House Bill 1107

By: Representative Cooper of the 43rd

A BILL TO BE ENTITLED

AN ACT

To amend Title 31 of the Official Code of Georgia Annotated, relating to health, so as to enact the "Therapeutic Cannabidiol Research Act of 2014"; to provide for legislative findings; to provide for definitions; to provide for state-wide expanded access clinical trials for cannabidiol for pediatric patients with severe forms of epilepsy; to provide for receipt and distribution of cannabidiol; to provide for an annual report; to provide for statutory construction; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

This Act shall be known and may be cited as the "Therapeutic Cannabidiol Research Act of 2014."

SECTION 2.

(a) The General Assembly finds and declares that:

(1) Research indicates that some chemicals in marijuana, like pharmaceutical medications derived from the poppy plant, may be useful medicines and therefore should be further studied. The fact that medications have been developed from the poppy plant does not make the plant itself a medicine. The same is true for marijuana. While certain of its unique chemicals, called cannabinoids, may become approved medicines, this does not make marijuana itself a medicine;

(2) Marijuana contains some 70 cannabinoids, including cannabidiol (CBD), that can be extracted from marijuana and purified, or synthesized in a laboratory, and tested in animals in preclinical research to ensure they are safe to administer to humans in clinical trials; and

(3) The Food and Drug Administration has approved several physician initiated expanded access investigational new drug (IND) applications that enable investigators to: (A) administer a purified CBD to children with refractory epilepsy who do not respond to

standard medications that has been tested in animals for five years to demonstrate that it is safe to administer to humans in clinical trials; and (B) gather evidence with respect to dosage, formulation, and mode of administration for advanced clinical trials. The Dravet Syndrome Foundation, the Epilepsy Foundation, and the American Epilepsy Society support this type of research.

(b) The intent of this Act is to increase the number of physician initiated expanded access IND applications at academic medical centers in Georgia so as to provide and to further test purified or synthesized CBD in children with rare forms of epilepsy. If further testing shows CBD is effective and the Food and Drug Administration approves it, physicians will be able to prescribe CBD to all children in the nation who suffer from intractable epilepsy.

SECTION 3.

Title 31 of the Official Code of Georgia Annotated, relating to health, is amended by adding a new chapter to read as follows:

"CHAPTER 49

31-49-1.

As used in this chapter, the term:

(1) 'Academic medical center' means a research hospital that operates a medical residency program for physicians and conducts research that involves human subjects.

(2) 'Approved source' means a provider approved by the federal Food and Drug Administration which produces cannabidiol that:

(A) Has been manufactured and tested in a facility approved or certified by the federal Food and Drug Administration or similar national regulatory agency in another country which has been approved by the federal Food and Drug Administration; and

(B) Has been tested in animals to demonstrate preliminary effectiveness and to ensure that it is safe to administer to humans.

(3) 'Cannabidiol' means a finished preparation containing, of its total cannabinoid content, at least 98 percent cannabidiol and no more than 0.30 percent tetrahydrocannabinol that has been extracted from marijuana or synthesized in a laboratory.

(4) 'Pediatric patients with severe forms of epilepsy' means children up to age 21 who suffer from refractory epilepsy and do not respond to standard medications.

(5) 'Physician' means a person licensed to practice medicine pursuant to Article 2 of Chapter 34 of Title 43.

31-49-2.

(a) A state-wide investigational new drug application may be established in this state, if approved by the federal Food and Drug Administration, to conduct expanded access clinical trials using cannabidiol on pediatric patients with severe forms of epilepsy.

(b) Any physician who is a board certified pediatric neurologist practicing in an academic medical center in this state and treating pediatric 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 federal Food and Drug Administration as the principal investigator in a state-wide investigational new drug application;

(2) Receives a license from the federal Drug Enforcement Administration; and

(3) Receives a permit from the Georgia Board of Pharmacy to obtain cannabidiol directly from an approved source.

(c) Such physician, acting as principal investigator, may include subinvestigators who are also board certified pediatric neurologists who practice in an academic medical center in this state and treat pediatric patients with severe forms of epilepsy. Such subinvestigators shall also comply with paragraphs (2) and (3) of subsection (b) of this Code 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 federal Food and Drug Administration, federal Drug Enforcement Administration, National Institute on Drug Abuse, Georgia Drugs and Narcotics Agency, and the Georgia Board of Pharmacy.

31-49-3.

(a) Expanded access clinical trials conducted pursuant to a state-wide investigational new drug application established pursuant to this chapter shall only utilize cannabidiol which is:

(1) From an approved source; and

(2) Approved by the federal 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.

(c) The ordering, receipt, handling, storage, and dispensing of cannabidiol pursuant to this chapter shall be subject to oversight and enforcement by the Georgia Board of Pharmacy and the Georgia Drugs and Narcotics Agency pursuant to Chapter 4 of Title 26, the 'Georgia Pharmacy Practice Act.'

31-49-4.

The physician acting as the principal investigator in the state-wide investigational new drug application established pursuant to this chapter shall annually provide an executive summary on the results of the expanded access clinical trials to the chairpersons of the House Committee on Health and Human Services and the Senate Health and Human Services Committee. Such executive summary shall redact the names of patients and may redact the names of physicians, if desired. Such executive summary may be from reports required by and submitted to the federal Food and Drug Administration, if appropriate.

31-49-5.

No state appropriations shall be required to implement the provisions of this chapter.

31-49-6.

In no way shall this chapter be construed so as to authorize the cultivating or processing of marijuana, cannabis, or hemp by any individual or entity in this state for any purpose.″

SECTION 4.

This Act shall become effective upon its approval by the Governor or upon its becoming law without such approval.

SECTION 5.

All laws and parts of laws in conflict with this Act are repealed.