

**ASSEMBLY BILL**

**No. 58**

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**Introduced by Assembly Member Wieckowski**

January 7, 2013

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

LEGISLATIVE COUNSEL'S DIGEST

AB 58, as introduced, 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:*

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

1 24177.5. (a) This chapter ~~shall~~ *does* not apply to ~~any~~ *a* medical  
2 experimental treatment that benefits a patient subject to a  
3 life-threatening emergency if all of the following conditions are  
4 met:

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

9 (2) The patient is in a life-threatening ~~situation~~ *emergency*  
10 necessitating urgent intervention and available treatments are  
11 unproven or unsatisfactory.

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

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

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

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

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

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

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