

AMENDED IN SENATE MARCH 27, 2001

SENATE BILL

No. 336

Introduced by Senator Ortiz

February 20, 2001

~~An act to add 24177.5 of the Health and Safety Code, relating to medical experiments, and declaring the urgency thereof, to take effect immediately. An act to amend Section 122405 of the Health and Safety Code, relating to hepatitis C.~~

LEGISLATIVE COUNSEL'S DIGEST

SB 336, as amended, Ortiz. ~~Exemption from Medical Experimentation Act~~ *Hepatitis C.*

Existing law contains various legislative findings, declarations, and statements of intent with respect to hepatitis C, including a statement of intent that the Legislature urge the State Department of Health Services to make funds available to community-based nonprofit organizations for education and outreach with respect to the hepatitis C virus.

This bill would instead declare the intent of the Legislature to enact legislation to make funds available to local public health jurisdictions and nonprofit organizations to develop a cost-effective system of care for those individuals diagnosed with hepatitis C. It would also declare the intent of the Legislature to enact legislation to develop an outreach and education program with respect to hepatitis C.

~~Existing law, the Protection of Human Subjects in Medical Experimentation Act, prohibits any person from being subjected to any medical experiment unless the informed consent of the person is obtained.~~

~~This bill would provide an exemption from the act for any medical experimental treatment that benefits a patient subject to a life-threatening emergency that is conducted in accordance with prescribed requirements even if the patient is unable to give informed consent because of the medical condition.~~

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

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

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

- 1 ~~SECTION 1.—Section 24177.5 is added to the Health and~~
 2 *SECTION 1. Section 122405 of the Health and Safety Code is*
 3 *amended to read:*
 4 122405. The Legislature hereby finds and declares all of the
 5 following:
 6 (a) Hepatitis C is classified as a silent killer, where no
 7 recognizable signs or symptoms occur until severe liver damage
 8 has occurred.
 9 (b) Hepatitis C has been characterized by the World Health
 10 Organization as a disease of primary concern to humanity.
 11 (c) Studies indicate that 1.8 percent of the population, nearly 4
 12 million Americans, carry the virus HCV that causes hepatitis C. In
 13 California, as many as 500,000 individuals may be carriers and
 14 could develop the debilitating and potentially deadly liver disease
 15 associated with hepatitis C in their lifetime. An expert panel,
 16 convened in March by the National Institutes of Health (NIH),
 17 estimated that 30,000 acute new infections occur each year in the
 18 United States, and only 25 to 30 percent of those are diagnosed.
 19 Current data sources indicate that 8,000 to 10,000 Americans die
 20 from hepatitis C each year.
 21 (d) Studies also indicate that 39.4 percent of male inmates and
 22 54.5 percent of female inmates in California correctional facilities
 23 have hepatitis C, 26 times higher than the general population.
 24 Upon their release from prison, these inmates present a significant
 25 health risk to the general population of California.
 26 (e) It is the intent of the Legislature to study the adequacy of the
 27 health care delivery system as it pertains to hepatitis C.



1 (f) It is the intent of the Legislature to ~~urge the department to~~
2 ~~make funds available to community-based nonprofit organizations~~
3 ~~for education and outreach with respect to the~~ *enact legislation to*
4 *make funds available to local public health jurisdictions and*
5 *nonprofit organizations to develop a cost-effective system of care*
6 *for those individuals diagnosed with hepatitis C virus.*

7 (g) *It is the intent of the Legislature to enact legislation to*
8 *develop an outreach and education program with respect to*
9 *hepatitis C.*

10 ~~Safety Code, to read:~~

11 ~~24177.5. (a) This chapter shall not apply to any medical~~
12 ~~experimental treatment that benefits a patient subject to a~~
13 ~~life-threatening emergency if all of the following conditions are~~
14 ~~met:~~

15 ~~(1) Care is provided in accordance with the procedures and the~~
16 ~~additional protections of the rights and welfare of the patient set~~
17 ~~forth in Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code~~
18 ~~of Federal Regulations, in effect on January 1, 1997.~~

19 ~~(2) The patient is in a life-threatening situation necessitating~~
20 ~~urgent intervention and available treatments are unproven or~~
21 ~~unsatisfactory.~~

22 ~~(3) The patient is unable to give informed consent as a result of~~
23 ~~the patient's medical condition.~~

24 ~~(4) Obtaining informed consent from the patient's legally~~
25 ~~authorized representatives is not feasible before the treatment~~
26 ~~must be administered. The proposed investigational plan shall~~
27 ~~define the length of time of the potential therapeutic window based~~
28 ~~on scientific evidence, and the investigator shall commit to~~
29 ~~attempting to contact a legally authorized representative for each~~
30 ~~subject within that length of time and, if feasible, to asking the~~
31 ~~legally authorized representative contacted for consent within that~~
32 ~~length of time rather than proceeding without consent.~~

33 ~~(5) There is no reasonable way to identify prospectively the~~
34 ~~individuals likely to become eligible for participation in the~~
35 ~~clinical investigation.~~

36 ~~(6) Valid scientific studies have been conducted that support~~
37 ~~the potential for the intervention to provide a direct benefit to the~~
38 ~~patient. Risks associated with the investigation shall be reasonable~~
39 ~~in relation to what is known about the medical condition of the~~
40 ~~potential class of subjects, the risks and benefits of standard~~



1 ~~therapy, if any, and what is known about the risks and benefits of~~
2 ~~the proposed intervention or activity.~~

3 ~~(b) Nothing in this section is intended to relieve any party of~~
4 ~~any other legal duty, including, but not limited to, the duty to act~~
5 ~~in a nonnegligent manner.~~

6 ~~SEC. 2.—This act is an urgency statute necessary for the~~
7 ~~immediate preservation of the public peace, health, or safety~~
8 ~~within the meaning of Article IV of the Constitution and shall go~~
9 ~~into immediate effect. The facts constituting the necessity are:~~

10 ~~California law must be amended to comply with federal~~
11 ~~regulations that allow the use of a new drug or device where the~~
12 ~~patient is unable to consent due to a life-threatening emergency in~~
13 ~~order to improve medical intervention and patient outcomes. In~~
14 ~~order to save as many lives as possible of people who are in~~
15 ~~life-threatening emergency medical situations, it is necessary that~~
16 ~~this act take effect immediately.~~

