

Introduced by Senator Strickland

February 18, 2010

An act to amend Section 24177.5 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1187, as introduced, Strickland. Human experimentation.

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. Existing law provides an exemption from the act, until January 1, 2011, for any medical experimental treatment that benefits a patient subject to a life-threatening emergency if prescribed conditions are met.

This bill would provide that this exemption shall remain in effect until January 1, 2021.

Vote: 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 of the Health and Safety Code
- 2 is amended to read:
- 3 24177.5. (a) This chapter shall not apply to any medical
- 4 experimental treatment that benefits a patient subject to a
- 5 life-threatening emergency if all of the following conditions are
- 6 met:
- 7 (1) Care is provided in accordance with the procedures and the
- 8 additional protections of the rights and welfare of the patient set
- 9 forth in Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code

1 of Federal Regulations, in effect on ~~January 1, 1997~~ *December*
2 *31, 2010*.

3 (2) The patient is in a life-threatening situation necessitating
4 urgent intervention and available treatments are unproven or
5 unsatisfactory.

6 (3) The patient is unable to give informed consent as a result
7 of the patient’s medical condition.

8 (4) Obtaining informed consent from the patient’s legally
9 authorized representatives is not feasible before the treatment must
10 be administered. The proposed investigational plan shall define
11 the length of time of the potential therapeutic window based on
12 scientific evidence, and the investigator shall commit to attempting
13 to contact a legally authorized representative for each subject
14 within that length of time and, if feasible, to asking the legally
15 authorized representative contacted for consent within that length
16 of time rather than proceeding without consent.

17 (5) There is no reasonable way to identify prospectively the
18 individuals likely to become eligible for participation in the clinical
19 investigation.

20 (6) Valid scientific studies have been conducted that support
21 the potential for the intervention to provide a direct benefit to the
22 patient. Risks associated with the investigation shall be reasonable
23 in relation to what is known about the medical condition of the
24 potential class of subjects, the risks and benefits of standard
25 therapy, if any, and what is known about the risks and benefits of
26 the proposed intervention or activity.

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

30 (c) This section shall remain in effect only until January 1,
31 ~~2011~~, *2021*, and as of that date is repealed, unless a later enacted
32 statute, that is enacted before January 1, ~~2011~~, *2021*, deletes or
33 extends that date.

O