AMENDED IN ASSEMBLY AUGUST 25, 1997

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) (Coauthor: Assembly Member Migden)

February 24, 1997

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 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

establishes a Research Advisory Panel to study and approve research projects concerning marijuana or hallucinogenic recommendation or approval of a physician. Existing law

studies intended to ascertain the general medical efficacy and the eenter program to raise funds and to include other projects to be included in the studies. The bill would authorize safety of marijuana and to solicit proposals for research create a California Medical Marijuana Research Center research projects in the studies. Program to develop and implement medical marijuana This bill would authorize the University of California to

The bill would appropriate \$1,000,000 from the General

Fund to the eenter program to conduct the studies.

assume the responsibility for creating the program if the within 60 days of the effective date of the bill. regents of the university do not implement those provisions The bill would require the Research Advisory Panel to

The bill would state that it is to take effect immediately as

an urgency statute. /3. Appropriation: yes.

Fiscal committee:

State-mandated local program: no.

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

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

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

following:

with more than six million voters votes, approved (a) On November 5, 1996, the people of California,

(b) There is public and scientific controversy

Proposition 215.

- 10 8 regarding the medical efficacy and safety of marijuana.
- efficacy and safety of marijuana as part of medica for administering medical marijuana. regarding the regarding the efficacy of, and appropriate methodologies (c) There is a need for objective scientific research

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

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

intended to ascertain the general medical safety and efficacy of marijuana and, if found valuable, to develop the California Medical Marijuana Research Center, the and use of marijuana. The eenter program shall include medical guidelines for the appropriate administration California Marijuana Research Program, which shall Safety Code, to read: develop and implement medical marijuana studies 11362.59. (a) The University of California shall create

18 the following elements: program shall use a peer review process to evaluate marijuana's general medical efficacy and safety. The uses of medical marijuana for various illnesses. program of research regarding the efficacy and potential and support personnel, who are prepared to develop a proposals. The peer reviewers shall judge research being both of the following: proposals on several criteria, foremost among the criteria (1) Key personnel, including clinicians or scientists

whether the research design and experimental procedures are potentially biased for or against a (A) The specific merit of the research plan, including

particular outcome.

demonstrated competence in conducting research speeches, endorsements, and public statements. personnel, as determined by their training and which shall include, but not be limited to, a review of their (B) An evaluation of the qualifications of the research

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

(3) A patient registry.

1 (4) An information system that is designed to record 2 information about possible study participants, 3 investigators, and clinicians, and deposit and analyze data 4 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, painful peripheral neuropathy in AIDS and other conditions, control of nausca and vomiting due to anticancer treatment, control of spasticity in conditions like multiple selecosis, intraocular pressure in glaucoma, and seizure disorders, marijuana addressing patients diagnosed with AIDS/HIV, cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The program may add research on other serious illnesses provided that resources are available and medical information justifies the research.

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

24 (7) A laboratory capable of analyzing marijuana, 25 provided to the program under the provisions of this 26 article, for purity and cannabinoid content and the 27 capacity to detect contaminants.

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

(1) The eenter program 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 eenter program is located shall accommodate the administrative offices, including the director, as well as a data management unit, and facilities for storage of specimens.

9 (2) The scientific and clinical operations of the eenter of program shall occur partly at the campus where the

University of California and non-University of California,
that have clinicians or scientists with expertise to conduct
the required studies. If more than one proposal for a
eenter program 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 eenter program 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 eenter program. As the first wave of studies is completed, it is anticipated that the eenter program 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 eenter program, 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.

(4) All proposals approved by the program shall be reviewed and approved also by the Research Advisory.

[Panel in accordance with Sections 11213 and 11480.]

(c) The eenter program 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 studies. All personnel involved in participation in proposals that are approved shall be authorized as required by Section 11604.

(d) The medical marijuana studies shall include the greatest amount of new scientific research possible on the medical uses of marijuana. The center, and medical hazards associated with, marijuana. The program shall consult with analogous agencies in other states in an

research and the wasting of research dollars. attempt to avoid the Research Advisory Panel, analogous federal government in an attempt to avoid duplicative agencies in other states, and appropriate agencies of the

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

(f) The center

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

(g) The medical marijuana studies shall follow

research methodologies. The marijuana studies shall employ state-of-the-art

(h) The center shall ensure that all medical marijuana

areas of study are being researched by the committee. approve, or incorporate studies and research by pursuant to Section 11478. The program may review, quality and quantity within six months, the Attorney supply marijuana for authorized research. The eenter If quality and shall be obtained from the National Institute possible, the medical marijuana shall be obtained from in the studies is of the appropriate medical quality. If independent groups presenting scientifically valid on Drug Abuse or any other federal agency designated to protocols for medical research regardless of whether the General of California shall provide an adequate supply the federal agencies fail to provide a supply of adequate The program shall ensure that all marijuana used

anticonvulsant, usefulness in chronic inanition (wasting), adverse effects of marijuana as a pharmacological agent, such as chronic pain, including AIDS neuropathy, utility clinical trials on the usefulness of marijuana in conditions disease or antineoplastic chemotherapy, utility as an of marijuana in treatment of nausea related to chronic the eenter program shall conduct focused controlled (h) (1) To enhance understanding of the efficacy and

