preparation thereof, which is chemically 18 identical with any of the substances referred to in 19 subparagraphs a through d of this paragraph, except 20 that the words "narcotic drug" as used in Section 2-21 101 et seq. of this title shall not include 22 decocainized coca leaves or extracts of coca leaves, 23 which extracts do not contain cocaine or ecgonine;

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27. "Opiate" means any substance having an addiction-forming or 1 2 addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or 3 addiction-sustaining liability. It does not include, unless 4 5 specifically designated as controlled under the Uniform Controlled Dangerous Substances Act, the dextrorotatory isomer of 3-methoxy-n-6 7 methyl-morphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms; 8

9 28. "Opium poppy" means the plant of the species Papaver10 somniferum L., except the seeds thereof;

11 29. "Peace officer" means a police officer, sheriff, deputy 12 sheriff, district attorney's investigator, investigator from the 13 Office of the Attorney General, or any other person elected or 14 appointed by law to enforce any of the criminal laws of this state 15 or of the United States;

16 30. "Person" means an individual, corporation, government or 17 governmental subdivision or agency, business trust, estate, trust, 18 partnership or association, or any other legal entity;

19 31. "Poppy straw" means all parts, except the seeds, of the 20 opium poppy, after mowing;

- 21 32. "Practitioner" means:
- a. (1) a medical doctor or osteopathic physician,
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- 24 (3) a podiatrist,

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(2) a dentist,

1 (4) an optometrist,

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- (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,

7 licensed, registered or otherwise permitted to prescribe, distribute, dispense, conduct research with 8 9 respect to, use for scientific purposes or administer 10 a controlled dangerous substance in the course of professional practice or research in this state, or 11 12 b. a pharmacy, hospital, laboratory or other institution 13 licensed, registered or otherwise permitted to 14 distribute, dispense, conduct research with respect 15 to, use for scientific purposes or administer a 16 controlled dangerous substance in the course of 17 professional practice or research in this state; 18 33. "Production" includes the manufacture, planting,

19 cultivation, growing or harvesting of a controlled dangerous
20 substance;

21 34. "State" means the State of Oklahoma or any other state of 22 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

1 use of a member of the person's household or for administration to 2 an animal owned by the person or by a member of the person's 3 household;

36. "Drug paraphernalia" means all equipment, products and 4 5 materials of any kind which are used, intended for use, or fashioned specifically for use in planting, propagating, cultivating, growing, 6 7 harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, 8 9 storing, containing, concealing, injecting, ingesting, inhaling or 10 otherwise introducing into the human body, a controlled dangerous substance in violation of the Uniform Controlled Dangerous 11 Substances Act including, but not limited to: 12

13 kits used, intended for use, or fashioned specifically a. 14 for use in planting, propagating, cultivating, growing 15 or harvesting of any species of plant which is a 16 controlled dangerous substance or from which a 17 controlled dangerous substance can be derived, 18 b. kits used, intended for use, or fashioned specifically 19 for use in manufacturing, compounding, converting, 20 producing, processing or preparing controlled 21 dangerous substances, 22 isomerization devices used, intended for use, or с.

fashioned specifically for use in increasing the

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- 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,
- 10 f. diluents and adulterants, such as quinine 11 hydrochloride, mannitol, mannite, dextrose and 12 lactose, used, intended for use, or fashioned 13 specifically for use in cutting controlled dangerous 14 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,
 capsules, balloons, envelopes and other containers
 used, intended for use, or fashioned specifically for

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- 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,
- 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,
- 18 (2) water pipes,

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- 19 (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,

