

AMENDED IN SENATE JUNE 3, 2003
AMENDED IN SENATE APRIL 21, 2003

SENATE BILL

No. 771

Introduced by Senator Ortiz

February 21, 2003

An act to amend and renumber Sections 125115, 125116, and 125117 of, to add Section 125305 to, to add the headings of Part 5.5 (commencing with Section 125300) and Chapter 1 (commencing with Section 125300) to Division 106 of, ~~to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of,~~ and to repeal the heading of Article 5 (commencing with Section 125115) of Chapter 1 of Part 5 of Division 106 of, the Health and Safety Code, relating to human tissue.

LEGISLATIVE COUNSEL'S DIGEST

SB 771, as amended, Ortiz. Human cells: embryo registry: egg cell donation.

Existing law declares the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted, as specified. Existing law authorizes the donation of a human embryo pursuant to specific requirements and prohibits the purchase or sale of embryonic or cadaveric fetal tissue for research purposes.

This bill would require the State Department of Health Services, *to the extent that private or other nonstate funding sources are available*, to establish and maintain an anonymous registry of embryos that would

provide researchers with access to embryos that are available for research purposes.

Existing law requires a physician and surgeon or other health care provider delivering fertility treatment to provide to his or her patient designated information regarding the disposition of any human embryos remaining after the fertility treatment and requires the individual electing to donate embryos to provide written consent.

This bill would make the failure to provide information pursuant to the above requirement unprofessional conduct. This bill would specify requirements for obtaining informed consent from any individual considering donating embryos for research. This bill would require a physician and surgeon or other health care provider to provide a form that sets forth advanced written directives regarding the disposition of embryos in specified circumstances.

~~This bill also would require, on and after January 1, 2005, a physician and surgeon, prior to providing assisted egg cell, also known as "oocyte," production, to provide to his or her patient a standardized written summary that would be developed by the department, as specified, of health and consumer issues relating to egg cell donation. The bill would require the physician and surgeon to obtain written consent from the prospective donor and would make it unprofessional conduct to fail to provide the summary or obtain written consent.~~

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

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

1 SECTION 1. The heading of Article 5 (commencing with
2 Section 125115) of Chapter 1 of Part 5 of Division 106 of the
3 Health and Safety Code is repealed.

4 SEC. 2. Section 125115 of the Health and Safety Code is
5 amended and renumbered to read:

6 125300. The policy of the State of California shall be as
7 follows:

8 (a) That research involving the derivation and use of human
9 embryonic stem cells, human embryonic germ cells, and human
10 adult stem cells from any source, including somatic cell nuclear
11 transplantation, shall be permitted and that full consideration of
12 the ethical and medical implications of this research be given.



1 (b) That research involving the derivation and use of human
2 embryonic stem cells, human embryonic germ cells, and human
3 adult stem cells, including somatic cell nuclear transplantation,
4 shall be reviewed by an approved institutional review board.

5 SEC. 3. Section 125116 of the Health and Safety Code is
6 amended and renumbered to read:

7 125315. (a) A physician and surgeon or other health care
8 provider delivering fertility treatment shall provide his or her
9 patient with timely, relevant, and appropriate information to allow
10 the individual to make an informed and voluntary choice regarding
11 the disposition of any human embryos remaining following the
12 fertility treatment. The failure to provide to a patient this
13 information constitutes unprofessional conduct within the
14 meaning of Chapter 5 (commencing with Section 2000) of
15 Division 2 of the Business and Professions Code.

16 (b) Any individual to whom information is provided pursuant
17 to subdivision (a) shall be presented with the option of storing any
18 unused embryos, donating them to another individual, discarding
19 the embryos, or donating the remaining embryos for research.
20 When providing fertility treatment, a physician and surgeon or
21 other health care provider shall provide a form to the male and
22 female partner, or the individual without a partner, as applicable,
23 that sets forth advanced written directives regarding the
24 disposition of embryos. This form shall indicate the time limit on
25 storage of the embryos at the clinic or storage facility and shall
26 provide, at a minimum, the following choices for disposition of the
27 embryos based on the following circumstances:

28 (1) In the event of the death of either the male or female partner,
29 the embryos shall be disposed of by one of the following actions:

- 30 (A) Made available to the living partner.
- 31 (B) Donation for research purposes.
- 32 (C) Thawed with no further action taken.
- 33 (D) Donation to another couple or individual.
- 34 (E) Other disposition that is clearly stated.

35 (2) In the event of the death of both partners or the death of a
36 patient without a partner, the embryos shall be disposed of by one
37 of the following actions:

- 38 (A) Donation for research purposes.
- 39 (B) Thawed with no further action taken.
- 40 (C) Donation to another couple or individual.



