

AMENDED IN SENATE JUNE 3, 1997
AMENDED IN SENATE MAY 23, 1997
AMENDED IN SENATE MAY 20, 1997
AMENDED IN SENATE APRIL 10, 1997
AMENDED IN SENATE MARCH 31, 1997

SENATE BILL

No. 535

**Introduced by Senator Vasconcellos
(Coauthor: Senator McPherson)**

February 24, 1997

An act to add Sections ~~11362.59 and 11362.62~~ Section 11362.59 to the Health and Safety Code, relating to marijuana, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 535, as amended, Vasconcellos. Marijuana implementation.

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 caregiver, 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 authorize the University of California to create a California Medical Marijuana Research Center to develop and implement medical marijuana studies and to solicit proposals for research projects to be included in the studies. The bill would authorize the center to raise funds and to include other research projects in the studies.

The bill would appropriate \$1,000,000 from the General Fund to the center to conduct the studies.
The bill would establish the Medical Marijuana Distribution System Task Force to aid the center in obtaining a source of marijuana for its studies and to research and design a statewide plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana. The bill would set forth the membership of the task force and would appropriate \$140,000 from the General Fund to the task force.

The bill would state that it is to take effect immediately as an urgency statute.

Vote: 2/3. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. This act shall be known and may be cited as the Proposition 215 Implementation Medical Marijuana Research Act of 1997.

SEC. 2. (a) The Legislature finds and declares that, on November 5, 1996, the people of California, by a margin of over one million voters, enacted Proposition 215. By their approval of Proposition 215, California voters affirmed all of the following:

(1) Medical marijuana is a drug with appropriate uses for the treatment of thousands of Californians suffering from serious illnesses.

(2) Physician/recommended use of medical marijuana is a health issue and not a criminal justice issue.

(3) Patients who use medical marijuana in a manner consistent with the measure are not criminals and must not be treated as such.

(4) California should develop a method for the safe, affordable distribution of medical marijuana to all patients in need of it.

(b) The Legislature also finds and declares all of the following:

(1) The greatest obstacle to patient access to medical marijuana in cases where it is medically appropriate is reticence on the part of some licensed physicians and surgeons to recommend it to seriously ill patients for the following reasons:

(A) There is a need for more, scientific research on the appropriate uses of medical marijuana.

(B) Physicians fear federal or state retribution for recommending or approving patient use of medical marijuana.

(9) The federal government has failed to conform its medical marijuana policy to the desires of the Legislature as expressed in Resolution Chapter 70 of the Statutes of 1992, and, therefore, the implementation of Proposition 215 is an urgent issue for the health and safety of suffering Californians.

(e) The Legislature hereby acts to resolve the impediments to the implementation of Proposition 215 SEC. 2. It is the intent of the Legislature that both the following apply:

(a) That Proposition 215, as approved by the voters on November 5, 1996, be implemented expeditiously and in a manner that is consistent with the understanding of the voters of California of the purpose and intent of the measure.

(b) That this act be enacted by urgency in order to ensure that the Legislature keeps the faith and will of the people and addresses the immediate needs of Californians who have a legitimate medical use of marijuana.

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

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1 nausea and vomiting due to anticancer treatment
 2 control of spasticity in conditions like multiple sclerosis;
 3 intraocular pressure in glaucoma, and seizure disorders
 4 (6) A specimen laboratory capable of housing plasma
 5 urine, and other tissue specimens necessary to study the
 6 concentration of cannabinoids in various tissues, as well
 7 as housing specimens for related studies of possible toxic
 8 effects of medical marijuana.
 9 (7) A laboratory capable of analyzing marijuana for
 10 purity and cannabinoid content and the capacity to
 11 detect contaminants.
 12 (b) It is the intent of the Legislature that the center be
 13 established as follows:

14 (1) The center shall be located at a University of
 15 California campus that has a core of faculty experienced
 16 in organizing multidisciplinary scientific endeavors and,
 17 in particular, strong experience in clinical trials involving
 18 psychopharmacologic agents. The campus at which the
 19 center is located shall accommodate the administrative
 20 offices, including the director, as well as a data
 21 management unit, and facilities for storage of specimens.
 22 (2) The scientific and clinical operations of the center
 23 shall occur partly at the campus where the center is
 24 located, and partly at other campuses, both University of
 25 California and non-University of California, that have
 26 clinicians or scientists with expertise to conduct the
 27 required studies. If more than one proposal for a center
 28 is submitted, criteria for selection shall include the
 29 elements listed in subdivision (a) and, additionally, shall
 30 give particular weight to the organizational plan,
 31 leadership qualities of the director, and plans to involve
 32 investigators and patient populations from multiple sites.

