AMENDED IN ASSEMBLY FEBRUARY 27, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL No. 58

Introduced by Assembly Member Wieckowski

January 7, 2013

An act to amend Section 24177.5 of the Health and Safety Code, relating to medical experiments.

LEGISLATIVE COUNSEL'S DIGEST

AB 58, as amended, Wieckowski. Medical experiments: human subjects.

Existing law regulates the conduct of medical experiments on human subjects and requires informed consent prior to conducting medical experiments on human subjects. Existing law, until January 1, 2014, exempts from this requirement a medical experimental treatment that benefits a patient subject to a life-threatening emergency if specified conditions are met, including that the patient is in a life-threatening situation necessitating urgent intervention and available treatments are unproven or unsatisfactory and informed consent cannot be obtained before treatment must be administered.

This bill would continue the exemption for life-threatening emergencies indefinitely.

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 does not apply to a 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~~ *April 1, 2012*.

(2) The patient is in a life-threatening emergency 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 prospectively identify 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) This section does not relieve any party of any other legal duty, including, but not limited to, the duty to act in a nonnegligent manner.

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