1	(6) miniature cocaine spoons and cocaine vials,
2	(7) chamber pipes,
3	(8) carburetor pipes,
4	(9) electric pipes,
5	(10) air-driven pipes,
6	(11) chillums,
7	(12) bongs, or
8	(13) ice pipes or chillers,
9	m. all hidden or novelty pipes, and
10	n. any pipe that has a tobacco bowl or chamber of less
11	than one-half $(1/2)$ inch in diameter in which there is
12	any detectable residue of any controlled dangerous
13	substance as defined in this section or any other
14	substances not legal for possession or use;
15	provided, however, the term "drug paraphernalia" shall not include
16	separation gins intended for use in preparing tea or spice, clamps
17	used for constructing electrical equipment, water pipes designed for
18	ornamentation in which no detectable amount of an illegal substance
19	is found or pipes designed and used solely for smoking tobacco,
20	traditional pipes of an American Indian tribal religious ceremony,
21	or antique pipes that are thirty (30) years of age or older;
22	37. a. "Synthetic controlled substance" means a substance:
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- 1 (1) the chemical structure of which is substantially 2 similar to the chemical structure of a controlled 3 dangerous substance in Schedule I or II,
- 4 (2) which has a stimulant, depressant, or
 5 hallucinogenic effect on the central nervous
 6 system that is substantially similar to or
 7 greater than the stimulant, depressant or
 8 hallucinogenic effect on the central nervous
 9 system of a controlled dangerous substance in
 10 Schedule I or II, or
- (3) 11 with respect to a particular person, which such 12 person represents or intends to have a stimulant, 13 depressant, or hallucinogenic effect on the 14 central nervous system that is substantially 15 similar to or greater than the stimulant, 16 depressant, or hallucinogenic effect on the 17 central nervous system of a controlled dangerous 18 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.

24 c. "Synthetic controlled substance" does not include:

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1 (1) a controlled dangerous substance,

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- (2) any substance for which there is an approved new drug application,
- 4 (3) with respect to a particular person any 5 substance, if an exemption is in effect for investigational use, for that person under the 6 7 provisions of Section 505 of the Federal Food, Drug and Cosmetic Act, Title 21 of the United 8 9 States Code, Section 355, to the extent conduct 10 with respect to such substance is pursuant to 11 such exemption, or
- 12 (4) any substance to the extent not intended for
 13 human consumption before such an exemption takes
 14 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;

20 38. "Tetrahydrocannabinols" means all substances that have been 21 chemically synthesized to emulate the tetrahydrocannabinols of 22 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:

15 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

20 b. conduct research that is overseen by the federal 21 Department of Health and Human Services and involves 22 human subjects;

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

1 has been manufactured and tested in a facility a. 2 approved or certified by the United States Food and 3 Drug Administration or similar national regulatory 4 agency in another country which has been approved by 5 the United States Food and Drug Administration, and b. has been tested on animals to demonstrate preliminary 6 7 effectiveness and to ensure that it is safe to administer to humans; 8

9 3. "Cannabidiol" means a nonpsychoactive cannabinoid found in 10 the plant Cannabis sativa L. or any other preparation thereof, that 11 has a tetrahydrocannabinol concentration of not more than three-12 tenths of one percent (0.3%) and that is delivered to the patient in 13 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

18 5. "Qualifying patient" means any person eighteen (18) years of 19 age or younger who suffers from Lennox-Gastaut Syndrome, Dravet 20 Syndrome, also known as Severe Myoclonic Epilepsy of Infancy, or any 21 other form of refractory epilepsy that is not adequately treated by 22 traditional medical therapies.

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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:

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

16 2. Receives a license from the United States Drug Enforcement 17 Administration; and

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

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1 to comply with the licensing requirement provided in paragraphs 2 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:

24 1. From an approved source; and

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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.

16 SECTION 7. NEW LAW A new section of law to be codified 17 in the Oklahoma Statutes as Section 2-805 of Title 63, unless there 18 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

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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.

8 C. Clinical trials and related research authorized by this act 9 shall conclude no later than December 31, 2017. Nothing in this act 10 shall be construed as to permit the continuation of clinical trials 11 after December 31, 2017, without approval by a concurrent resolution 12 approved by the Legislature expressing approval of such 13 continuation.

14 The State Commissioner of Health shall submit a report to D. 15 the Chair and Vice Chair of the Senate Health and Human Services 16 Committee, the Chair and Vice Chair of the House Alcohol, Tobacco 17 and Dangerous Drugs Committee, and the Chair and Vice Chair of the 18 House Public Health Committee on or before December 31, 2017. Such 19 report shall include a summary of findings from clinical trials 20 authorized by this act. The Commissioner shall, upon request by the 21 Chair and Vice Chair of the Committees specified in this subsection, 22 make available any data, excluding individual health records, 23 relating to clinical trials authorized by this act.

