### 107TH CONGRESS 2D SESSION S. 2439

To prohibit human cloning while preserving important areas of medical research, including stem cell research.

#### IN THE SENATE OF THE UNITED STATES

May 1, 2002

Mr. SPECTER (for himself, Mrs. FEINSTEIN, Mr. HATCH, Mr. KENNEDY, Mr. HARKIN, Mrs. BOXER, Mr. DURBIN, Mr. MILLER, Mr. CORZINE, Ms. MI-KULSKI, Mrs. CLINTON, and Mr. THURMOND) introduced the following bill; which was read twice and referred to the Committee on the Judiciary

## A BILL

- To prohibit human cloning while preserving important areas of medical research, including stem cell research.
- 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 "Human Cloning Prohi-
- 5 bition Act of 2002".

#### 6 SEC. 2. FINDINGS.

- 7 Congress makes the following findings:
- 8 (1) Human cloning is unsafe, immoral, and un-
- 9 acceptable.

(2) Federal legislation should be enacted to pro hibit anyone from attempting to conduct human
 cloning, whether using Federal or non-Federal
 funds.

5 (3) To deter human cloning, any attempt to
6 create a human clone should be a felony subject to
7 severe punishment.

8 (4) The National Academies (including the Na-9 tional Academy of Sciences and the Institute of 10 Medicine) and the National Bioethics Advisory Com-11 mission recommended that any legislative action un-12 dertaken to ban human cloning should be careful not 13 to interfere with important areas of scientific re-14 search, such as nuclear transplantation to produce 15 stem cells.

16 (5) The National Academies found that there 17 are significant differences between human cloning 18 and nuclear transplantation. Specifically, the Acad-19 emies determined that, unlike human cloning, the 20 creation of embryonic stem cells by nuclear trans-21 plantation does not involve implantation of an em-22 bryo in a uterus and thus cannot produce a com-23 plete, live-born animal (that is, a "clone").

24 (6) The National Academies found that sci-25 entific and medical considerations that justify a ban

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on human cloning are not applicable to nuclear
 transplantation.

(7) The National Academies concluded that nu-3 4 clear transplantation has great potential to increase 5 the understanding and potential treatment of var-6 ious diseases and debilitating disorders, as well as 7 our fundamental biological knowledge. These dis-8 eases and disorders include Lou Gehrig's disease, 9 Parkinson's disease, Alzheimer's disease, spinal-cord 10 injury, cancer, cardiovascular diseases, diabetes, 11 rheumatoid arthritis, and many others.

12 (8) The National Academies determined that 13 nuclear transplantation research could improve our 14 ability to transplant healthy tissue derived from 15 stem cells into patients with damaged or diseased or-16 gans. Such research could greatly reduce the likeli-17 hood that a person's body would reject that tissue 18 and also help obviate the need for immuno-19 suppressive drugs, which often have severe and po-20 tentially life-threatening side effects.

(9) Based on these expert conclusions and recommendations and other evidence, nuclear transplantation is a valuable area of research that could
potentially save millions of lives and relieve the suf-

fering of countless others, and thus should not be
 banned.

3 (10) The National Academies recommended
4 that nuclear transplantation experiments should be
5 subject to close scrutiny under the Federal proce6 dures and rules concerning human-subjects research.

7 (11) Given the need for additional oversight in
8 this area, strict ethical requirements for human sub9 jects research, including informed consent, safety
10 and privacy protections, and review by an ethics
11 board, should be prescribed for all research involving
12 nuclear transplantation, whether using Federal or
13 non-Federal funds.

14 (12)(A) Biomedical research and clinical facili15 ties engage in and affect interstate commerce.

16 (B) The services provided by clinical facilities17 move in interstate commerce.

18 (C) Patients travel regularly across State lines19 in order to access clinical facilities.

20 (D) Biomedical research and clinical facilities
21 engage scientists, doctors, and others in an inter22 state market, and contract for research and pur23 chase medical and other supplies in an interstate
24 market.

#### 1 SEC. 3. PURPOSES.

2 It is the purpose of this Act to prohibit human3 cloning and to protect important areas of medical re-4 search, including stem cell research.

#### 5 SEC. 4. PROHIBITION ON HUMAN CLONING.

6 (a) IN GENERAL.—Title 18, United States Code, is
7 amended by inserting after chapter 15, the following:

# 8 "CHAPTER 16—PROHIBITION ON HUMAN 9 CLONING

"Sec. "301. Prohibition on human cloning.