33 (3) The funds received by the center shall be allocated
 34 to various research studies in accordance with a scientific
 35 plan developed by the group of investigators who wish to
 36 be part of the center. As the first wave of studies is
 37 completed, it is anticipated that the center will receive
 38 requests for funding of additional studies. These requests
 39 shall be reviewed by a council of investigators consisting

1 (a) On November 5, 1996, the people of California,
 2 with more than six million voters, approved Proposition
 3 215.

4 (b) There is public controversy regarding the medical
 5 efficacy of marijuana.
 6 (c) There is a need for objective scientific research
 7 regarding the efficacy of, and appropriate methodologies
 8 for administering medical marijuana.

9 SEC. 3. It is the intent of the Legislature that the state
 10 commission objective scientific research by the premier
 11 research institute of the world, the University of
 12 California, regarding the efficacy and appropriateness of
 13 administering medical marijuana.

14 SEC. 4. Section 11362.59 is added to the Health and
 15 Safety Code, to read:
 16 11362.59. (a) The University of California shall create
 17 the California Medical Marijuana Research Center,
 18 which shall develop and implement medical marijuana
 19 studies intended to ascertain the general medical safety
 20 and efficacy of marijuana and, if found valuable, to
 21 develop medical guidelines for the appropriate
 22 administration and use of marijuana. The center shall
 23 include the following elements:

24 (1) Key personnel, including clinicians or scientists
 25 and support personnel, who are prepared to develop a
 26 program of research on regarding the efficacy and
 27 potential uses of medical marijuana for various illnesses.
 28 (2) Procedures for outreach to patients with various
 29 medical conditions that may be suitable participants in
 30 research on medical marijuana.

31 (3) A patient registry.
 32 (4) An information system that is designed to record
 33 information about possible study participants,
 34 investigators, and clinicians, and deposit and analyze data
 35 that accrues as part of clinical trials.

36 (5) Protocols suitable for research on medicinal
 37 marijuana addressing several diseases for which evidence
 38 exists that marijuana may be useful, including, but not
 39 limited to, wasting in AIDS, painful peripheral
 40 neuropathy in AIDS and other conditions, control of

of senior scientists associated with the center, as well as by an advisory group of scientists and informed citizens.

(4) It is the intent of the Legislature that indirect cost recovery by the University of California shall be limited to a maximum of 15 percent of the annual state allocation to the center.

(c) The center may immediately solicit proposals for research projects to be included in the medical marijuana studies. The center shall focus its efforts on medical indications for which existing research shows marijuana use to be most promising therapeutically.

(d) The medical marijuana studies shall include the greatest amount of new scientific research possible on the medical uses of marijuana. The center shall consult with analogous agencies in other states in an attempt to avoid duplicative research and the wasting of research dollars.

(e) The medical marijuana studies shall be designed to include the broadest variety of patients, physicians, and medical conditions as possible feasible.

(f) The center shall make every effort to recruit patients and physicians from throughout the state for the medical marijuana studies.

(g) The medical marijuana studies shall employ state-of-the-art research methodologies.

(h) The center shall ensure that all medical marijuana used in the studies is of the appropriate medical quality.

If possible, the medical marijuana shall be obtained from the National Institute on Drug Abuse or any other federal agency designated to supply marijuana for authorized research. The center shall ensure that all medical marijuana used in the studies is of the appropriate medical quality authorized research. The center may review, approve, or incorporate studies and research by independent groups presenting scientifically valid

1 protocols for medical research regardless of whether the
2 areas of study are being researched by the committee.

3 (4) (1) To enhance understanding of the efficacy and
4 adverse effects of marijuana as a pharmacological agent,
5 the center shall conduct focused controlled clinical trials
6 on the usefulness of marijuana in conditions such as
7 chronic pain, including AIDS neuropathy, utility of
8 marijuana in treatment of nausea related to chronic
9 disease or antineoplastic chemotherapy, utility as an
10 anticonvulsant, usefulness in chronic inanition, (wasting),
11 and treatment of glaucoma. The trials shall focus on
12 comparisons between routes of delivery, including
13 inhalational and oral, evaluate possible uses of marijuana
14 as a primary or adjunctive treatment, and develop
15 further information on optimal dosage, timing, mode of
16 administration, and variations in the effects of different
17 cannabinoids and varieties of marijuana.

