

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

Sponsor: REPRESENTATIVE MENTZER

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1 Amend Bill, page 1, lines 4 through 37; page 2, lines 1
2 through 51; page 3, lines 1 through 8 (A05835), by striking out
3 all of said lines on all of said pages and inserting
4 Statewide expanded access clinical trials for cannabinoids; and
5 requiring certain physicians to provide annual reports.

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

18 Section 1. Short title.

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

21 Section 2. Legislative findings and intent.

22 The General Assembly finds and declares that:

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

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

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

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

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

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

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

10 Section 3. Definitions.

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

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

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

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

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

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

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

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

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

38 Section 4. Expanded access clinical trials.

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

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

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

1 (d) Compliance with rules and regulations.--The sponsor,
2 sponsor-investigator or investigator, and all subinvestigators,
3 shall adhere to the rules and regulations established by the
4 relevant institutional review board for each participating
5 academic medical center and by the Food and Drug Administration,
6 Drug Enforcement Administration, National Institute on Drug
7 Abuse, Department of Health and the State Board of Pharmacy,
8 where applicable.

9 Section 5. Requirements for cannabinoids.

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

14 (1) From an approved source.

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

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

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

27 Section 6. Duty to provide annual report.

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

38 Section 7. Construction.

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

42 Section 8. Effective date.

43 This act shall take effect in 60 days.