

Senate Bill No. 160

CHAPTER 68

An act to add and repeal Section 24177.5 of the Health and Safety Code, relating to health, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor July 14, 1997. Filed with
Secretary of State July 14, 1997.]

LEGISLATIVE COUNSEL'S DIGEST

SB 160, Watson. Health: informed consent.

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, until January 1, 2001, for any medical experimental treatment that benefits a patient subject to a life-threatening emergency that is conducted in accordance with prescribed requirements.

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

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

SECTION 1. Section 24177.5 is added to the Health and Safety Code, 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 January 1, 1997.

(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, 2001, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2001, deletes or extends that date.

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

California law must be amended as soon as possible to comply with recently adopted federal regulations that allow the use of a new drug or device where the patient is unable to consent due to life-threatening emergencies in order to improve medical interventions and patient outcomes. In order to save as many persons' lives who are in life-threatening emergency medical situations as soon as possible, it is necessary that this act take effect immediately.