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

(j) Within six months of the operative date of this
section, the center shall report to the Legislature on the
progress of the medical marijuana studies.

(k) Thereafter, the center shall issue a report to the
Legislature every six months detailing the progress of the
studies. The interim reports shall include, but shall not be
limited to, data on all of the following:

(1) The names and number of diseases or conditions
under studies.

(2) The number of patients enrolled in the study per
disease.

(3) Any scientifically valid preliminary findings.
(4) To enhance understanding of the efficacy and
adverse effects of marijuana as a pharmacological agent,
the center shall conduct focused controlled clinical trials
on the usefulness of marijuana in conditions such as

1 chronic pain, including AIDS neuropathy, utility of
 2 marijuana in treatment of nausea related to chronic
 3 disease or antineoplastic chemotherapy, utility as an
 4 anti-emetic, usefulness in chronic incontinence (wasting),
 5 and treatment of glaucoma. The trials shall focus on
 6 comparisons between routes of delivery, including
 7 inhalational and oral, evaluate possible uses of marijuana
 8 as a primary or adjunctive treatment, and develop
 9 further information on optimal dosage, timing, mode of
 0 administration, and variations in the effects of different
 1 cannabinoids and varieties of marijuana.

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

7 (l) The center shall no longer receive funding for the
 8 medical marijuana studies after three years.

9 (m) In order to maximize the scope and size of the
 0 medical marijuana studies, the California Medical
 1 Marijuana Research Center may do both of the following:

- 2 (1) Solicit, apply for, and accept funds from
- 3 foundations, private individuals, and all other funding
- 4 sources that can be used to expand the scope or
- 5 timeframe of the medical marijuana studies that are
- 6 authorized under subdivision (a). In no case shall the
- 7 center expend more than 5 percent of its allocated
- 8 general fund funding in efforts to obtain money from
- 9 outside sources.
- 0 (2) Include within the scope of the medical marijuana
- 1 studies other medical marijuana research projects that
- 2 are independently funded and that meet the
- 3 requirements set forth in subdivision (a).

4 (n) No provision of this section or Section 11352.62
 5 shall apply to the University of California except to the
 6 extent that the Regents of the University of California, by
 7 appropriate resolution, make that provision applicable.

1 (n) It is the intent of the Legislature that the
 2 California Medical Marijuana Research Center
 3 (CMMRC) be established as follows:

- 4 (1) The CMMRC shall be located at a University of
 5 California campus that has a core of faculty experienced
 6 in organizing multidisciplinary scientific endeavors and,
 7 in particular, strong experience in clinical trials involving
 8 psychopharmacologic agents. The campus at which the
 9 CMMRC is located shall accommodate the administrative
 0 offices, including the director, as well as a data
 1 management unit, and facilities for storage of specimens.
- 2 (2) The scientific and clinical operations of the center
 3 shall occur partly at the campus where the center is
 4 located, and partly at other campuses, both University of
 5 California and non-University of California, that have
 6 clinicians or scientists with expertise to conduct the
 7 required studies. If more than one proposal for a CMMRC
 8 is submitted, criteria for selection shall include the
 9 elements listed in subdivision (a) of Section 11352.59 and,
 0 additionally, shall give particular weight to the
 1 organizational plan, leadership qualities of the director,
 2 and plans to involve investigators and patient populations
 3 from multiple sites.

4 (3) The funds received by the center shall be allocated
 5 to various research studies in accordance with a scientific
 6 plan developed by the group of investigators who wish to
 7 be part of the center. As the first wave of studies is
 8 completed, it is anticipated that the center will receive
 9 requests for funding of additional studies. These requests
 0 shall be reviewed by a council of investigators consisting
 1 of senior scientists associated with the center, as well as
 2 by an advisory group of scientists and informed citizens.

3 (4) It is the intent of the Legislature that indirect cost
 4 recovery by the University of California shall be limited
 5 to a maximum of 15 percent of the annual state allocation
 6 to the CMMRC.

