

AMENDED IN SENATE APRIL 12, 1999

SENATE BILL

No. 847

**Introduced by Senators Vasconcellos, Figueroa, Hayden,
and ~~Johnston~~ *Johnston, and McPherson***
(Coauthors: Assembly Members Aroner, Keeley, Longville,
Mazzoni, Migden, and Strom-Martin)

February 25, 1999

An act to add Section 11362.9 to the Health and Safety Code, relating to controlled substances, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 847, as amended, Vasconcellos. Marijuana Research Act of 1999.

Existing law, the Compassionate Use Act of 1996, prohibits any physician from being punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes. The act prohibits the provisions of law making unlawful the possession or cultivation of marijuana from applying to a patient, or to a patient's primary care giver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician. Existing law establishes a Research Advisory Panel to study and approve research projects concerning marijuana or hallucinogenic drugs.

This bill would establish the Marijuana Research Act of 1999.

The bill would provide that either the Regents of the University of California, if they elect to do so, or if not, the Research Advisory Panel, shall implement a 3-year program, to be called the California Marijuana Research Program, under which funds would be provided for studies intended to ascertain the general medical safety and efficacy of marijuana and, if found valuable, to develop medical guidelines for the appropriate administration and use of marijuana.

The bill would appropriate \$1,000,000 from the General Fund for the first year of program operation, and would express legislative intent to appropriate \$1,000,000 for each of the final 2 years of program operation pursuant to the Budget Act.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. This act shall be known, and may be
2 cited as, the Marijuana Research Act of 1999.

3 SEC. 2. The Legislature finds and declares all of the
4 following:

5 (a) On November 5, 1996, the people of California,
6 with more than six million votes, approved Proposition
7 215.

8 (b) There is public and scientific controversy
9 regarding the medical efficacy and safety of marijuana.

10 (c) There is a need for objective scientific research
11 regarding the efficacy and safety of marijuana as part of
12 medical treatment.

13 SEC. 3. Section 11362.9 is added to the Health and
14 Safety Code, to read:

15 11362.9. (a) (1) It is the intent of the Legislature
16 that the state commission objective scientific research by
17 the premier research institute of the world, the
18 University of California, regarding the efficacy and safety
19 of administering marijuana as part of medical treatment.
20 If the Regents of the University of California, by



1 appropriate resolution, accept this responsibility, the
2 University of California shall create a three-year
3 program, to be known as the California Marijuana
4 Research Program.

5 (2) The program shall develop and conduct studies
6 intended to ascertain the general medical safety and
7 efficacy of marijuana and, if found valuable, shall develop
8 medical guidelines for the appropriate administration
9 and use of marijuana.

10 (3) If the Regents of the University of California do not
11 implement the program provided for in this section
12 within 60 days of the effective date of this section, the
13 Research Advisory Panel established pursuant to Section
14 11480 shall assume the responsibility for selecting a
15 program in accordance with this section ~~from proposals~~
16 ~~submitted by researchers at the University of California.~~

17 (b) The program may immediately solicit proposals
18 for research projects to be included in the marijuana
19 studies. Program requirements to be used when
20 evaluating responses to its solicitation for proposals, shall
21 include, but not be limited to, all of the following:

22 (1) Proposals shall demonstrate the use of key
23 personnel, including clinicians or scientists and support
24 personnel, who are prepared to develop a program of
25 research regarding marijuana's general medical efficacy
26 and safety.

27 (2) Proposals shall contain procedures for outreach to
28 patients with various medical conditions who may be
29 suitable participants in research on marijuana.

30 (3) Proposals shall contain provisions for a patient
31 registry.

32 (4) Proposals shall contain provisions for an
33 information system that is designed to record information
34 about possible study participants, investigators, and
35 clinicians, and deposit and analyze data that accrues as
36 part of clinical trials.

37 (5) Proposals shall contain protocols suitable for
38 research on marijuana, addressing patients diagnosed
39 with the acquired immunodeficiency syndrome (AIDS)
40 or the human immunodeficiency virus (HIV), cancer,



1 glaucoma, or seizures or muscle spasms associated with a
2 chronic, debilitating condition. The proposal may also
3 include research on other serious illnesses, provided that
4 resources are available and medical information justifies
5 the research.

6 (6) Proposals shall demonstrate the use of a specimen
7 laboratory capable of housing plasma, urine, and other
8 specimens necessary to study the concentration of
9 cannabinoids in various tissues, as well as housing
10 specimens for studies of toxic effects of marijuana.

