

SENATE No. 00151

The Commonwealth of Massachusetts

PRESENTED BY:

Cynthia S. Creem

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act clarifying chapter 111L - biotechnology
.

PETITION OF:

NAME:

Cynthia S. Creem

DISTRICT/ADDRESS:

First Middlesex and Norfolk

SENATE No. 00151

By Ms. Creem, petition (accompanied by bill, Senate, No. 151) of Creem for legislation to clarify Chapter 111L-biotechnology [Joint Committee on Economic Development and Emerging Technologies].

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE
SENATE
, NO. 193 OF 2009-2010.]

The Commonwealth of Massachusetts

In the Year Two Thousand Eleven

An Act clarifying chapter 111L - biotechnology

□.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Paragraph (c) of Section 1 of Chapter 111L of the General Laws as
2 appearing in the 2006 Official Edition, is hereby amended by striking in lines 15-16 the words
3 “placental and umbilical cord cells and human adult stem cells”, and inserting at the end of this
4 same paragraph the following sentence: Nothing in this chapter shall prohibit research or clinical
5 applications involving human adult stem cells, umbilical cord cells, amniotic fluid cells or
6 placental cells.

7 SECTION 2. Section 2 of Chapter 111L of the General Laws as appearing in the 2006
8 Official Edition, is hereby amended by striking the definition of "Donated to research" in lines
9 7-14 and inserting in place thereof the following:

10 "Donated to research", when, in the absence of valuable consideration and after
11 fulfillment of the requirements of informed consent, the persons from whose gametes or cells the
12 pre-implantation embryo has originated or will originate gives the pre-implantation embryo,
13 gametes or cells to another person; provided, however, that the recipient shall not transfer the
14 extant or resultant pre-implantation embryo to a uterus or uterine-like environment or nurture the
15 pre-implantation embryo beyond 14 days of development.

16 SECTION 3. Said Section 2 is hereby further amended by inserting the following new
17 definitions:

18 "ESCRO committee", means an Embryonic Stem Cell Research Oversight committee
19 that is constituted and operated in a manner consistent with the guidelines of either the National
20 Academies of Sciences or the International Society for Stem Cell Research.'

21 "Reasonable costs", for purposes of reimbursing oocyte donors, may include, but are not
22 limited to, any of the following types of costs if approved by an institutional review board:
23 travel, temporary lodging, childcare, medical care, health insurance (if limited to co-pays and
24 deductibles and the purchase of time-limited accident insurance coverage for complications
25 arising directly from the egg donation process) and actual lost wages, and any other types of such
26 costs as may be approved by such institutional review board.

27 SECTION 4. Said Section 2 is further amended by striking the definition of "Valuable
28 consideration" in lines 90-93 and replacing it with the following:

29 “Valuable consideration”, any consideration beyond reimbursement for reasonable costs
30 incurred in connection with the donation, removal, processing, disposal, preservation, quality
31 control or storage of gametes or embryos for research purposes.

32 SECTION 5. Section 3(a) of Chapter 111L of the General Laws as appearing in the
33 2006 Official Edition, shall be deleted and new language inserted as follows:

34 Research and clinical applications involving the derivation and use of human embryonic stem
35 cells from materials donated to research, including, without limitation, pre-implantation
36 embryos, whether created by the method of fertilization or by somatic cell nuclear transfer,
37 parthenogenesis or other asexual means, gametes, somatic cells and parthenotes shall be
38 permitted.

39 SECTION 6. Section 3 (b) of Chapter 111L of the General Laws as appearing in the
40 2006 Official Edition, shall be amended by inserting in line 9 after the words “duly authorized
41 institutional review board” the following:

42 or ESCRO committee; provided that if such research is approved only by an ESCRO committee,
43 documentation shall be maintained by the ESCRO committee that an institutional review board
44 or another equivalent body determined that any human embryos, cells or gametes to be used in
45 the research were donated to research, as defined in section 2 or in a manner permitted under the
46 laws of the state or foreign country where the donation to research occurred and in a manner
47 otherwise acceptable to the ESCRO.