7 (o) It is the intent of the Legislature that if the
 8 National Institutes of Health issues research protocol
 9 guidelines, the CMMRC shall comply with the guidelines.

SEC. 5. Section 11362.68 is added to the Health and Safety Code, to read:

(a) Pursuant to subparagraph (C) of paragraph (1) of subdivision (b) of Section 11362.5 and in keeping with the will of the voters, the Legislature hereby creates the Medical Marijuana Distribution System Task Force, which is charged with the research and design of a statewide plan to provide for the safe and affordable distribution of marijuana to all patients in medical need of marijuana. The first order of business of the task force shall be to aid the California Medical Marijuana Research Center in obtaining a source of marijuana for the studies required to be conducted by the center pursuant to Section 11362.50. The task force shall analyze the attributes of public and private distribution systems and the attributes of existing means of distribution. The task force shall confer with appropriate federal agencies and shall consider the federal perspective in its analysis.

(b) In order to provide breadth of perspective and public credibility, the task force shall consist of 13 members broadly reflective of the general public of California, including ethnic minorities, women, and persons of varying economic levels.

(c) The membership of the task force shall include all of the following:

(1) Three University of California faculty members appointed by the President of the University of California; One appointee shall be an expert in pharmacology; one in agriculture; one in medicine. The President shall appoint one of the three faculty members to chair the task force.

(2) Three citizen members appointed by the Governor, one from each of the following categories: organized statewide associations of physicians representing a wide array of specialties; law enforcement or criminologists; and the health care industry.

(3) Three citizen members appointed by the Senate Committee on Rules, one from each of the following categories: law enforcement or criminologist; medical

marijuana patients; either past or present; and organized registered nurses' societies or groups.

(4) Three citizen members appointed by the Speaker of the Assembly, one from each of the following categories: medical marijuana patient advocates; medical marijuana patients; either past or present; and the judiciary.

(d) The Governor shall appoint the vice chair of the task force.

(e) The Director of the California Medical Marijuana Research Center shall serve as a nonvoting member to facilitate information transfer between the center and the task force.

(f) Each appointing authority shall make the required appointments within 30 days of the operative date of this section. The chair or his or her designee shall call the first meeting of the task force within 45 days of the operative date of this section.

(g) All members shall be appointed for a term of two years and shall serve without compensation.

(h) In the event of a resignation, the inability of a member to continue service, or other vacancy, a new member shall be appointed to the task force by the original appointing authority in accordance with the requirements applicable to an original appointment.

(i) Task force members shall be reimbursed for normal travel and per diem expenses required to attend meetings.

(j) The chairperson shall appoint a search committee reflective of the composition of the task force which shall, in turn, make recommendations concerning selection of appropriate staff.

(k) The task force shall hold at least four public hearings per year to gather public input regarding a medical marijuana implementation system. The public hearings shall be held in different regions of the state in order to gather input from the largest number of citizens.

(l) The task force shall complete its work and report to the Legislature within two years of the first meeting

1 and shall provide the Legislature with an interim report
2 of its progress within one year from that date.

3 (m) The task force's report shall recommend to the
4 Legislature a medical marijuana distribution system that
5 meets the criteria outlined in Section 11362.5.

6 SEC. 6:

7 SEC. 5. The Legislature hereby appropriates one
8 million dollars (\$1,000,000) from the General Fund to the
9 California Medical Marijuana Research Center to
0 conduct the medical marijuana studies pursuant to
1 Section 11352.59 of the Health and Safety Code. It is the
2 intent of the Legislature to appropriate a like amount
3 through the budget process for the second and third years
4 of the studies.

5 SEC. 7. The sum of one hundred forty thousand
6 dollars (\$140,000) is hereby appropriated from the
7 General Fund to the Medical Marijuana Distribution
8 System Task Force for the purposes of Section 11352.62 of
9 the Health and Safety Code. It is the intention of the
0 Legislature to appropriate a like amount through the
1 budget process for the second year of the task force.