#### 10 "§ 301. Prohibition on human cloning

11 "(a) DEFINITIONS.—In this section:

"(1) HUMAN CLONING.—The term 'human
cloning' means implanting or attempting to implant
the product of nuclear transplantation into a uterus
or the functional equivalent of a uterus.

16 "(2) HUMAN SOMATIC CELL.—The term
17 'human somatic cell' means any human cell other
18 than a haploid germ cell.

19 "(3) NUCLEAR TRANSPLANTATION.—The term
20 'nuclear transplantation' means transferring the nu21 cleus of a human somatic cell into an oocyte from
22 which the nucleus or all chromosomes have been or
23 will be removed or rendered inert.

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1	"(4) NUCLEUS.—The term 'nucleus' means the
2	cell structure that houses the chromosomes.
3	"(5) OOCYTE.—The term 'oocyte' means the fe-
4	male germ cell, the egg.
5	"(b) Prohibitions on Human Cloning.—It shall
6	be unlawful for any person or other legal entity, public
7	or private—
8	((1) to conduct or attempt to conduct human
9	cloning; or
10	((2) to ship the product of nuclear transplan-
11	tation in interstate or foreign commerce for the pur-
12	pose of human cloning in the United States or else-
13	where.
14	"(c) PROTECTION OF RESEARCH.—Nothing in this
15	section shall be construed to restrict practices not ex-
16	pressly prohibited in this section.
17	"(d) Penalties.—
18	"(1) CRIMINAL PENALTIES.—Whoever inten-
19	tionally violates paragraph $(1)$ or $(2)$ of subsection
20	(b) shall be fined under this title and imprisoned not
21	more than 10 years.
22	"(2) CIVIL PENALTIES.—Whoever intentionally
23	violates paragraph $(1)$ or $(2)$ of subsection $(b)$ shall
24	be subject to a civil penalty of \$1,000,000 or three

1 times the gross pecuniary gain resulting from the 2 violation, whichever is greater. 3 "(3) FORFEITURE.—Any property, real or per-4 sonal, derived from or used to commit a violation or 5 attempted violation of the provisions of subsection 6 (b), or any property traceable to such property, shall 7 be subject to forfeiture to the United States in ac-8 cordance with the procedures set forth in chapter 46 9 of title 18, United States Code. 10 "(e) RIGHT OF ACTION.—Nothing in this section 11 shall be construed to give any individual or person a private right of action.". 12 13 (b) ETHICAL REQUIREMENTS FOR NUCLEAR TRANS-PLANTATION RESEARCH.—Part H of title IV of the Public 14 15 Health Service Act (42 U.S.C. 289 et seq.) is amended by adding at the end the following: 16 17 "SEC. 498C. ETHICAL REQUIREMENTS FOR NUCLEAR 18 TRANSPLANTATION RESEARCH, INCLUDING 19 INFORMED CONSENT, INSTITUTIONAL RE-20 **VIEW BOARD REVIEW, AND PROTECTION FOR** 21 SAFETY AND PRIVACY. 22 "(a) DEFINITIONS.—In this section:

23 "(1) HUMAN SOMATIC CELL.—The term
24 'human somatic cell' means any human cell other
25 than a haploid germ cell.

1	"(2) NUCLEAR TRANSPLANTATION.—The term
2	'nuclear transplantation' means transferring the nu-
3	cleus of a human somatic cell into an oocyte from
4	which the nucleus or all chromosomes have been or
5	will be removed or rendered inert.
6	"(3) NUCLEUS.—The term 'nucleus' means the
7	cell structure that houses the chromosomes.
8	"(4) OOCYTE.—The term 'oocyte' means the fe-
9	male germ cell, the egg.
10	"(b) Applicability of Federal Ethical Stand-
11	ARDS TO NUCLEAR TRANSPLANTATION RESEARCH.—Re-
12	search involving nuclear transplantation shall be con-
13	ducted in accordance with subparts A and B of part 46
14	of title 45, Code of Federal Regulations (as in effect on
15	the date of enactment of the Human Cloning Prohibition
16	Act of 2002).
17	"(c) Civil Penalties.—Whoever intentionally vio-
18	lates subsection (b) shall be subject to a civil penalty in
19	an amount that is appropriate for the violation involved,

20 but not more than \$250,000.
21 "(d) ENFORCEMENT.—The Secretary of Health and
22 Human Services shall have the exclusive authority to en-

23 force this section.".