40 38 37

glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The program may add inhalational patients diagnosed with AIDS/HIV, cancer, comparisons between routes of delivery, including on optimal dosage, timing, mode of administration, and adjunctive treatment, and develop further information oral, evaluate possible uses of marijuana as a primary or the drug to patients, including inhalational, tinctural, and resources are available and medical information justifies research on other serious illnessess provided that and treatment of glaucoma. The trials shall focus on variations in the effects of different cannabinoids and both the efficacy and safety of methods of administering the research. The studies shall focus on comparisons of varieties of marijuana.

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

function in medically ill persons.

marijuana as part of medical treatment and should not be construed as encouraging or sanctioning the social or scientific research to ascertain the efficacy and safety of recreational use of the drug. (3) This section is limited to providing for objective 海になる ここ

section, the program shall report to the Legislature, the section, the center shall report to the Legislature on the the medical marijuana studies. Governor, and the Attorney General on the progress of (i) Within six months of the operative date of this

(k) Thereafter, the center of the same

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

(1) The names and number of diseases or conditions

disease. (2) The number of patients enrolled in the study per 日本 はのは、これでは、日本のでは

(3) Any scientifically valid preliminary findings.

the medical marijuana studies after three years. (k) The program shall no longer receive funding for

Marijuana Research Center may do both of the following: medical marijuana studies, the California Medical marijuana studies, the program may: (1) In order to maximize the scope and size of the Silver of one fig.

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

requirements set forth in subdivision (a). In no case shall studies other medical marijuana research projects that efficacy and safety of marijuana as part of medical are conditions other than that the funds be used to study the control over the use of these funds. will be used to study both the possible benefits and detriments of marijuana and that he or she will have no the program accept any funds that are offered with any treatment. Any donor shall be advised that funds given (2) Include within the scope of the medical marijuana independently funded and that meet the

38 37 38 32 32 32 section within 60 days of the effective date of this section, of the University of California do not implement this resolution, make that provision applicable. If the Regents University of California except to the extent that the Regents of the University of California, by appropriate Section 11480 shall assume the responsibility accorded to the University of California by subdivision (a). the Research Advisory Panel established pursuant to (n) No provision of this section or Section 11352.62 (m) No provision of this section shall apply to the

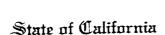
> research protocol guidelines from the National Institutes of Health and shall, if the National Institutes of Health guidelines, the CMMRC shall comply with the guidelines. guidelines. If after a reasonable period of time of not less issues research protocol guidelines, comply with those shall, before any proposals are approved, seek to obtain National Institutes of Health issues research protocol than six months, but not more than a year, from seeking program may proceed using research protocol guidelines to obtain guidelines none have been approved, the (n) It is the intent of the Legislature that the program (0) It is the intent of the Legislature that if the

medical marijuana studies pursuant to Section 11352.59 it develops. the Legislature to appropriate a like amount through the California Medical Marijuana Research million dollars (\$1,000,000) from the General Fund to the the studies. California Marijuana Research Program to conduct the budget process for the second and for the third years of 11362.59 of the Health and Safety Code. It is the intent of SEC. 5. The Legislature hereby appropriates one Center to

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

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

- marijuana ought to be resolved by the expeditious Of conduct of objective scientific research.



Office of the Attorney General Daniel E. Lungren

August 26, 1997

Honorable John Vasconcellos

California State Senate

State Capitol

Sacramento, Catifornia 95814

Dear Senator Vasconcellos:

I am pleased to endorse the latest amendments incorporated into Senate Bill 535. These amendments make it possible for this office to support the legislation.

Law enforcement and California's citizens will benefit from a thorough, objective study of the controversy surrounding the use of marijuana as medicine. It is unfortunate that this sort of definitive study could not have occurred before the passage of Proposition 215, but it is never too late to let good science shine light on a subject so that false notions can be set aside.

You and your staff are to be complimented for your willingness to work with many disparate interests to put this research structure in place, I am pleased to support this effort.