11 (7) Proposals shall demonstrate the use of a laboratory
12 capable of analyzing marijuana, provided to the program
13 under this section, for purity and cannabinoid content
14 and the capacity to detect contaminants.

15 (c) In order to ensure objectivity in evaluating
16 proposals, the program shall use a peer review process
17 that is modeled on the process used by the National
18 Institutes of Health, and that guards against funding
19 research that is biased in favor of or against particular
20 outcomes. Peer reviewers shall be selected for their
21 expertise in the scientific substance and methods of the
22 proposed research, and their lack of bias or conflict of
23 interest regarding the applicants or the topic of an
24 approach taken in the proposed research. Peer reviewers
25 shall judge research proposals on several criteria,
26 foremost among which shall be both of the following:

27 (1) The scientific merit of the research plan, including
28 whether the research design and experimental
29 procedures are potentially biased for or against a
30 particular outcome.

31 (2) Researchers' expertise in the scientific substance
32 and methods of the proposed research, and their lack of
33 bias or conflict of interest regarding the topic of, and the
34 approach taken in, the proposed research.

35 (d) If the program is administered by the Regents of
36 the University of California any grant research proposals
37 approved by the program shall also require review and
38 approval by the research advisory panel.

39 (e) It is the intent of the Legislature that the program
40 be established as follows:



1 (1) The program shall be located at one or more
2 University of California campuses that have a core of
3 faculty experienced in organizing multidisciplinary
4 scientific endeavors and, in particular, strong experience
5 in clinical trials involving psychopharmacologic agents.
6 The campuses at which research under the auspices of the
7 program is to take place shall accommodate the
8 administrative offices, including the director of the
9 program, as well as a data management unit, and facilities
10 for storage of specimens.

11 (2) When awarding grants under this section, the
12 program shall utilize principles and parameters of the
13 other well-tested statewide research programs
14 administered by the University of California, modeled
15 after programs administered by the National Institutes of
16 Health, including peer review evaluation of the scientific
17 merit of applications.

18 (3) The scientific and clinical operations of the
19 program shall occur, partly at University of California
20 campuses, and partly at other postsecondary institutions,
21 that have clinicians or scientists with expertise to conduct
22 the required studies. Criteria for selection of research
23 locations shall include the elements listed in subdivision
24 (b) and, additionally, shall give particular weight to the
25 organizational plan, leadership qualities of the program
26 director, and plans to involve investigators and patient
27 populations from multiple sites.

28 (4) The funds received by the program shall be
29 allocated to various research studies in accordance with
30 a scientific plan developed by the Scientific Advisory
31 Council. As the first wave of studies is completed, it is
32 anticipated that the program will receive requests for
33 funding of additional studies. These requests shall be
34 reviewed by the Scientific Advisory Council.

35 (5) The size, scope, and number of studies funded shall
36 be commensurate with the amount of appropriated and
37 available program funding.

38 (e) All personnel involved in implementing approved
39 proposals shall be authorized as required by Section
40 11604.



1 (f) Studies conducted pursuant to this section shall
2 include the greatest amount of new scientific research
3 possible on the medical uses of, and medical hazards
4 associated with, marijuana. The program shall consult
5 with the Research Advisory Panel analogous agencies in
6 other states, and appropriate federal agencies in an
7 attempt to avoid duplicative research and the wasting of
8 research dollars.

9 (g) The program shall make every effort to recruit
10 qualified patients and qualified physicians from
11 throughout the state.

12 (h) The marijuana studies shall employ state-of-the-art
13 research methodologies.

14 (i) The program shall ensure that all marijuana used in
15 the studies is of the appropriate medical quality and shall
16 be obtained from National Institute on Drug Abuse or any
17 other federal agency designated to supply marijuana for
18 authorized research. If these federal agencies fail to
19 provide a supply of adequate quality and quantity within
20 six months of the effective date of this section, the
21 Attorney General shall provide an adequate supply
22 pursuant to Section 11478.

23 (j) The program may review, approve, or incorporate
24 studies and research by independent groups presenting
25 scientifically valid protocols for medical research,
26 regardless of whether the areas of study are being
27 researched by the committee.

