

107TH CONGRESS
1ST SESSION

H. R. 2172

To amend the Federal Food, Drug, and Cosmetic Act with respect to the cloning of humans, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 2001

Mr. GREENWOOD (for himself, Mr. WOLF, Mr. OWENS, Mr. NEAL of Massachusetts, Mr. PALLONE, Mrs. MCCARTHY of New York, Mr. DEUTSCH, Mr. GILLMOR, and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to the cloning of humans, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Cloning Prohibition
5 Act of 2001”.

6 **SEC. 2. PROHIBITION AGAINST HUMAN CLONING.**

7 (a) IN GENERAL.—The Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 301 et seq.) is amended by add-
9 ing at the end the following:

1 “CHAPTER X—HUMAN CLONING

2 “PROHIBITION AGAINST HUMAN CLONING

3 “SEC. 1001. (a) NUCLEAR TRANSFER TECH-
4 NOLOGY.—5 “(1) IN GENERAL.—It shall be unlawful for any
6 person—7 “(A) to use or attempt to use human so-
8 matic cell nuclear transfer technology with the
9 intent to initiate a pregnancy; or10 “(B) to ship or transport the cellular prod-
11 uct resulting from human somatic cell nuclear
12 transfer technology knowing that the product is
13 intended to be used to initiate a pregnancy.14 “(2) DEFINITION.—For purposes of this sec-
15 tion, the term ‘human somatic cell nuclear transfer
16 technology’ means transferring the nucleus of a
17 human somatic cell into an egg cell from which the
18 nucleus has been removed or rendered inert.19 “(b) RULE OF CONSTRUCTION.—This section may
20 not be construed as applying to any of the following:21 “(1) The use of somatic cell nuclear transfer
22 technology to clone molecules, DNA, cells, or tissues.23 “(2) The use of mitochondrial, cytoplasmic, or
24 gene therapy.

1 “(3) The use of in vitro fertilization, the admin-
2 istration of fertility-enhancing drugs, or the use of
3 other medical procedures to assist a woman in be-
4 coming or remaining pregnant.

5 “(4) The use of somatic cell nuclear transfer
6 technology to clone or otherwise create animals other
7 than humans.

8 “(5) Any other activity (including biomedical,
9 microbiological, or agricultural research or practices)
10 not expressly prohibited in subsection (a).

11 “(c) REGISTRATION.—

12 “(1) IN GENERAL.—Each individual who in-
13 tends to perform human somatic cell nuclear trans-
14 fer technology shall, prior to first performing such
15 technology, register with the Secretary his or her
16 name and place of business (except that, in the case
17 of an individual who performed such technology be-
18 fore the date of the enactment of the Cloning Prohi-
19 bition Act of 2001, the individual shall so register
20 not later than 60 days after such date). The Sec-
21 retary may by regulation require that the registra-
22 tion provide additional information regarding the
23 identity and business locations of the individual, and
24 information on the training and experience of the in-

1 dividual regarding the performance of such tech-
2 nology.

3 “(2) ATTESTATION.—A registration under
4 paragraph (1) shall include a statement, signed by
5 the individual submitting the registration, declaring
6 that the individual is aware of the prohibitions de-
7 scribed in subsection (a) and will not engage in any
8 violation of such subsection.

9 “(3) CONFIDENTIALITY.—Information provided
10 in a registration under paragraph (1) shall not be
11 disclosed to the public by the Secretary except to the
12 extent that—

13 “(A) the individual submitting the reg-
14 istration has in writing authorized the disclo-
15 sure; or

16 “(B) the disclosure does not identify such
17 individual or any place of business of the indi-
18 vidual.

