House Study Bill 205 - Introduced

HOUS	E FILE
ВУ	(PROPOSED COMMITTEE ON
	STATE GOVERNMENT BILL BY
	CHAIRPERSON COWNIE)

A BILL FOR

- 1 An Act relating to the use of adult stem cells in this state,
- 2 including uses relating to the practice of medicine, the
- 3 practice of pharmacy, and clinical research.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

H.F. ____

- 1 Section 1. NEW SECTION. 136E.1 Definitions.
- 2 As used in this chapter unless the context otherwise
- 3 requires:
- 4 1. "Adult stem cells" means autologous or allogeneic
- 5 cellular material including but not limited to stem cells,
- 6 immune cells, and other types of mature cells that may have
- 7 been or may be combined with naturally occurring biomaterials
- 8 or materials approved or cleared for any purpose by the United
- 9 States food and drug administration or other applicable agency
- 10 or authority.
- 11 2. "Allogeneic" means originating from the body of another 12 person.
- 3. "Autologous" means originating from a person's own body.
- 4. "Cell or tissue bank" means a facility that stores adult
- 15 stem cells or tissue.
- 16 Sec. 2. <u>NEW SECTION</u>. 136E.2 Practices relating to adult
- 17 stem cells.
- 18 1. Notwithstanding any law to the contrary:
- 19 a. A person licensed to practice medicine pursuant to
- 20 chapter 148 in this state may extract, process, or administer
- 21 autologous adult stem cells.
- 22 b. A person licensed or authorized to administer or assist
- 23 in the administration of medicine or health care in this state
- 24 may extract, process, or administer autologous adult stem
- 25 cells to the extent permitted under the person's license or
- 26 authorization.
- 27 c. A person may operate a cell or tissue bank in this state.
- 28 d. A pharmacy owned or operated in this state, or a
- 29 pharmacist licensed pursuant to chapter 155A, may compound a
- 30 drug, medicine, or health product using adult stem cells as an
- 31 ingredient.
- 32 e. A person licensed to practice medicine in this state may
- 33 conduct adult stem cell clinical research for development of
- 34 therapies and cures consistent with chapter 707C. This chapter
- 35 shall not be interpreted to limit or prohibit any activity

H.F.

1 otherwise authorized pursuant to chapter 707C.

- 2 f. A person authorized to conduct adult stem cell clinical 3 research in the state may import into this state any compound 4 or drug containing adult stem cells if the compound or drug is 5 obtained in accordance with the laws of the jurisdiction from 6 which the compound or drug is obtained and the compound or drug 7 is used for the purposes of clinical research.
- 8 g. A person who is authorized to extract, process, or 9 administer autologous adult stem cells under this section 10 may import into this state compounds and drugs used in the 11 administration of such stem cells if the compound or drug is 12 obtained in accordance with the laws of the jurisdiction from 13 which the compound or drug is obtained and the compound or drug 14 is used for administration of autologous adult stem cells to a 15 person in a treatment plan by a person licensed or authorized 16 to extract, process, or administer autologous adult stem cells.
- 2. a. The board of medicine, the board of pharmacy, and other appropriate licensing boards established pursuant to chapter 147 shall adopt rules in accordance with this chapter. The rules adopted shall not prohibit the activities authorized in this chapter and shall not impose disciplinary action or civil or criminal penalties against a person for engaging in any activity authorized by this chapter. This paragraph shall not be interpreted to authorize the adoption of rules that absolve a person from civil or criminal liability or disciplinary action otherwise applicable if the person engages in an activity authorized under this chapter but fails to use the reasonable care, skill, or knowledge ordinarily used in rendering medical services under similar circumstances.
- 30 b. The board of medicine, the board of pharmacy, and other 31 appropriate licensing boards may adopt rules to regulate the 32 procedures used to administer adult stem cells in this state.
- 33 EXPLANATION
- This bill relates to the use of adult stem cells in the state, including uses relating to the practice of medicine, the

H.F.

1 practice of pharmacy, and clinical research.

- 2 The bill defines terms used in the bill and authorizes
- 3 certain activities relating to adult stem cells. The bill
- 4 authorizes a person licensed to practice medicine in the state
- 5 to extract, process, or administer autologous adult stem cells.
- 6 "Autologous" means originating from the person's own body.
- 7 The bill also provides that a person licensed or authorized
- 8 to administer or assist in the administration of medicine or
- 9 health care in this state may extract, process, or administer
- 10 autologous adult stem cells to the extent permitted under the
- 11 person's license or authorization.
- 12 The bill authorizes all of the following: the operation
- 13 of a cell or tissue bank in this state; a pharmacy owned or
- 14 operated in the state or a licensed pharmacist to compound
- 15 a drug, medicine, or health product using adult stem cells
- 16 as an ingredient; a person licensed to practice medicine to
- 17 conduct adult stem cell clinical research for development of
- 18 therapies and cures consistent with Code chapter 707C (human
- 19 stem cell research and cloning) while clarifying that the
- 20 bill is not to be interpreted as limiting or prohibiting
- 21 any activity authorized under chapter 707C; a person who is
- 22 authorized to conduct adult stem cell clinical research to
- 23 import any compound or drug containing adult stem cells if
- 24 the compound or drug is obtained in accordance with the laws
- 25 of the originating jurisdiction and is used for clinical
- 26 research; and a person who is authorized to extract, process,
- 27 or administer autologous adult stem cells to import compounds
- 28 and drugs used in the administration of such stem cells if the
- 29 compound or drug is obtained in accordance with the laws of the
- 30 originating jurisdiction and the compound or drug is used for
- 31 administration of autologous adult stem cells to a person in a
- 32 treatment plan by a person licensed or authorized to extract,
- 33 process, or administer autologous adult stem cells.
- 34 The bill directs the board of medicine, the board of
- 35 pharmacy, and other appropriate licensing boards to adopt rules

H.F. ____

1 in accordance with the bill, but provides that the rules shall

- 2 not prohibit the activities authorized in the bill and shall
- 3 not impose disciplinary action or civil or criminal penalties
- 4 against a person for engaging in any activity authorized
- 5 under the bill. However, the bill is not to be interpreted
- 6 to authorize the adoption of rules that absolve a person who
- 7 engages in an activity authorized under the bill from civil or
- 8 criminal liability or disciplinary action otherwise applicable
- 9 for failure to use the reasonable care, skill, or knowledge
- 10 ordinarily used in rendering medical services under similar
- 11 circumstances. The bill does authorize the board of medicine,
- 12 the board of pharmacy and other appropriate licensing boards to
- 13 adopt rules to regulate the procedures used to administer adult
- 14 stem cells in this state.