AMENDED IN SENATE APRIL 29, 2010

SENATE BILL No. 1187

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 amended, 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~~ *2014*.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

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

SECTION 1. Section 24177.5 of the Health and Safety Code is amended to read:

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

(1) Care is provided in accordance with the procedures and the additional protections of the rights and welfare of the patient set forth in Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code of Federal Regulations, in effect on December 31, 2010.

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

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

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

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

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

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

(c) This section shall remain in effect only until January 1, ~~2021~~ *2014*, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2021~~ *2014*, deletes or extends that date.

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