- 1 (D) Other disposition that is clearly stated.
- 2 (3) In the event of separation or divorce of the partners, the
- 3 embryos shall be disposed of by one of the following actions:
- 4 (A) Made available to the female partner.
- 5 (B) Made available to the male partner.
- 6 (C) Donation for research purposes.
- 7 (D) Thawed with no further action taken.
- 8 (E) Donation to another couple or individual.
- 9 (F) Other disposition that is clearly stated.
- 10 (4) In the event of the partners' decision or a patient's decision
- 11 who is without a partner, to abandon the embryos by request or a
- 12 failure to pay storage fees, the embryos shall be disposed of by one
- 13 of the following actions:
- 14 (A) Donation for research purposes.
- 15 (B) Thawed with no further action taken.
- 16 (C) Donation to another couple or individual.
- 17 (D) Other disposition that is clearly stated.
- 18 (c) A physician and surgeon or other health care provider
- 19 delivering fertility treatment shall obtain written consent from any
- 20 individual who elects to donate embryos remaining after fertility
- 21 treatments for research. For any individual considering donating
- 22 the embryos for research, to obtain informed consent, the health
- 23 care provider shall convey all of the following to the individual:
- 24 (1) A statement that the early human embryos will be used to
- 25 derive human pluripotent stem cells for research and that the cells
- 26 may be used, at some future time, for human transplantation
- 27 research.
- 28 (2) A statement that all identifiers associated with the embryos
- 29 will be removed prior to the derivation of human pluripotent stem
- 30 cells.
- 31 (3) A statement that donors will not receive any information
- 32 about subsequent testing on the embryo or the derived human
- 33 pluripotent cells.
- 34 (4) A statement that derived cells or cell lines, with all
- 35 identifiers removed, may be kept for many years.
- 36 (5) Disclosure of the possibility that the donated material may
- 37 have commercial potential, and a statement that the donor will not
- 38 receive financial or any other benefits from any future commercial
- 39 development.



1 (6) A statement that the human pluripotent stem cell research
2 is not intended to provide direct medical benefit to the donor.

3 (7) A statement that early human embryos donated will not be
4 transferred to a woman’s uterus, will not survive the human
5 pluripotent stem cell derivation process, and will be handled
6 respectfully, as is appropriate for all human tissue used in research.

7 SEC. 4. Section 125117 of the Health and Safety Code is
8 amended and renumbered to read:

9 125320. (a) A person may not knowingly, for valuable
10 consideration, purchase or sell embryonic or cadaveric fetal tissue
11 for research purposes pursuant to this chapter.

12 (b) For purposes of this section, “valuable consideration” does
13 not include reasonable payment for the removal, processing,
14 disposal, preservation, quality control, storage, transplantation, or
15 implantation of a part.

16 (c) Embryonic or cadaveric fetal tissue may be donated for
17 research purposes pursuant to this chapter.

18 SEC. 5. A heading is added as Part 5.5 (commencing with
19 Section 125300) of Division 106 of the Health and Safety Code,
20 to read:

21
22 PART 5.5. USE OF HUMAN CELLS

23
24 SEC. 6. A heading is added as Chapter 1 (commencing with
25 Section 125300) of Part 5.5 of Division 106 of the Health and
26 Safety Code, to read:

27
28 CHAPTER 1. EMBRYO REGISTRY

29
30 SEC. 7. Section 125305 is added to the Health and Safety
31 Code, to read:

32 125305. (a) The department shall establish and maintain an
33 anonymous registry of embryos that are available for research. The
34 purpose of this registry is to provide researchers with access to
35 embryos that are available for research purposes.

36 (b) The department may contract with the University of
37 California, private organizations, or public entities to establish and
38 administer the registry.

39 (c) This section shall be implemented only to the extent that
40 funds for the purpose of establishing and administering the



1 registry are received by the department from private or public
2 sources, excluding the General Fund *other nonstate sources*.

3 SEC. 8. Chapter 2 (commencing with Section 125330) is
4 added to Part 5.5 of Division 106 of the Health and Safety Code,
5 to read:

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7 CHAPTER 2. OOCYTE OR EGG CELL DONATION

8

9 125330. The following definitions shall apply to this chapter:

10 (a) “Assisted oocyte production” or “AOP” means
11 pharmaceutically induced manipulation of oocyte production
12 through the use of injectable, also known as nonoral, stimulation
13 drugs.

14 (b) “Department” means the State Department of Health
15 Services.

16 (c) “Egg cell donor” or “oocyte donor” means an individual
17 who voluntarily gives her egg cells to another woman for the
18 purpose of conception or gives her egg cells to another person for
19 the purpose of research or development of medical therapies.

20 (d) “Oocyte” means an egg cell.

21 125335. (a) On and after January 1, 2005, prior to providing
22 AOP, a physician and surgeon shall provide to his or her
23 prospective oocyte donor the standardized written summary of
24 health and consumer issues described in subdivision (b). The
25 failure to provide to an oocyte donor this standardized written
26 summary constitutes unprofessional conduct within the meaning
27 of Chapter 5 (commencing with Section 2000) of Division 2 of the
28 Business and Professions Code.

29 (b) (1) No later than July 1, 2004, the department, after
30 consultation with the appropriate national medical specialty
31 societies, shall develop a standardized written summary in
32 laymen’s language and in several languages, as necessary,
33 regarding health and consumer issues relating to oocyte donation.
34 The summary shall be printed and made available by the
35 department to physicians and surgeons. The summary shall
36 include, but not be limited to, disclosures concerning the potential
37 risks of oocyte donation, including the risk of decreased fertility
38 and the risks associated with using the drugs, medications, and
39 hormones prescribed for ovarian stimulation during the oocyte
40 donation process.



1 ~~(2) The department shall utilize existing health and consumer~~
2 ~~guidelines for assisted reproductive technologies developed by~~
3 ~~national medical societies as the basis for the information~~
4 ~~contained within the standardized written summary.~~
5 ~~125340. On and after January 1, 2005, prior to providing~~
6 ~~AOP, a physician and surgeon shall obtain written consent from his~~
7 ~~or her prospective oocyte donor. The failure to obtain written~~
8 ~~consent from the oocyte donor constitutes unprofessional conduct~~
9 ~~within the meaning of Chapter 5 (commencing with Section 2000)~~
10 ~~of Division 2 of the Business and Professions Code.~~

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