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ENGR. S. A. TO ENGR. H. B. NO. 2154

1	E. The Oklahoma State Bureau of Narcotics and Dangerous Drugs
2	Control, the State Board of Health, and the Oklahoma State Regents
3	for Higher Education shall promulgate rules to implement the
4	provisions of this act.
5	SECTION 7. It being immediately necessary for the preservation
6	of the public peace, health and safety, an emergency is hereby
7	declared to exist, by reason whereof this act shall take effect and
8	be in full force from and after its passage and approval."
9	Passed the Senate the 15th day of April, 2015.
10	
11	Presiding Officer of the Senate
12	
13	Passed the House of Representatives the day of,
14	2015.
15	
16	Presiding Officer of the House
17	of Representatives
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1	ENGROSSED HOUSE
2	BILL NO. 2154 By: Echols, Grau, Montgomery, Casey, Jordan and Cannaday
3	of the House
4	and
5	Crain of the Senate
6	
7	
8	An Act relating to public health and safety; creating
9	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
10	definitions of the Uniform Controlled Dangerous Substances Act; modifying exception to certain
11	definition; defining terms; providing for the establishment of statewide investigational new drug
12	applications for certain clinical trials; authorizing physicians to serve as principal investigators for
13	clinical trials under certain circumstances; providing for subinvestigators; directing
14	investigators and subinvestigators to adhere to certain rules and regulations; providing guidelines
15	for establishing statewide investigational new drug applications; providing exemptions from criminal or
16	civil penalties; providing for codification; providing for noncodification; and declaring an
17	emergency.
18	
19	
20	BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:
21	SECTION 8. NEW LAW A new section of law not to be
22	codified in the Oklahoma Statutes reads as follows:
23	This act shall be known and may be cited as "Katie's Law".
24	

1 SECTION 9. AMENDATORY 63 O.S. 2011, Section 2-101, as 2 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: 3 4 Section 2-101. As used in the Uniform Controlled Dangerous 5 Substances Act: 6 1. "Administer" means the direct application of a controlled 7 dangerous substance, whether by injection, inhalation, ingestion or any other means, to the body of a patient, animal or research 8 9 subject by: 10 a practitioner (or, in the presence of the a. 11 practitioner, by the authorized agent of the 12 practitioner), or 13 b. the patient or research subject at the direction and 14 in the presence of the practitioner; 15 "Agent" means a peace officer appointed by and who acts in 2. 16 behalf of the Director of the Oklahoma State Bureau of Narcotics and 17 Dangerous Drugs Control or an authorized person who acts on behalf 18 of or at the direction of a person who manufactures, distributes, 19 dispenses, prescribes, administers or uses for scientific purposes 20 controlled dangerous substances but does not include a common or 21 contract carrier, public warehouser or employee thereof, or a person 22 required to register under the Uniform Controlled Dangerous 23 Substances Act;

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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,
6 manufacture, salt, derivative, mixture or preparation of coca
7 leaves, except derivatives of coca leaves which do not contain
8 cocaine or ecgonine;

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

11 7. "Control" means to add, remove or change the placement of a 12 drug, substance or immediate precursor under the Uniform Controlled 13 Dangerous Substances Act;

14 8. "Controlled dangerous substance" means a drug, substance or 15 immediate precursor in Schedules I through V of the Uniform 16 Controlled Dangerous Substances Act or any drug, substance or 17 immediate precursor listed either temporarily or permanently as a 18 federally controlled substance. Any conflict between state and 19 federal law with regard to the particular schedule in which a 20 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;

3 10. "Deliver" or "delivery" means the actual, constructive or 4 attempted transfer from one person to another of a controlled 5 dangerous substance or drug paraphernalia, whether or not there is 6 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;

14 12. "Distribute" means to deliver other than by administering 15 or dispensing a controlled dangerous substance;

16 13. "Distributor" means a commercial entity engaged in the 17 distribution or reverse distribution of narcotics and dangerous 18 drugs and who complies with all regulations promulgated by the 19 federal Drug Enforcement Administration and the Oklahoma State 20 Bureau of Narcotics and Dangerous Drugs Control;

21 14. "Drug" means articles:

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

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specified in this paragraph;

10 provided, however, the term "drug" does not include devices or their 11 components, parts or accessories;

15. "Drug-dependent person" means a person who is using a 12 13 controlled dangerous substance and who is in a state of psychic or 14 physical dependence, or both, arising from administration of that 15 controlled dangerous substance on a continuous basis. Drug 16 dependence is characterized by behavioral and other responses which 17 include a strong compulsion to take the substance on a continuous 18 basis in order to experience its psychic effects, or to avoid the 19 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;

