AMENDMENTS TO SENATE BILL NO. 3 (As amended by A05835)

Sponsor: REPRESENTATIVE MENTZER

Printer's No. 889

Amend Bill, page 1, lines 4 through 37; page 2, lines 1 through 51; page 3, lines 1 through 8 (A05835), by striking out all of said lines on all of said pages and inserting

Statewide expanded access clinical trials for cannabinoids; and requiring certain physicians to provide annual reports.

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Amend Bill, page 3, lines 12 through 48; page 4 through 44, lines 1 through 51; page 45, lines 1 through 6 (A05835), by striking out all of said lines and inserting

Section 1. Short title.

This act shall be known and may be cited as the Therapeutic Cannabinoid Research Act.

Section 2. Legislative findings and intent.

The General Assembly finds and declares that:

(1) Pennsylvania's citizens with severe or life-threatening diseases or conditions may not be able to access critical medications that are still in clinical trials.

(2) The Food and Drug Administration (FDA) has established Expanded Access Programs to allow limited, supervised access to such medications.

(3) While certain of its unique chemicals, called cannabinoids, may become approved medicines, this does not make marijuana itself a medicine.

(4) Marijuana contains at least 85 cannabinoids that can be extracted from marijuana and purified, or synthesized in a laboratory, and tested in animals in preclinical research to

ensure that they are safe to administer to humans in clinical trials.

(5) The FDA has approved several expanded access investigational new drug (IND) applications that enable investigators to utilize cannabinoids.

(6) The intent of this act is to increase the number of expanded access IND applications at academic medical centers in this Commonwealth so as to provide and further test the medical uses of cannabinoids.

Section 3. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Academic medical center." A hospital that operates a medical residency program for physicians and conducts research that involves human subjects.

"Approved source." A provider which produces cannabinoids that:

(1) Have been manufactured and tested in a facility approved or certified by the Food and Drug Administration or similar national regulatory agency in the United States or another country.

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

"Investigator." An individual who actually conducts a clinical investigation and under whose immediate direction a drug is administered or dispensed to a subject.

"Physician." A person licensed to practice medicine in this Commonwealth.

"Sponsor." A person, including an individual or pharmaceutical company, governmental agency, academic institution, private organization or other organization, who takes responsibility for and initiates a clinical investigation.

"Sponsor-investigator." An individual who both initiates and conducts an investigation and under whose immediate direction an investigational drug is administered or dispensed.

Section 4. Expanded access clinical trials.

(a) Authorization.--Statewide investigational new drug applications may be established in this Commonwealth, if submitted by a sponsor or sponsor-investigator and approved by the Food and Drug Administration, to conduct expanded access clinical trials using cannabinoids.

(b) Physicians as sponsor-investigators or investigators.--A physician practicing in an academic medical center in this Commonwealth shall serve as the sponsor-investigator or investigator for the clinical trials.

(c) Subinvestigators.--A physician, acting as a sponsor-investigator or investigator, may include subinvestigators who are physicians practicing in an academic medical center in this Commonwealth.

(d) Compliance with rules and regulations.--The sponsor, sponsor-investigator or 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 Food and Drug Administration, Drug Enforcement Administration, National Institute on Drug Abuse, Department of Health and the State Board of Pharmacy, where applicable.

Section 5. Requirements for cannabinoids.

(a) General rule.--Expanded access clinical trials conducted pursuant to a Statewide investigational new drug application established pursuant to this act shall only utilize cannabinoids that are:

(1) From an approved source.

(2) Authorized by the Food and Drug Administration to be used for treatment of a condition specified in an investigational new drug application.

(b) Source of cannabinoids.--The sponsor, sponsor-investigator or investigator, and any subinvestigator, may receive cannabinoids directly from an approved source or authorized distributor for an approved source for use in the expanded access clinical trials.

(c) Oversight and enforcement.--The ordering, receipt, handling, storage and dispensing of cannabinoids pursuant to this act shall be subject to oversight and enforcement by the State Board of Pharmacy.

Section 6. Duty to provide annual report.

The sponsor or sponsor-investigator in the Statewide investigational new drug application established pursuant to this act shall annually provide a report on the results of the expanded access clinical trials to the chairpersons of the Committee on Public Health and Welfare of the Senate and Committee on Health of the House of Representatives. The report shall redact the names of patients and may redact the names of physicians, if desired. The information in the report may be derived from reports required by and submitted to the Food and Drug Administration, if appropriate.

Section 7. Construction.

Nothing in this act shall be construed to authorize the cultivating or processing of marijuana, cannabis or hemp by any individual or entity in this Commonwealth for any purpose.

Section 8. Effective date.

This act shall take effect in 60 days.