

AMENDED IN ASSEMBLY APRIL 23, 2013

CALIFORNIA LEGISLATURE—2013–14 REGULAR SESSION

ASSEMBLY BILL

No. 926

Introduced by Assembly Member Bonilla
(Coauthors: Assembly Members Atkins, Garcia, and Skinner)

February 22, 2013

An act to add Section 125356 to, and to repeal and add Section 125355 of, the Health and Safety Code, relating to reproductive health.

LEGISLATIVE COUNSEL'S DIGEST

AB 926, as amended, Bonilla. Reproductive health and research.

Existing law prohibits human oocytes or embryos from being acquired, sold, offered for sale, received, or otherwise transferred for valuable consideration for medical research or otherwise transferred for valuable consideration for medical research or development of medical therapies, and prohibits payment in excess of the amount of reimbursement of direct expenses to be made to any research subject to encourage her to produce human oocytes for the purposes of medical research.

This bill would instead require women providing human oocytes for research to be compensated for their time, trouble, and inconvenience in the same manner as other research subjects, as prescribed. The bill would require an institutional review board to disregard the amount of compensation if a woman providing human oocytes for fertility is compensated, human oocytes or embryos in excess of those needed for fertility are offered for research, and certain conditions are met.

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

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The purpose of this act is to create protections for research
4 subjects and it should not be construed to affect any other form of
5 medical care.

6 (b) Scientific research can be most effectively achieved by
7 establishing protocols to protect, respect, and promote human
8 health, safety, dignity, autonomy, and rights in conducting research.

9 (c) This act seeks to support the requirements in current law
10 upholding the principle of voluntary and informed consent and to
11 tailor them to this new area of pioneering research that utilizes
12 human oocytes.

13 (d) For all research subjects, there is a concern for exploitation
14 when subjects are asked to subject themselves to drugs, devices,
15 or procedures they might not otherwise need to do for their own
16 health but for the benefit of all. This can range from persons with
17 terminal illnesses who might be so desperate for help they would
18 subject themselves to a high-risk procedure with limited benefit,
19 to otherwise healthy people who might be motivated primarily by
20 a financial award. To address this concern of exploitation, and to
21 recognize the need for people to participate in research,
22 mechanisms were created to balance the need to reward research
23 participants without creating undue inducement.

24 (e) In California, the mechanisms dedicated to judging this
25 balance include human subject research panels, institutional review
26 boards, and stem cell research organizations.

27 (f) Concerns that women will be exploited if compensated for
28 providing human oocytes for research have not borne out in the
29 states where compensation is allowed.

30 (g) The current ban on compensation for women providing
31 human oocytes for research was created due to concerns regarding
32 the high volume of oocytes needed for embryonic stem cell
33 research, but extends to all research. Without compensation, few
34 women participate in research, creating barriers to reproductive
35 research that could benefit all women. As an example, more
36 research could be done on embryo quality so that women
37 undergoing in vitro fertilization (IVF) can confidently choose to
38 have a single embryo implanted with a high probability of

1 achieving a successful pregnancy, instead of multiple embryos.
2 Lowering the rate of multiple pregnancies in IVF is a high priority
3 goal that benefits women, parents, the resulting children, and
4 society. The best source of available embryos for research comes
5 from embryos created for fertility using a compensated donor, as
6 she is more likely to produce a higher volume of oocytes and excess
7 viable embryos than the infertile woman. Due to the ban on
8 compensation, oocytes and embryos not needed for fertility will
9 be unsuitable for research and will likely be discarded.

10 (h) All patients, including those participating in research are
11 due a reasonable duty of care. In addition, all women undergoing
12 ovarian stimulation and oocyte retrieval have another layer of
13 regulation as all cycles are reported to the federal Centers for
14 Disease Control and Prevention.

15 (i) Sufficient protections are in place to treat women providing
16 human oocytes for research, similar to any other research subject,
17 knowing women are competent and able to make decisions for
18 themselves.

19 (j) This bill will reverse the current ban on compensation for
20 women providing human oocytes for research. Compensation
21 amounts will be determined by human subject research panels and
22 institutional review boards.

23 SEC. 2. Section 125355 of the Health and Safety Code is
24 repealed.

25 SEC. 3. Section 125355 is added to the Health and Safety Code,
26 to read:

27 125355. Notwithstanding Section 125350, a woman providing
28 human oocytes for research shall be compensated for her time,
29 discomfort, and inconvenience in the same manner as other
30 research subjects. Payment pursuant to this section shall not be for
31 the human oocytes themselves or predicated on the number of
32 oocytes obtained, including if no human oocytes are obtained.
33 *Whether a proposed compensation amount is appropriate shall*
34 *be determined by a human subject research panel or institutional*
35 *review board. In the event that a human subject research panel or*
36 *institutional review board determines that a proposed*
37 *compensation amount is inappropriate, the panel or board shall*
38 *determine an appropriate compensation amount.*

39 SEC. 4. Section 125356 is added to the Health and Safety Code,
40 to read:

- 1 125356. If a woman providing human oocytes for the purposes
2 of fertility is compensated, and any human oocytes or embryos in
3 excess of those needed for fertility are offered for research, the
4 institutional review board shall disregard the amount of
5 compensation if all of the following conditions are met:
- 6 (a) The clinic performing oocyte retrieval is a member of the
7 Society for Assisted Reproductive Technology.
- 8 (b) The procurement and disposition for research purposes of
9 human oocytes initially provided for reproductive uses, either for
10 use by the donor or another woman, shall not knowingly
11 compromise the optimal reproductive success of the woman in the
12 infertility treatment.
- 13 (c) The infertility treatment protocol is established prior to
14 requesting or obtaining consent for donation for research purposes
15 and the prospect of donation for research does not alter the timing,
16 method, or procedures selected for clinical care.
- 17 (d) The woman in infertility treatment makes the determination
18 that she does not want or need the oocytes for her own reproductive
19 success.
- 20 (e) The donation of oocytes for research is done without valuable
21 consideration as defined in Section 125350.