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"Home care services" means skilled or personal care 1 17. 2 services provided to clients in their place of residence for a fee; "Hospice" means a centrally administered, nonprofit or 3 18. 4 profit, medically directed, nurse-coordinated program which provides 5 a continuum of home and inpatient care for the terminally ill patient and the patient's family. Such term shall also include a 6 7 centrally administered, nonprofit or profit, medically directed, nurse-coordinated program if such program is licensed pursuant to 8 9 the provisions of this act. A hospice program offers palliative and 10 supportive care to meet the special needs arising out of the 11 physical, emotional and spiritual stresses which are experienced 12 during the final stages of illness and during dying and bereavement. 13 This care is available twenty-four (24) hours a day, seven (7) days 14 a week, and is provided on the basis of need, regardless of ability 15 to pay. "Class A" Hospice refers to Medicare certified hospices. 16 "Class B" refers to all other providers of hospice services; 17 19. "Imitation controlled substance" means a substance that is 18 not a controlled dangerous substance, which by dosage unit 19 appearance, color, shape, size, markings or by representations made, 20

20 would lead a reasonable person to believe that the substance is a 21 controlled dangerous substance. In the event the appearance of the 22 dosage unit is not reasonably sufficient to establish that the 23 substance is an "imitation controlled substance", the court or 24 authority concerned should consider, in addition to all other

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1 factors, the following factors as related to "representations made" 2 in determining whether the substance is an "imitation controlled 3 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,
- 9 c. whether the substance is packaged in a manner normally
 10 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
- 18 f. the proximity of the substances to controlled
 19 dangerous substances;

20 20. "Immediate precursor" means a substance which the Director 21 has found to be and by regulation designates as being the principal 22 compound commonly used or produced primarily for use, and which is 23 an immediate chemical intermediary used, or likely to be used, in

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1 the manufacture of a controlled dangerous substance, the control of 2 which is necessary to prevent, curtail or limit such manufacture; 3 21. "Laboratory" means a laboratory approved by the Director as 4 proper to be entrusted with the custody of controlled dangerous 5 substances and the use of controlled dangerous substances for scientific and medical purposes and for purposes of instruction; 6 7 22. "Manufacture" means the production, preparation, propagation, compounding or processing of a controlled dangerous 8 9 substance, either directly or indirectly by extraction from 10 substances of natural or synthetic origin, or independently by means 11 of chemical synthesis or by a combination of extraction and chemical 12 synthesis. "Manufacturer" includes any person who packages, 13 repackages or labels any container of any controlled dangerous 14 substance, except practitioners who dispense or compound prescription orders for delivery to the ultimate consumer; 15 16 "Marihuana" means all parts of the plant Cannabis sativa 23.

17 L., whether growing or not; the seeds thereof; the resin extracted 18 from any part of such plant; and every compound, manufacture, salt, 19 derivative, mixture or preparation of such plant, its seeds or 20 resin, but shall not include:

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the mature stalks of such plant \overline{r} or fiber produced from such stalks,

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a.

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 b.
 oil or cake made from the seeds of such plant,

 2
 including cannabidiol derived from the seeds of the

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 marihuana plant,
- 4c.any other compound, manufacture, salt, derivative,5mixture or preparation of such mature stalks (except6the resin extracted therefrom), including cannabidiol7derived from mature stalks, fiber, oil or cake, or
 - <u>d.</u> the sterilized seed of such plant which is incapable of germination<u>.</u>
- 10e.for persons eighteen (18) years of age or younger11participating in a clinical trial or in an expanded-12access program related to administering cannabidiol13for the treatment of severe forms of epilepsy pursuant14to Section 4 of this act, a drug or substance approved15by the federal Food and Drug Administration for use by16those participants, or
- 17 f. for persons eighteen (18) years of age or younger, or 18 the parents, legal guardians, or caretakers of the 19 person, who have received a written certification from 20 a physician licensed in this state that the person has 21 been diagnosed by a physician as having Lennox-Gastaut 22 Syndrome, Dravet Syndrome, also known as Severe 23 Myoclonic Epilepsy of Infancy, or any other severe 24 form of epilepsy that is not adequately treated by