28 (k) (1) To enhance understanding of the efficacy and
29 adverse effects of marijuana as a pharmacological agent,
30 the program shall conduct focused controlled clinical
31 trials on the usefulness of marijuana in patients diagnosed
32 with AIDS or HIV, cancer, glaucoma, or seizures or
33 muscle spasms associated with a chronic, debilitating
34 condition. The program may add research on other
35 serious illnesses, provided that resources are available and
36 medical information justifies the research. The studies
37 shall focus on comparisons of both the efficacy and safety
38 of methods of administering the drug to patients,
39 including inhalational, tinctural, and oral, evaluate
40 possible uses of marijuana as a primary or adjunctive



1 treatment, and develop further information on optimal
2 dosage, timing, mode of administration, and variations in
3 the effects of different cannabinoids and varieties of
4 marijuana.

5 (2) The program shall examine the safety of marijuana
6 in patients with various medical disorders, including
7 marijuana's interaction with other drugs, relative safety
8 of inhalation versus oral forms, and the effects on mental
9 function in medically ill persons.

10 (3) The program shall be limited to providing for
11 objective scientific research to ascertain the efficacy and
12 safety of marijuana as part of medical treatment, and
13 should not be construed as encouraging or sanctioning
14 the social or recreational use of marijuana.

15 (l) (1) Subject to paragraph (2), the program shall,
16 prior to any approving proposals, seek to obtain research
17 protocol guidelines from the National Institutes of Health
18 and shall, if the National Institutes of Health issues
19 research protocol guidelines, comply with those
20 guidelines.

21 (2) If, after a reasonable period of time of not less than
22 six months and not more than a year has elapsed from the
23 date the program seeks to obtain guidelines pursuant to
24 paragraph (1), no guidelines have been approved, the
25 program may proceed using research protocol guidelines
26 it develops.

27 (m) In order to maximize the scope and size of the
28 marijuana studies, the program may do any of the
29 following:

30 (1) Solicit, apply for, and accept funds from
31 foundations, private individuals, and all other funding
32 sources that can be used to expand the scope or
33 timeframe of the marijuana studies that are authorized
34 under this section. The program shall not expend more
35 than 5 percent of its General Fund allocation in efforts to
36 obtain money from outside sources.

37 (2) Include within the scope of the marijuana studies
38 other marijuana research projects that are independently
39 funded and that meet the requirements set forth in
40 subdivisions (a) to (c), inclusive. In no case shall the



1 program accept any funds that are offered with any
2 conditions other than that the funds be used to study the
3 efficacy and safety of marijuana as part of medical
4 treatment. Any donor shall be advised that funds given
5 for purposes of this section will be used to study both the
6 possible benefits and detriments of marijuana and that he
7 or she will have no control over the use of these funds.

8 (n) (1) Within six months of the effective date of this
9 section, the program shall report to the Legislature, the
10 Governor, and the Attorney General on the progress of
11 the marijuana studies.

12 (2) Thereafter, the program shall issue a report to the
13 Legislature every six months detailing the progress of the
14 studies. The interim reports required under this
15 paragraph shall include, but not be limited to, data on all
16 of the following:

17 (A) The names and number of diseases or conditions
18 under study.

19 (B) The number of patients enrolled in each study by
20 disease.

21 (C) Any scientifically valid preliminary findings.

22 (o) If the Regents of the University of California
23 implement this section, the President of the University of
24 California shall appoint a multidisciplinary Scientific
25 Advisory Council, not to exceed 15 members, to provide
26 policy guidance in the creation and implementation of
27 the program. Members shall be chosen on the basis of
28 scientific expertise. Members of the council shall serve on
29 a voluntary basis, with reimbursement for expenses
30 incurred in the course of their participation. The
31 members shall be reimbursed for travel and other
32 necessary expenses incurred in their performance of the
33 duties of the council.

34 (p) No more than 10 percent of the total funds
35 appropriated be used for all aspects of the administration
36 of this section.

37 SEC. 4. (a) There is appropriated the sum of one
38 million dollars (\$1,000,000) from the General Fund to the
39 University of California for establishing and operating,
40 during its first year, the California Marijuana Research



1 Program provided for pursuant to Section 11362.9 of the
2 Health and Safety Code.

3 (b) It is the intent of the Legislature to appropriate,
4 pursuant to the Budget Act, one million dollars
5 (\$1,000,000) for each of the final two years for program
6 operation.

7 SEC. 5. This act is an urgency statute necessary for the
8 immediate preservation of the public peace, health, or
9 safety within the meaning of Article IV of the
10 Constitution and shall go into immediate effect. The facts
11 constituting the necessity are:

12 The people of California have expressed their wishes
13 regarding the medical use of marijuana by passing
14 Proposition 215 in November 1996. In order to enable the
15 controversy regarding the medical efficacy and safety of
16 marijuana to be resolved at the earliest possible time, it
17 is necessary that this act go into immediate effect.