2 SEC. 8:

3 SEC. 6. This act is an urgency statute necessary for the
4 immediate preservation of the public peace, health, or
5 safety within the meaning of Article IV of the
6 Constitution and shall go into immediate effect. The facts
7 constituting the necessity are:

8 *In The people of California have expressed their wishes*
9 *regarding the use of medical marijuana by passing*
0 *Proposition 215 in November 1996. Controversy*
1 *regarding the medical efficacy of marijuana is being used*
2 *to prevent seriously ill Californians from pursuing their*
3 *options in this regard in a timely fashion, and the*
4 *controversy ought to be resolved by the expeditious*
5 *conduct of objective scientific research. In order to*
6 *ensure that the Legislature keeps the faith and will of the*
7 *people, and addresses the immediate needs of*
8 *Californians who have a legitimate medical use of*

1 marijuana, it is necessary that this act take effect
2 immediately.



State of California
Office of the Attorney General
Daniel E. Lungren
Attorney General

June 6, 1997

Honorable John Vasconcellos
California State Senate
State Capitol, Room 2004
Sacramento, California 95814

Re: SB 535

Dear Senator Vasconcellos:

This office has reviewed SB 535 as amended June 3, 1997. These amendments clearly reflect a conscientious effort on your part to meet the concerns which were expressed in the March 27, 1997 letter sent in opposition to the original version (February 24, 1997) of the proposal. Your effort deserves a serious and constructive response on our part.¹

Your May 21, 1997, letter requesting that we consider no further opposition to SB 535, states, "I hope you will agree we have an obligation to the 6 million Californians who voted for Proposition 215 to pursue the truth about medicinal marijuana." I am sure you would also agree that we have an obligation to all thirty-three million Californians to support objective scientific research to determine whether marijuana has any medical uses and whether any such uses are outweighed by detrimental effects.

Your amended proposal still contains language that is of concern to this office. We have not previously addressed these issues because of our belief that the overall constitutional problem was of greatest concern. Since the constitutional issue has been removed from this bill, we now believe it is appropriate to address the substantive language of the proposal.

My staff has prepared a "mark-up" of the bill containing appropriate language directed at the issue whether marijuana has any medical uses. This "mark-up" is attached. As you will see, our concerns are threefold.

¹It is, in our view, unfortunate that you have decided to continue to pursue what we believe to be unconstitutional attempts to amend Health and Safety Code section 11362.5 in another bill. However, removing these objectionable provisions from this bill does permit what we hope will be a beneficial exchange of views.

Honorable John Vasconcellos

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First, we read the current version of S.B. 535 as being skewed toward the conclusion that marijuana does have medicinal value. As you know, this conclusion has not yet been established. The vast majority of studies conducted to date have concluded that marijuana (as opposed to F.D.A.-approved products such as Marinol) has no medical value; and, in the opinion of some researchers, is even harmful. This use of skewed language does not create the framework for objective scientific research which you seek. Also, the proposal fails to exclude from research the participation of persons who have already reached a conclusion about the safety and/or efficacy of marijuana. The amendments we have offered in our "mark-up" address their problems and create a framework for truly objective scientific research.

Second, our "mark-up" requires greater efforts at cooperation with the federal government. As stated in our March 27, 1997, letter, the ultimate arbiter as to this issue is the federal government. For this reason, we believe that every effort should be made to obtain federal cooperation and approval of this study. After all, the language approved by the voters encouraged exactly this sort of cooperation in the distribution context (see section 11362.5(b)(1)(C)). It is important to remember that the federal government was fully cooperative and supportive with respect to the Cannabis Therapeutic Research Program conducted between 1980 and 1988 pursuant to state legislation (see the Report to the Legislature, January, 1989, a copy of which accompanies this letter). It is also important to emphasize that this previous study, conducted with the approval of the federal government" . . . was a factor in the decisions of the U.S. Food and Drug Administration (F.D.A.) to permit its (Marinol) marketing." (Report to the Legislature, Executive Summary, page vi).

Our "mark up" includes a role for the California Research Advisory Panel which successfully supervised the Cannabis Therapeutic Research Program study. By including the Research Advisory Panel we utilize a proven process that insures objective scientific answers to the important questions these studies will address.

Third, the version of your proposal marked up may well place the State of California, physicians, and other participating professionals in violation of Federal and State laws prohibiting furnishing marijuana.

The "mark-up" addresses this problem by limiting the proposal to the medical conditions delineated in *Conant, et al. v. McCaffrey, et al.* No. C97-0139 FMS, U.S.D.C., Northern District of California (see page 21 of opinion filed April 30, 1997). This limitation will serve to insure that participating physicians do not risk their prescription rights. The "mark up" incorporates the Health and Safety Code sections that immunize participants from criminal prosecution.