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1		traditional medical therapies, the substance
2		cannabidiol, a nonpsychoactive cannabinoid, found in
3		the plant Cannabis sativa L. or any other preparation
4		thereof, that has a tetrahydrocannabinol concentration
5		of not more than three-tenths of one percent (0.3%)
6		and that is delivered to the patient in the form of a
7		liquid, or
8	<u>a.</u>	industrial hemp, from the plant Cannabis sativa L. and
9		any part of such plant, whether growing or not, with a
10		delta-9 tetrahydrocannabinol concentration of not more
11		than three-tenths of one percent (0.3%) on a dry
12		weight basis which shall not be grown anywhere in the
13		State of Oklahoma but may be shipped to Oklahoma

14 pursuant to the provisions of subparagraph e or f of 15 this paragraph;

16 24. "Medical purpose" means an intention to utilize a 17 controlled dangerous substance for physical or mental treatment, for 18 diagnosis, or for the prevention of a disease condition not in 19 violation of any state or federal law and not for the purpose of 20 satisfying physiological or psychological dependence or other abuse;

21 25. "Mid-level practitioner" means an advanced practice nurse 22 as defined and within parameters specified in Section 567.3a of 23 Title 59 of the Oklahoma Statutes, or a certified animal euthanasia 24 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:

10 a. opium, coca leaves and opiates,

- b. a compound, manufacture, salt, derivative or
 preparation of opium, coca leaves or opiates,
 c. cocaipe, its salts, optical and geometric isomers, and
- c. cocaine, its salts, optical and geometric isomers, and
 salts of isomers,
- d. ecgonine, its derivatives, their salts, isomers and
 salts of isomers, and
- a substance, and any compound, manufacture, salt, 17 e. 18 derivative or preparation thereof, which is chemically 19 identical with any of the substances referred to in 20 subparagraphs a through d of this paragraph, except 21 that the words "narcotic drug" as used in Section 2-22 101 et seq. of this title shall not include 23 decocainized coca leaves or extracts of coca leaves, 24 which extracts do not contain cocaine or ecgonine;

27. "Opiate" means any substance having an addiction-forming or 1 2 addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or 3 addiction-sustaining liability. It does not include, unless 4 5 specifically designated as controlled under the Uniform Controlled Dangerous Substances Act, the dextrorotatory isomer of 3-methoxy-n-6 7 methyl-morphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms; 8

9 28. "Opium poppy" means the plant of the species Papaver10 somniferum L., except the seeds thereof;

11 29. "Peace officer" means a police officer, sheriff, deputy 12 sheriff, district attorney's investigator, investigator from the 13 Office of the Attorney General, or any other person elected or 14 appointed by law to enforce any of the criminal laws of this state 15 or of the United States;

16 30. "Person" means an individual, corporation, government or 17 governmental subdivision or agency, business trust, estate, trust, 18 partnership or association, or any other legal entity;

19 31. "Poppy straw" means all parts, except the seeds, of the 20 opium poppy, after mowing;

- 21 32. "Practitioner" means:
- 22 a. (1) a medical doctor or osteopathic physician,
- 23 (2) a dentist,
- 24 (3) a podiatrist,

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1 (4) an optometrist,

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- (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,

7 licensed, registered or otherwise permitted to prescribe, distribute, dispense, conduct research with 8 9 respect to, use for scientific purposes or administer 10 a controlled dangerous substance in the course of 11 professional practice or research in this state, or 12 b. a pharmacy, hospital, laboratory or other institution 13 licensed, registered or otherwise permitted to 14 distribute, dispense, conduct research with respect 15 to, use for scientific purposes or administer a 16 controlled dangerous substance in the course of 17 professional practice or research in this state; 18 33. "Production" includes the manufacture, planting,

19 cultivation, growing or harvesting of a controlled dangerous
20 substance;

21 34. "State" means the State of Oklahoma or any other state of 22 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

1 use of a member of the person's household or for administration to 2 an animal owned by the person or by a member of the person's 3 household;

36. "Drug paraphernalia" means all equipment, products and 4 5 materials of any kind which are used, intended for use, or fashioned specifically for use in planting, propagating, cultivating, growing, 6 7 harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, 8 9 storing, containing, concealing, injecting, ingesting, inhaling or 10 otherwise introducing into the human body, a controlled dangerous substance in violation of the Uniform Controlled Dangerous 11 Substances Act including, but not limited to: 12