Sincerely,

DANZEL E. LUNGREN

Attorney General

NEWS RELEASE



Attorney General Dan Lungren California Department of Justice

http://caag.state.ca.us

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ATTORNEY GENERAL LUNGREN ANNOUNCES HIS SUPPORT FOR SENATE BILL 535 -- RESEARCH INTO MEDICAL MARIJUANA

CONTACT:Rob Stutzman (916) 324-5500

FOR IMMEDIATE RELEASE August 26, 1997 97-87

SACRAMENTO -- Attorney General Dan Lungren today announced his support for Senate Bill 535 which will establish a three-year study into the efficacy and safety of marijuana for medicinal purposes.

Lungren said, "the voters of California have made it clear that they want -- in the words of the initiative -- 'seriously ill Californians to have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate.' The still unanswered question is, when is it appropriate for marijuana to be used?"

Senate Bill 535 calls for an unbiased group of researchers based at the University of California to study the scientific controversy surrounding medical marijuana.

Lungren originally opposed Senate Bill 535, authored by Senator Vasconcellos (D-Santa Clara). Over the past year, Senator Vasconcellos worked with Lungren's office to revise the bill so that it addressed Lungren's concerns

"Past studies of marijuana, notwithstanding, California needs a definitive study," said Lungren. "This bill will fill the many information gaps that have made it difficult for ordinary Californians to know whether marijuana has any medicinal value."

Lungren also called on Californians to renew strong opposition to the recreational use of drugs and for California's youth to not misconstrue the purpose of SB 535.

"I also want to make a special point to California's youth," stated Lungren. "We are calling for a study of marijuana for medicinal purposes. We are not condoning the use of marijuana or any other illegal drug. A recent study showed declining rates of youth marijuana use in 48 states, but increases in two -- California and Arizona -- where pro-marijuana ballot measures passed in November. So while I hope that this legislation will clearly define the medicinal value of marijuana, if any is to be found, I also hope we will redouble our efforts to re-stigmatize recreational use of marijuana as stupid behavior which destroys life potential."



CALIFORNIA DISTRICT ATTORNEYS ASSOCIATION

731 K Street, Third Floor • Sacramento, CA 95814 • (916) 443-2017

August 22, 1997

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

RE: SB 535--Support as to be amended

Dear Senator Vasconcellos:

On behalf of the California District Attorneys Association, I am pleased to offer our support of your measure SB 535, as proposed to be amended. Your measure proposes to appropriate \$1 million to the University of California to research what, if any, medicinal value marijuana possesses.

As you are probably aware, CDAA opposed Proposition 215. We believed, as we still do today, that the measure was poorly drafted and could lead to abuses beyond what the public envisioned when it passed the initiative by a sizable margin.

However, the voters have spoken. Physician-recommended use of marijuana is now an affirmative defense to the possession and cultivation of marijuana under California law. As such, it is now vitally important that there be sufficient data on which physicians can determine whether to recommend marijuana to their patients. The CDAA Board of Directors concurs with your assessment that existing data on this matter is inadequate.

If I may answer any questions, please do not hesitate to contact me.

Very truly yours,

Lawrence G. Brown Executive Director

LGB/klh

pc: Honorable Daniel E. Lungren, Attorney General Honorable George Kennedy, President, CDAA

EXECUTIVE DIRECTOR LAWRENCE G. BROWN

Ealisornia Narcotic Officers' Association

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Immediate Past President BRIAN MCAULEY Riverside P.D. (ret)

August 25, 1997

Honorable John D. Vasconcellos California State Senate State Capitol, Room 4061 Sacramento, CA 95814

Re: SB 535

Dear Senator Vasconcellos:

The California Narcotic Officer's Association (C. N. O. A.) with a current strength of approximately 7,000 members dedicated to the suppression of illegal controlled substances in California, offer our support to SB 535 as it is proposed to be amended. SB 535 appropriates \$1 million of general fund money to conduct scientific research to determine what, if any, medicinal value marijuana possesses. There clearly is a difference of opinion within the medical profession and the public at large as to what, if any value that smoking marijuana may have on sick and dying people. Only a scientific study should substantiate whether smoking marijuana has any value as a medicine.

Surely, if scientific studies determine that smoking marijuana provides medical relief for critically ill patients. CNOA could support marijuana as a scheduled controlled substance that could be prescribed similar to any other medicine and obtained at any pharmacy.

Do not hesitate to contact me if I can answer any additional questions on this issue.

Sincerely,

Legislative Chairman



PUBLIC ISSUES OFFICE, CALIFORNIA DIVISION, INC.

July 24, 1997

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

Subject:

SB 535 - Support

Dear Senator Vasconcellos:

On behalf of the volunteers and staff of the American Cancer Society, I am pleased to inform you of our SUPPORT of SB 535 and commend you for introducing such an important piece of legislation.

Pain is a major health problem in this country; especially the kind of pain that is sometimes encountered in patients with cancer. According to experts, the treatment of pain and accompanying symptoms (i.e., fear, anxiety, depression, weakness, nausea, and vomiting) needs to be considerably improved. This is in spite of the fact that there are agents and techniques presently available that can provide relief for the majority of those patients.