It is our tentative opinion that the present triplicate prescription system is perfectly adequate for distribution if and when scientific data can be presented to the federal government that would persuade them to permit physicians to prescribe marijuana. The triplicate system was utilized in connection with the Cannabis Therapeutic Research Program. The observed result was that it provided the necessary forms of marijuana or T.H.C. to the study subjects without any diversion to unapproved uses, in accordance with the goal of Health and Safety Code section 11362.5(b)(2).

If the changes set out in our "mark-up" can be incorporated into SB 535 we could not only withdraw our opposition, but would also join you and Senator McPherson in supporting the research.

Honorable John Vasconcellos
Page 3

As we have previously stated, this office is ready and willing to work with you to eliminate the basis for our opposition. Please contact Assistant Attorney General Jack Stevens at 324-5477 if you wish to discuss the matter further.

Sincerely,



DANIEL E. LUNGREN
Attorney General

Enclosures

cc: State Senator Bruce McPherson

SENATE BILL No. 535

An act to add Section 11362.59 to the Health and Safety Code, relating to marijuana, making an appropriation therefor, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 535, as amended, Vasconcellos. Marijuana:

Existing law, the Compassionate Use Act of 1996, ~~prohibits~~ *creates an affirmative legal defense against a criminal charge for a ~~any~~ physician for having recommended marijuana to a patient for medical purposes.* The act ~~prohibits~~ *creates an affirmative legal defense to charges of the provisions of law making unlawful the possession or cultivation of marijuana from applying for to a patient, or for to a patient's primary caregiver, 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 authorize the University of California to create a California ~~Medical~~ Marijuana Research Center to develop and implement ~~medical~~ marijuana studies and to solicit proposals for research projects to be included in the studies. ~~The bill would authorize the center to raise funds and to include other research projects in the studies.~~

The bill would appropriate \$1,000,000 from the General Fund to the center to conduct the studies.

The bill would state that it is to take effect immediately as an urgency statute.

Vote: 2/3. Appropriation: yes. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. This act shall be known and may be cited as the ~~Medical~~ Marijuana Research Act of 1997.

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

- (a) On November 5, 1996, the people of California, with more than six million voters, approved Proposition 215.
- (b) There is public ~~and scientific~~ controversy regarding the medical efficacy ~~and safety~~ of marijuana.
- (c) There is a need for objective scientific research regarding the efficacy of, and ~~appropriate methodologies for administering medical~~ safety of administering medical ~~treatment.~~

SEC 3. It is the intent of the Legislature that the state commission objective scientific research by the premier research institute of the world, the University of California, regarding the efficacy and ~~appropriateness~~ safety of administering medical marijuana ~~as part of medical treatment.~~

SEC. 4. Section 11362.59 is added to Health and Safety

Code, to read:

11362.59. (a) The University of California shall create the California Medical Marijuana Research Center, which shall develop and implement ~~medical marijuana~~ studies intended to ascertain the general medical efficacy and safety of marijuana. The center shall include the following elements:

(1) Key personnel, including clinicians or scientists and support personnel, who are prepared to develop a program of research regarding ~~the efficacy and potential uses of medical marijuana for various illnesses~~ marijuana's general medical efficacy and safety. The personnel selected shall not include any person who has through speeches, endorsements of political candidates or measures, writings, public appearances or statements, litigation or any other means been an advocate either for or against marijuana's use as a medical treatment.

(2) Procedures for outreach to patients with various medical conditions that may be suitable participants in research on medical marijuana.

(3) A patient registry.

(4) An information system that is designed to record information about possible study participants, investigators, and clinicians, and deposit and analyze data that accrues as part of clinical trials.

(5) Protocols suitable for research on medicinal marijuana addressing ~~several diseases for which evidence exists that marijuana may be useful, including, but not limited to, wasting in AIDS wasting in AIDS painful peripheral neuropathy in AIDS and other conditions, control of nausea and vomiting due to anticancer treatment, control of spasticity in conditions like multiple sclerosis, intraocular pressure in glaucoma, and seizure disorders~~ patients diagnosed with AIDS/HIV, cancer, glaucoma, and/or seizures or muscle spasms associated with a chronic, debilitating condition.

(6) A specimen laboratory capable of housing plasma, urine, and other tissue specimens necessary to study the concentration of the cannabinoids in various tissues, as well as housing specimens for related studies of possible toxic effects of medicinal marijuana.