13 kits used, intended for use, or fashioned specifically a. 14 for use in planting, propagating, cultivating, growing 15 or harvesting of any species of plant which is a 16 controlled dangerous substance or from which a 17 controlled dangerous substance can be derived, 18 kits used, intended for use, or fashioned specifically b. 19 for use in manufacturing, compounding, converting, 20 producing, processing or preparing controlled 21 dangerous substances, 22 isomerization devices used, intended for use, or с.

fashioned specifically for use in increasing the

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- 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,
- 10 f. diluents and adulterants, such as quinine 11 hydrochloride, mannitol, mannite, dextrose and 12 lactose, used, intended for use, or fashioned 13 specifically for use in cutting controlled dangerous 14 substances,
- 15 g. separation gins and sifters used, intended for use, or 16 fashioned specifically for use in removing twigs and 17 seeds from, or in otherwise cleaning or refining, 18 marihuana,
- h. blenders, bowls, containers, spoons and mixing devices
 used, intended for use, or fashioned specifically for
 use in compounding controlled dangerous substances,
 capsules, balloons, envelopes and other containers
 used, intended for use, or fashioned specifically for

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- 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,
- 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,
- 18 (2) water pipes,

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- 19 (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,

 (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 i any detectable residue of any controlled dangerous substance as defined in this section or any other
 4 (9) electric pipes, 5 (10) air-driven pipes, 6 (11) chillums, 7 (12) bongs, or 8 (13) ice pipes or chillers, 9 m. all hidden or novelty pipes, and 10 n. any pipe that has a tobacco bowl or chamber of less 11 than one-half (1/2) inch in diameter in which there i 12 any detectable residue of any controlled dangerous
5 (10) air-driven pipes, 6 (11) chillums, 7 (12) bongs, or 8 (13) ice pipes or chillers, 9 m. all hidden or novelty pipes, and 10 n. any pipe that has a tobacco bowl or chamber of less 11 than one-half (1/2) inch in diameter in which there i any detectable residue of any controlled dangerous
 6 (11) chillums, 7 (12) bongs, or 8 (13) ice pipes or chillers, 9 m. all hidden or novelty pipes, and 10 n. any pipe that has a tobacco bowl or chamber of less 11 than one-half (1/2) inch in diameter in which there i 12 any detectable residue of any controlled dangerous
<pre>7 (12) bongs, or 8 (13) ice pipes or chillers, 9 m. all hidden or novelty pipes, and 10 n. any pipe that has a tobacco bowl or chamber of less 11 than one-half (1/2) inch in diameter in which there i 12 any detectable residue of any controlled dangerous</pre>
8 (13) ice pipes or chillers, 9 m. all hidden or novelty pipes, and 10 n. any pipe that has a tobacco bowl or chamber of less 11 than one-half (1/2) inch in diameter in which there i 12 any detectable residue of any controlled dangerous
9 m. all hidden or novelty pipes, and 10 n. any pipe that has a tobacco bowl or chamber of less 11 than one-half (1/2) inch in diameter in which there i 12 any detectable residue of any controlled dangerous
 n. any pipe that has a tobacco bowl or chamber of less than one-half (1/2) inch in diameter in which there i any detectable residue of any controlled dangerous
11 than one-half (1/2) inch in diameter in which there i 12 any detectable residue of any controlled dangerous
12 any detectable residue of any controlled dangerous
13 substance as defined in this section or any other
14 substances not legal for possession or use;
15 provided, however, the term "drug paraphernalia" shall not include
16 separation gins intended for use in preparing tea or spice, clamps
17 used for constructing electrical equipment, water pipes designed fo
18 ornamentation in which no detectable amount of an illegal substance
19 is found or pipes designed and used solely for smoking tobacco,
20 traditional pipes of an American Indian tribal religious ceremony,
21 or antique pipes that are thirty (30) years of age or older;
22 37. a. "Synthetic controlled substance" means a substance:
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- (1) the chemical structure of which is substantially
 similar to the chemical structure of a controlled
 dangerous substance in Schedule I or II,
- 4 (2) which has a stimulant, depressant, or
 5 hallucinogenic effect on the central nervous
 6 system that is substantially similar to or
 7 greater than the stimulant, depressant or
 8 hallucinogenic effect on the central nervous
 9 system of a controlled dangerous substance in
 10 Schedule I or II, or
- 11 with respect to a particular person, which such (3) 12 person represents or intends to have a stimulant, 13 depressant, or hallucinogenic effect on the 14 central nervous system that is substantially 15 similar to or greater than the stimulant, 16 depressant, or hallucinogenic effect on the 17 central nervous system of a controlled dangerous 18 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.