In its amended form of June 3, 1997, SB 535 focuses on medical marijuana research. American Cancer Society now supports SB 535 because it is consistent with our long-held position of supporting research of any agent or technique for which there may be evidence of a therapeutic advantage.

I look forward to working with you on this issue. If I can assist you in any way, including research, testimony or other kinds of material support, please feel free to call.

Sincerely,

Theresa M. Renken Legislative Advocate



Senator, District 13

The Heart of Silicon Valley

Chair: Committee on Public Safety, Select Committee on Economic Development, Subcommittee on Aging

FOR IMMEDIATE RELEASE

August 26, 1997

Contact: Rand Martin

916/445-9740

Lungren, Law Enforcement Support Medical Marijuana Research Bill

Senator John Vasconcellos (D-Santa Clara) and Attorney General Dan Lungren today announced agreement on amendments to SB 535 that have gained the endorsement of California's law enforcement community. SB 535 appropriates \$1 million to the University of California to conduct research on the efficacy and safety of marijuana as medical treatment.

"Eleven months ago, Dan Lungren and I were on opposite sides of Proposition 215, one of the most passionately debated initiatives of the 1996 general election," said Vasconcellos. "Whatever our differences about that medical marijuana initiative, together we appreciate the critical importance of our state conducting objective, responsible, peer-reviewed research on medical marijuana. Questions have been raised, the federal government to date has failed to try to answer them; the voters of California have placed us on the cutting edge of this issue, it is incumbent our state fill that research void.

"I appreciate Mr. Lungren's offer to negotiate amendments to SB 535 and the heroic work of his staff and mine. After two months of negotiations, we have an agreement that maintains the integrity of the bill's research goals while responding to law enforcement concerns. The Attorney General and I share a commitment to pure, unbiased research, a goal which SB 535 embodies."

Law enforcement support was represented by Santa Clara County District Attorney George Kennedy, President of the California District Attorneys Association, and Mike Gilbert, Past President of the California Narcotics Officers Association. Vasconcellos and Lungren were joined by the bill's coauthors, Senator Bruce McPherson (R-Santa Cruz) and Assemblywoman Carole Migden (D-San Francisco).

-more-

Page Two

The major amendments to SB 535 include the following:

- makes explicit the peer review process must ensure the objectivity of research personnel, evaluating their qualifications including their speeches, endorsements and public statements.
- prohibits private donations to marijuana research under this bill that come with any conditions or restrictions.
- requires the state to comply with research guidelines developed by the National Institutes of Health unless NIH fails to provide such guidelines within six months of the state's request.
- conforms to existing law by requiring research protocols be reviewed and approved by the state's existing Research Advisory Panel.
- requires the Attorney General to provide an adequate supply of the drug if the federal government fails to provide a supply within six months of the state's request.
 - provides legal protection and authorization for research personnel.
- clarifies that this section is not intended to condone social/recreational use of marijuana.

Vasconcellos was also pleased to announce the American Cancer Society joined the California Medical Association and California Nurses Association in supporting SB 535.

SB 535 passed the Senate floor with 7 Republican and 20 Democratic votes and the Assembly Higher Education committee with 2 Republican and 6 Democratic votes. It is pending in the Assembly Appropriations Committee.

#####

PLEASE RESPOND TO: ☐ SACRAMENTO OFFICE

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Assembly California Legislature

CAROLE MIGDEN

ASSEMBLYWOMAN, THIRTEENTH DISTRICT

Chairwoman **Assembly Committee on Appropriations**

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SB 535: MARIJUANA RESEARCH ACT OF 1997 STATEMENT OF ASSEMBLYWOMAN CAROLE MIGDEN **AUGUST 26, 1977**

These days there's a lot of talk about marijuana. That it's the gateway to harder drug use. That more and more young people are using it. That Proposition 215 has put us on the proverbial slippery slope.

Well SB 535 isn't about any of that, and I am proud to be here today to support it. SB 535 will provide the mechanism to once and for all -- and in a logical and scientific way -answering the question of whether marijuana can be used to help relieve the suffering of people with HIV/AIDS and other debilitating conditions. That is what Proposition 215 was all about -being compassionate -- not fostering an "alternative lifestyle". And that's why the people of California voted for it.

SB 535 will bring the resources of the great University of California to bear on whether the medical use of marijuana is efficacious and safe. In other words, it should make all the objections go "up in smoke". The results of this objective research will give doctors better knowledge of the effective uses of marijuana and in the long run enable them to prescribe it for their patients without fear of being arrested. It will also give real people with real suffering an effective alternate treatment without fear of social stigma or legal consequences.

SB 535 allows us to be both compassionate and responsible.