~~(7) A laboratory capable of analyzing marijuana for purity and cannabinoid content and the capacity to detect contaminants.~~

(b) It is the intent of the Legislature that the center be established as follows:

(1) The center shall be located at a University of California campus that has a core of faculty experienced in organizing multidisciplinary scientific endeavors and, in particular, strong experience in clinical trials involving psychopharmacologic agents. The campus at which the center is located shall accommodate the administrative offices, including the director, as well as a data management unit, and facilities for storage of specimens.

(2) The scientific and clinical operations of the center shall occur partly at the campus where the center is located, and partly at other campuses, both University of California and non-University of California, that have clinicians or scientists with

expertise to conduct the required studies and who are not disqualified for any of the reasons set out in subsection (a)(1). If more than one proposal for a center is submitted, criteria for selection shall include the elements listed in subdivision (a) and, additionally, shall give particular weight to the organizational plan, leadership qualities of the director, and plans to involve investigators and patient populations from multiple sites.

(3) The funds received by the center shall be allocated to various research studies in accordance with a scientific plan developed by the group of investigators who wish to be part of the center. As the first wave of studies is completed, it is anticipated that the center will receive requests for funding of additional studies. These requests shall be reviewed by a council of investigators consisting of senior scientists associated with the center, as well as by an advisory group of scientists and informed citizens who are not disqualified for any of the reasons set out in subsection (a)(1). All such requests shall be subject to approval as required by Health and Safety Code section 11213 and 11480. All personnel involved in participation in requests which are approved shall be authorized as required by Health and Safety Code section 11604.

(4) It is the intent of the Legislature that indirect cost recovery by the University of California shall be limited to a maximum of 15 percent of the annual state allocation to the center.

(c) The center may immediately solicit proposals for research projects to be included in the ~~medical~~ marijuana studies. ~~The center shall focus its efforts on medical indications for which existing research shows marijuana use to be most promising therapeutically.~~ The center shall not consider proposals from persons who through speeches, endorsements of political candidates or measures, writings, public appearances or statements, litigation or any other means been an advocate either for or against marijuana's use as a medical treatment. All such proposals shall be subject to approval as required by Health and Safety Code section 11213 and 11480. All personnel involved in participation in proposals which are approved shall be authorized as required by Health and Safety Code section 11604.

(d) The ~~medical~~ marijuana studies shall include the greatest amount of new scientific research possible on the medical uses of and medical hazards associated with marijuana. The center shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate agencies of the federal government in an attempt to avoid duplicative research and the wasting of research dollars.

~~(e) The medical marijuana studies shall be designed to include the broadest variety of patients, physicians, and medical conditions as feasible.~~

(ef) The center shall make every effort to recruit qualified patients and qualified physicians from throughout the state for the medical marijuana studies.

(fg) The ~~medical~~ marijuana studies shall employ state-of-the-art research methodologies.

~~(gh) The center shall ensure that all medical marijuana used in the studies is of the appropriate medical quality. If possible, the medical marijuana shall be obtained from "the National Institute on Drug Abuse or any other federal" agency designated to supply marijuana for authorized research. The center may review, approve, or incorporate studies and research by independent groups presenting scientifically valid protocols for medical research regardless of whether the areas of study are being researched by the committee.~~

~~(hi) (1) To enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent, the center shall conduct focused controlled clinical trials on the usefulness of marijuana in conditions such as chronic pain, including AIDS neuropathy, utility of marijuana in treatment of nausea related to chronic disease or antineoplastic chemotherapy, utility as an anticonvulsant, usefulness in chronic inanition (wasting), and treatment of glaucoma. in patients diagnosed with AIDS/HIV, cancer, glaucoma, and/or seizures or muscle spasms associated with a chronic, debilitation condition. The trials shall focus on comparisons between routes of delivery, The studies shall focus on comparisons of both the efficacy and safety of methods of administering the drug to patients including inhalational and oral, evaluate possible uses of marijuana as a primary or adjunctive treatment, and develop further information on optimal dosage, timing, mode of administration, and variations in the effects on mental function in medically ill persons.~~

~~(2) Regardless whether marijuana is determined to be useful under certain circumstances, because it is a psychoactive drug, society has a stake in preventing individuals, particularly children and adolescents, from experimenting with marijuana or becoming regular users. The center shall develop new and more targeted approaches, whose efficacy can be established, and thereby establish a scientific basis for efforts at prevention. The center shall take a lead in developing new treatment techniques directed at those who become regular marijuana users.~~