24 c. "Synthetic controlled substance" does not include:

1 (1) a controlled dangerous substance,

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- (2) any substance for which there is an approved new drug application,
- 4 (3) with respect to a particular person any 5 substance, if an exemption is in effect for investigational use, for that person under the 6 7 provisions of Section 505 of the Federal Food, Drug and Cosmetic Act, Title 21 of the United 8 9 States Code, Section 355, to the extent conduct 10 with respect to such substance is pursuant to 11 such exemption, or
- 12 (4) any substance to the extent not intended for
 13 human consumption before such an exemption takes
 14 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;

20 38. "Tetrahydrocannabinols" means all substances that have been 21 chemically synthesized to emulate the tetrahydrocannabinols of 22 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

1 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 2 3 the optical, positional or geometric isomer. As used in paragraph 4 of subsection A of Section 2-206 of this title, the term "isomer" 4 5 means the optical or geometric isomer; 6 40. "Hazardous materials" means materials, whether solid, 7 liquid or gas, which are toxic to human, animal, aquatic or plant life, and the disposal of which materials is controlled by state or 8 9 federal guidelines; and 10 41. "Anhydrous ammonia" means any substance that exhibits 11 cryogenic evaporative behavior and tests positive for ammonia. A new section of law to be codified 12 SECTION 10. NEW LAW 13 in the Oklahoma Statutes as Section 2-801 of Title 63, unless there 14 is created a duplication in numbering, reads as follows: 15 As used in this act: 16 "Academic medical center" means a medical school and its 1. affiliated teaching hospitals and clinics that: 17 18 operate a medical residency program for physicians, a. 19 and 20 b. conduct research that is overseen by the federal 21 Department of Health and Human Services and involves 22 human subjects;

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

1 has been manufactured and tested in a facility a. 2 approved or certified by the United States Food and Drug Administration or similar national regulatory 3 4 agency in another country which has been approved by 5 the United States Food and Drug Administration, and has been tested on animals to demonstrate preliminary 6 b. 7 effectiveness and to ensure that it is safe to administer to humans; 8

9 3. "Cannabidiol" means a nonpsychoactive cannabinoid found in 10 the plant Cannabis sativa L. or any other preparation thereof, that 11 has a tetrahydrocannabinol concentration of not more than three-12 tenths of one percent (0.3%) and that is delivered to the patient in 13 the form of a liquid;

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

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

22 SECTION 11. NEW LAW A new section of law to be codified 23 in the Oklahoma Statutes as Section 2-802 of Title 63, unless there 24 is created a duplication in numbering, reads as follows:

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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:

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

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.

7 SECTION 12. NEW LAW A new section of law to be codified 8 in the Oklahoma Statutes as Section 2-803 of Title 63, unless there 9 is created a duplication in numbering, reads as follows:

10 A. Expanded-access clinical trials conducted pursuant to a 11 statewide investigational new drug application established pursuant 12 to the provisions of this act shall only utilize cannabidiol which 13 is:

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1. From an approved source; and

15 2. Approved by the United States Food and Drug Administration
16 to be used for treatment of a condition specified in an
17 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.

22 SECTION 13. NEW LAW A new section of law to be codified 23 in the Oklahoma Statutes as Section 2-804 of Title 63, unless there 24 is created a duplication in numbering, reads as follows:

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1	A person acting in compliance with the provisions of this act
2	shall not be subject to arrest, prosecution, or any civil or
3	administrative penalty, including a civil penalty or disciplinary
4	action by a professional licensing board, or be denied any right or
5	privilege, for the use, prescription, administration, possession,
6	manufacture, or distribution of medical cannabidiol.
7	SECTION 14. It being immediately necessary for the preservation
8	of the public peace, health and safety, an emergency is hereby
9	declared to exist, by reason whereof this act shall take effect and
10	be in full force from and after its passage and approval.
11 12	Passed the House of Representatives the 11th day of February, 2015.
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14	Presiding Officer of the House of Representatives
15 16	Passed the Senate the day of, 2015.
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18	Presiding Officer of the Senate
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