19 “(d) PREEMPTION OF STATE LAW.—This section su-
20 persedes any State or local law that—

21 “(1) establishes prohibitions, requirements, or
22 authorizations regarding human somatic cell nuclear
23 transfer technology that are different than, or in ad-
24 dition to, those established in subsection (a) or (c);
25 or

1 “(2) with respect to humans, prohibits or re-
2 stricts research regarding or practices constituting—

3 “(A) somatic cell nuclear transfer;

4 “(B) mitochondrial or cytoplasmic therapy;

5 or

6 “(C) the cloning of molecules, DNA, cells,
7 tissues, or organs;

8 except that this subsection does not apply to any State
9 or local law that was in effect as of the day before the
10 date of the enactment of the Cloning Prohibition Act of
11 2001.

12 “(e) SUNSET.—This section and section 301(bb) do
13 not apply to any activity described in subsection (a) that
14 occurs on or after the expiration of the 10-year period be-
15 ginning on the date of the enactment of the Cloning Prohi-
16 bition Act of 2001.

17 “(f) RIGHT OF ACTION.—This section may not be
18 construed as establishing any private right of action.”.

19 (b) PROHIBITED ACTS.—

20 (1) IN GENERAL.—Section 301 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 331) is
22 amended by adding at the end the following:

23 “(bb) The violation of section 1001(a), or the failure
24 to register in accordance with section 1001(c).”.

1 (2) CRIMINAL PENALTY.—Section 303(b) of the
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
3 333(b)) is amended by adding at the end the fol-
4 lowing:

5 “(7) Notwithstanding subsection (a), any person who
6 violates section 301(bb) shall be imprisoned not more than
7 10 years or fined in accordance with title 18, United
8 States Code, or both.”.

9 (3) CIVIL PENALTY.—Section 303 of the Fed-
10 eral Food, Drug, and Cosmetic Act (21 U.S.C. 333)
11 is amended by adding at the end the following:

12 “(h)(1) Any person who violates section 301(bb) shall
13 be liable to the United States for a civil penalty in an
14 amount not to exceed the greater of—

15 “(A) \$1,000,000; or

16 “(B) an amount equal to the amount of any
17 gross pecuniary gain derived from such violation
18 multiplied by 2.

19 “(2) Paragraphs (3) through (5) of subsection (g)
20 apply with respect to a civil penalty under paragraph (1)
21 of this subsection to the same extent and in the same man-
22 ner as such paragraphs (3) through (5) apply with respect
23 to a civil penalty under paragraph (1) or (2) of subsection
24 (g).”.

1 (4) FORFEITURE.—Section 303 of the Federal
2 Food, Drug, and Cosmetic Act, as amended by para-
3 graph (3), is amended by adding at the end the fol-
4 lowing:

5 “(i) Any property, real or personal, derived from or
6 used to commit a violation of section 301(bb), or any prop-
7 erty traceable to such property, shall be subject to for-
8 feiture to the United States.”.

9 **SEC. 3. STUDY BY INSTITUTE OF MEDICINE.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this section as the “Sec-
12 retary”) shall request the Institute of Medicine to enter
13 into an agreement with the Secretary under which such
14 Institute conducts a study to—

15 (1) review the current state of knowledge about
16 the biological properties of stem cells obtained from
17 embryos, fetal tissues, and adult tissues;

18 (2) evaluate the current state of knowledge
19 about biological differences among stem cells ob-
20 tained from embryos, fetal tissues, and adult tissues
21 and the consequences for research and medicine; and

22 (3) assess what is currently known about the
23 ability of stem cells to generate neurons, heart, kid-
24 ney, blood, liver and other tissues and the potential
25 clinical uses of these tissues.

1 (b) OTHER ENTITIES.—If the Institute of Medicine
2 declines to conduct the study described in subsection (a),
3 the Secretary shall enter into an agreement with another
4 appropriate public or nonprofit private entity to conduct
5 the study.

6 (c) REPORT.—The Secretary shall ensure that, not
7 later than three years after the date of the enactment of
8 this Act, the study required in subsection (a) is completed
9 and a report describing the findings made in the study
10 is submitted to the Committee on Energy and Commerce
11 in the House of Representatives and the Committee on
12 Health, Education, Labor, and Pensions in the Senate.

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