~~(3) This legislation is limited to providing for objective scientific research to ascertain the efficacy and safety of marijuana as part of medical treatment and should not be construed either encouraging or sanctioning the social/recreational use of the drug.~~

~~(ij) Within six months of the operative date of this section, the center shall report to the Legislature, the Governor, and the Attorney General on the progress of the studies. The interim reports shall include, but shall not be limited to, data on all of the following:~~

- ~~(1) The names and number of diseases or conditions under studies.~~
- ~~(2) The number of patients enrolled in the study per disease.~~
- ~~(3) Any scientifically valid preliminary findings.~~

~~(j±) The center shall no longer receive funding for the medical marijuana studies after three years.~~

~~(km) In order to maximize the scope and size of medical marijuana studies, the California Medical Marijuana Research~~

Center may do both of the following:

~~(1) Solicit, apply for, and accept funds from foundations, private individuals, and all other funding sources that can be used to expand the scope or timeframe of the medical marijuana studies that are authorized under subdivision (a). In no case shall the center expend more than 5 percent of its allocated general fund funding in efforts to obtain money from outside sources.~~

~~(2) Include within the scope of the medical marijuana studies other medical marijuana research projects that are independently funded and that meet the requirements set forth in subdivision (a).~~

~~(ln) No provision of this section or Section 11352.62 shall apply to the University of California except to the extent that the Regents of the University of California, by appropriate resolution, make that provision applicable.~~

~~(mo) It is the intent of the Legislature that if the National Institute of Health issues research protocol guidelines, the CMMRE shall comply with the guidelines. The center shall, before any proposals are approved, seek to obtain research protocol guidelines from the National Institute of Health and shall, if the National Institute of Health issues research protocol guidelines, comply with such guidelines. If after a reasonable period of time of not less than six months, but not more than a year, from seeking to obtain guidelines none have been approved, the center may proceed using research protocol guidelines it develops.~~

SEC. 5. The Legislature hereby appropriates one million dollars (\$1,000,000) from the General Fund to the California Medical Marijuana Research Center to conduct the medical marijuana studies pursuant to Section 11352.59 of the Health and Safety Code. It is the intent of the Legislature to appropriate a like amount through the budget process for the second and third years of the studies.

SEC. 6. This act is an urgency statute necessary for the immediate preservations of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

The people of California have expressed their wishes regarding the use of medical marijuana by passing Proposition 215 in November 1996. Controversy regarding the medical efficacy and safety of marijuana is being used to prevent seriously ill Californians from pursuing their options in this regard in a timely fashion, and the controversy ought to be resolved by the expeditious conduct of objective scientific research. In order to ensure that the legislature keeps the faith and will of the people, and addresses the immediate needs to Californians who have a legitimate medical use of marijuana, it is necessary that this act take effect immediately.

DANIEL E. LUNGREN
Attorney General

JG
State of California
DEPARTMENT OF JUSTICE



1300 I STREET, SUITE 125
P.O. BOX 944255
SACRAMENTO, CA 94244-2550
Public: (916) 445-9555

Facsimile: (916) 322-2630
(916) 324-5477

June 5, 1997

The Honorable John Vasconcellos
California State Senate
State Capitol, Room 4061
Sacramento, California 95814

RE: Opposition to Your Measure, SB 54

Dear Senator Vasconcellos:

As you know from our March 27, 1997 letter with respect to SB 535, we believe that the amendments you propose are unconstitutional unless they are submitted to and approved by the electorate. For this reason, we regret that we must oppose SB 54 in its current form.

If you have any questions concerning our position on this bill, please contact Senior Assistant Attorney General John Gordnier at (916) 324-5169.

Sincerely,

DANIEL E. LUNGREN
Attorney General

JACK R. STEVENS
Assistant Attorney General
Legislative Affairs

JRS:rvo

cc: The Honorable John Vasconcellos, Chairman
Senate Committee on Public Safety
The Honorable Richard K. Rainey, Vice-Chairman
Senate Committee on Public Safety
Senate Committee on Public Safety
Mr. Charles Fennessey, Governor's Office
Mr. David Shaw, OCJP
Ms. Amy Frees, CPOA