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. Mikulski, 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.

- 1 (2) Federal legislation should be enacted to pro-2 hibit anyone from attempting to conduct human 3 cloning, whether using Federal or non-Federal 4 funds.
 - (3) To deter human cloning, any attempt to create a human clone should be a felony subject to severe punishment.
 - (4) The National Academies (including the National Academy of Sciences and the Institute of Medicine) and the National Bioethics Advisory Commission recommended that any legislative action undertaken to ban human cloning should be careful not to interfere with important areas of scientific research, such as nuclear transplantation to produce stem cells.
 - (5) The National Academies found that there are significant differences between human cloning and nuclear transplantation. Specifically, the Academies determined that, unlike human cloning, the creation of embryonic stem cells by nuclear transplantation does not involve implantation of an embryo in a uterus and thus cannot produce a complete, live-born animal (that is, a "clone").
 - (6) The National Academies found that scientific and medical considerations that justify a ban

- on human cloning are not applicable to nuclear transplantation.
 - (7) The National Academies concluded that nuclear transplantation has great potential to increase the understanding and potential treatment of various diseases and debilitating disorders, as well as our fundamental biological knowledge. These diseases and disorders include Lou Gehrig's disease, Parkinson's disease, Alzheimer's disease, spinal-cord injury, cancer, cardiovascular diseases, diabetes, rheumatoid arthritis, and many others.
 - (8) The National Academies determined that nuclear transplantation research could improve our ability to transplant healthy tissue derived from stem cells into patients with damaged or diseased organs. Such research could greatly reduce the likelihood that a person's body would reject that tissue and also help obviate the need for immunosuppressive drugs, which often have severe and potentially 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.
 - (10) The National Academies recommended that nuclear transplantation experiments should be subject to close scrutiny under the Federal procedures and rules concerning human-subjects research.
 - (11) Given the need for additional oversight in this area, strict ethical requirements for human subjects research, including informed consent, safety and privacy protections, and review by an ethics board, should be prescribed for all research involving nuclear transplantation, whether using Federal or non-Federal funds.
 - (12)(A) Biomedical research and clinical facilities engage in and affect interstate commerce.
 - (B) The services provided by clinical facilities move in interstate commerce.
 - (C) Patients travel regularly across State lines in order to access clinical facilities.
 - (D) Biomedical research and clinical facilities engage scientists, doctors, and others in an interstate market, and contract for research and purchase medical and other supplies in an interstate market.

1 SEC. 3. PURPOSES.

- 2 It is the purpose of this Act to prohibit human
- 3 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:
- 12 "(1) Human cloning.—The term 'human
- 13 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
- than a haploid germ cell.
- 19 "(3) Nuclear transplantation.—The term
- 20 'nuclear transplantation' means transferring the nu-
- 21 cleus of a human somatic cell into an oocyte from
- 22 which the nucleus or all chromosomes have been or
- will be removed or rendered inert.

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	eloning; 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

- times the gross pecuniary gain resulting from the 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 pri-
- 12 vate right of action.".
- 13 (b) ETHICAL REQUIREMENTS FOR NUCLEAR TRANS-
- 14 PLANTATION RESEARCH.—Part H of title IV of the Public
- 15 Health Service Act (42 U.S.C. 289 et seq.) is amended
- 16 by adding at the end the following:
- 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.".