

107TH CONGRESS
1ST SESSION

H. R. 2608

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

JULY 24, 2001

Mr. GREENWOOD (for himself and Mr. DEUTSCH) 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, or the
9 product of such technology, to initiate a preg-
10 nancy or with the intent to initiate a pregnancy;
11 or12 “(B) to ship, mail, transport, or receive the
13 product of such technology knowing that the
14 product is intended to be used to initiate a
15 pregnancy.16 “(2) DEFINITION.—For purposes of this sec-
17 tion, the term ‘human somatic cell nuclear transfer
18 technology’ means transferring the nuclear material
19 of a human somatic cell into an egg cell from which
20 the nuclear material has been removed or rendered
21 inert.22 “(b) RULE OF CONSTRUCTION.—This section may
23 not be construed as applying to any of the following:24 “(1) The use of somatic cell nuclear transfer
25 technology to clone molecules, DNA, cells, or tissues.

1 “(2) The use of mitochondrial, cytoplasmic, or
2 gene therapy.

3 “(3) The use of in vitro fertilization, the admin-
4 istration of fertility-enhancing drugs, or the use of
5 other medical procedures (excluding those using
6 human somatic cell nuclear transfer or the product
7 thereof) to assist a woman in becoming or remaining
8 pregnant.

9 “(4) The use of somatic cell nuclear transfer
10 technology to clone or otherwise create animals other
11 than humans.

12 “(5) Any other activity (including biomedical,
13 microbiological, or agricultural research or practices)
14 not expressly prohibited in subsection (a).

15 “(c) REGISTRATION.—

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

1 tion provide additional information regarding the
2 identity and business locations of the individual, and
3 information on the training and experience of the in-
4 dividual regarding the performance of such tech-
5 nology.

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

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

16 “(A) the individual submitting the reg-
17 istration has in writing authorized the disclo-
18 sure; or

19 “(B) the disclosure does not identify such
20 individual or any place of business of the indi-
21 vidual.

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

24 “(1) establishes prohibitions, requirements, or
25 authorizations regarding human somatic cell nuclear

1 transfer technology that are different than, or in ad-
2 dition to, those established in subsection (a) or (c);
3 or

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

6 “(A) somatic cell nuclear transfer;

7 “(B) mitochondrial or cytoplasmic therapy;

8 or

9 “(C) the cloning of molecules, DNA, cells,
10 tissues, or organs;

11 except that this subsection does not apply to any State
12 or local law that was in effect as of the day before the
13 date of the enactment of the Cloning Prohibition Act of
14 2001.

15 “(e) RIGHT OF ACTION.—This section may not be
16 construed as establishing any private right of action.

17 “(f) DEFINITION.—For purposes of this section, the
18 term ‘person’ includes governmental entities.

19 “(g) SUNSET.—This section and section 301(bb) do
20 not apply to any activity described in subsection (a) that
21 occurs on or after the expiration of the 10-year period be-
22 ginning on the date of the enactment of the Cloning Prohi-
23 bition Act of 2001.”.

24 (b) PROHIBITED ACTS.—

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

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

6 (2) CRIMINAL PENALTY.—Section 303(b) of the
7 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
8 333(b)) is amended by adding at the end the fol-
9 lowing:

10 “(7) Notwithstanding subsection (a), any person who
11 violates section 301(bb) shall be imprisoned not more than
12 10 years or fined in accordance with title 18, United
13 States Code, or both.”.

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

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

20 “(A) \$1,000,000; or

21 “(B) an amount equal to the amount of any
22 gross pecuniary gain derived from such violation
23 multiplied by 2.

24 “(2) Paragraphs (3) through (5) of subsection (g)
25 apply with respect to a civil penalty under paragraph (1)

1 of this subsection to the same extent and in the same man-
2 ner as such paragraphs (3) through (5) apply with respect
3 to a civil penalty under paragraph (1) or (2) of subsection
4 (g).”.

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

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

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

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

19 (1) review the current state of knowledge about
20 the biological properties of stem cells obtained from
21 embryos, fetal tissues, and adult tissues;

22 (2) evaluate the current state of knowledge
23 about biological differences among stem cells ob-
24 tained from embryos, fetal tissues, and adult tissues
25 and the consequences for research and medicine; and

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

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

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

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