48 And said section 3 (b) is further, by inserting in lines 9-10 after the words “approval of the
49 institutional review board”, the following: “or ESCRO committee”.

50 And further, by inserting in line 13 after the words “permanent record by the board”, the
51 following: “or ESCRO committee”.

52 And further, by inserting in line 14 after the words “for which the board”, the following:
53 “or ESCRO committee”.

54 SECTION 7. Section 8(c) of Chapter 111L of the General Laws as appearing in the
55 2006 Official Edition, shall be amended by deleting in lines 12- 13 the words: “or cadaveric
56 tissue”; and by inserting in line 17 after the words “regulate the use” the following: “or study”

57 SECTION 8. Section 9(e) of Chapter 111L of the General Laws as appearing in the
58 2006 Official Edition, shall be amended by deleting all language following the words “not less
59 than twice a year”; and by inserting language as follows:

60 Notwithstanding section 11A 1/2 of chapter 30A of the General Laws, the council may conduct
61 its meetings by telephone conference or similar communications equipment which allows all
62 persons participating in the meeting to hear each other at the same time. Participation by such
63 means shall constitute presence in person at a meeting. Notice of a meeting held in this manner
64 shall be provided in accordance with the requirements of section 11A 1/2 of chapter 30A of the
65 General Laws, and shall state that members of the public will be afforded a location, as specified
66 in the notice, where they may attend the meeting by conference telephone or similar
67 communications equipment.

68 SECTION 9. Section 10(f) of Chapter 111L of the General Laws as appearing in the
69 2006 Official Edition, shall be amended by deleting all language after the words “and (ii)” in line
70 74 and inserting the following language: provides documentation to the department
71 demonstrating that the institution has either an institutional review board or ESCRO committee

72 or both, or provides a copy of a contract between the institution and either a private or public
73 institutional review board or ESCRO committee, as applicable, which shall provide any review
74 required by this chapter. Any institution which submits an application and meets the
75 requirements for a certificate of registration pursuant to this section shall not have the certificate
76 of registration unreasonably withheld. A certificate may be withheld if the department
77 determines that the applicant institution has violated subsection (m).

78 SECTION 10. Section 10(i) of Chapter 111L of the General Laws as appearing in the
79 2006 Official Edition, shall be amended by deleting all language following the words “pursuant
80 to subsection (f)” and inserting the following language:

81 shall submit an annual report to the department providing a summary of the human embryonic
82 stem cell research approved during each calendar year pursuant to section 3(b) of this chapter
83 and a statement representing that such research was reviewed in accordance with this chapter, if
84 applicable.

85 SECTION 11. In Section 10(n), subsection (2) shall be deleted in its entirety, and the
86 following language inserted as follows:

87 (2) The department may, after an opportunity for an adjudicatory proceeding conducted
88 pursuant to chapter 30A, upon determination that an institution conducting research pursuant to
89 this chapter has violated this subsection undertake the following actions:

90 (i) for the violation of clause (iii) of paragraph (n)(1), revoke or refuse to renew
91 such certificate of registration or assess upon the holder a civil administrative penalty not to
92 exceed \$250,000 and may require the holder to submit to additional oversight as a condition or
93 retention, or future consideration of reinstatement of the certificate of registration;

94 (ii) for a violation of clause (i), (ii), (iv), (vi) or (vii) of paragraph (n)(1), assess
95 upon the holder a civil administrative penalty not to exceed \$100,000; or

96 (iii) for a first violation of clause (v) of paragraph (n)(1) censure a holder; and for
97 each subsequent violation of said clause (v) of said paragraph (n)(1), suspend such certificate of
98 registration until compliance with subsection (i), and impose a civil administrative penalty, as
99 determined by the department not to exceed \$1,000.“