

PROVIDING FOR CONSIDERATION OF H.R. 2505, HUMAN
CLONING PROHIBITION ACT OF 2001

JULY 30, 2001.—Referred to the House Calendar and ordered to be printed

Mrs. MYRICK, from the Committee on Rules,
submitted the following

REPORT

[To accompany H. Res. 214]

The Committee on Rules, having had under consideration House Resolution 214, by a nonrecord vote, report the same to the House with the recommendation that the resolution be adopted.

SUMMARY OF PROVISIONS OF THE RESOLUTION

The resolution provides for consideration of H.R. 2505, the Human Cloning Ban Act of 2001, a structured rule providing one hour of debate in the House equally divided and controlled by the chairman and ranking minority member of the Committee on the Judiciary. The rule waives all points of order against the bill.

The rule provides that the amendments recommended by the Committee on the Judiciary now printed in the bill shall be considered as adopted. The rule makes in order the amendment printed in this report, if offered by Representative Scott or a designee, which shall be separately debatable for 10 minutes equally divided and controlled by the proponent and an opponent. The rule further makes in order the amendment in the nature of a substitute printed in this report, if offered by Representative Greenwood or a designee, which shall be considered as read and shall be separately debatable for one hour equally divided and controlled by the proponent and an opponent. The rule waives all points of order against the amendment in the nature of a substitute printed in this report.

Finally, the rule provides one motion to recommit with or without instructions.

SUMMARY OF AMENDMENTS MADE IN ORDER UNDER THE RULE

Scott: Provides for a study, conducted by the General Accounting Office, to be reported to Congress within 4 years of enactment, to

assess the need (if any) for amendment of the prohibition on human cloning; and provides that the study should include a discussion of new developments in medical technology, the possibility of medical advances, public attitudes, and ethical views.

Greenwood/Deutsch/DeGette/Schiff: Makes it a criminal act, subject to criminal and civil penalties, to use somatic cell nuclear transfer, or the products from this technology, to initiate a pregnancy or with the intent to initiate a pregnancy; makes it illegal to ship, mail, transport, or receive the products of somatic cell nuclear transfer if the products will be used to initiate a pregnancy; specifically protects other uses of somatic cell nuclear transfer, including therapeutic cloning; requires all individuals or companies who plan to perform somatic cell nuclear transfer to register with the Secretary and attest that they know that initiating a pregnancy through such means is illegal; provides that such registration is deemed confidential, following the same fashion as the FDA's treatment of trade secrets when a company files an Investigational New Drug application; preempts future state laws that are different from federal cloning law or prohibit protected types of research; sunsets the ban ten years after enactment; requires those who break the law to forfeit equipment, other property, and any monetary gains; requires a study by the Institute of Medicine on the properties of embryonic, fetal and adult stem cells.

Text of amendments made in order under the rule:

1. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE SCOTT OF VIRGINIA, OR A DESIGNEE, DEBATABLE FOR 10 MINUTES

Page 4, after line 8, insert the following:

SEC. 3. STUDY BY GENERAL ACCOUNTING OFFICE.

(a) IN GENERAL.—The General Accounting Office shall conduct a study to assess the need (if any) for amendment of the prohibition on human cloning, as defined in section 301 of title 18, United States Code, as added by this Act, which study should include—

(1) a discussion of new developments in medical technology concerning human cloning and somatic cell nuclear transfer, the need (if any) for somatic cell nuclear transfer to produce medical advances, current public attitudes and prevailing ethical views concerning the use of somatic cell nuclear transfer, and potential legal implications of research in somatic cell nuclear transfer; and

(2) a review of any technological developments that may require that technical changes be made to section 2 of this Act.

(b) REPORT.—The General Accounting Office shall transmit to the Congress, within 4 years after the date of enactment of this Act, a report containing the findings and conclusions of its study, together with recommendations for any legislation or administrative actions which it considers appropriate.

2. AN AMENDMENT TO BE OFFERED BY REPRESENTATIVE GREENWOOD OF PENNSYLVANIA, OR REPRESENTATIVE DEUTSCH OF FLORIDA, OR A DESIGNEE, DEBATABLE FOR 60 MINUTES

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

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

SEC. 2. PROHIBITION AGAINST HUMAN CLONING.

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

“CHAPTER X—HUMAN CLONING

“PROHIBITION AGAINST HUMAN CLONING

“SEC. 1001. (a) NUCLEAR TRANSFER TECHNOLOGY.—

“(1) IN GENERAL.—It shall be unlawful for any person—

“(A) to use or attempt to use human somatic cell nuclear transfer technology, or the product of such technology, to initiate a pregnancy or with the intent to initiate a pregnancy; or

“(B) to ship, mail, transport, or receive the product of such technology knowing that the product is intended to be used to initiate a pregnancy.

“(2) DEFINITION.—For purposes of this section, the term ‘human somatic cell nuclear transfer technology’ means transferring the nuclear material of a human somatic cell into an egg cell from which the nuclear material has been removed or rendered inert.

“(b) RULE OF CONSTRUCTION.—This section may not be construed as applying to any of the following:

“(1) The use of somatic cell nuclear transfer technology to clone molecules, DNA, cells, or tissues.

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

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

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

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

“(c) REGISTRATION.—

“(1) IN GENERAL.—Each individual who intends to perform human somatic cell nuclear transfer technology shall, prior to first performing such technology, register with the Secretary his or her name and place of business (except that, in the case of an individual who performed such technology before the date of the enactment of the Cloning Prohibition Act of 2001, the individual shall so register not later than 60 days after such date). The Secretary may by regulation require that the registration provide additional information regarding the identity and business locations of the individual, and information on the training and experience of the individual regarding the performance of such technology.

“(2) ATTESTATION.—A registration under paragraph (1) shall include a statement, signed by the individual submitting the registration, declaring that the individual is aware of the pro-

hibitions described in subsection (a) and will not engage in any violation of such subsection.

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

“(A) the individual submitting the registration has in writing authorized the disclosure; or

“(B) the disclosure does not identify such individual or any place of business of the individual.

“(d) PREEMPTION OF STATE LAW.—This section supersedes any State or local law that—

“(1) establishes prohibitions, requirements, or authorizations regarding human somatic cell nuclear transfer technology that are different than, or in addition to, those established in subsection (a) or (c); or

“(2) with respect to humans, prohibits or restricts research regarding or practices constituting—

“(A) somatic cell nuclear transfer;

“(B) mitochondrial or cytoplasmic therapy; or

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

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

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

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

“(g) SUNSET.—This section and section 301(bb) do not apply to any activity described in subsection (a) that occurs on or after the expiration of the 10-year period beginning on the date of the enactment of the Cloning Prohibition Act of 2001.”.

(b) PROHIBITED ACTS.—

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

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

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

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

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

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

“(A) \$1,000,000; or

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

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

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

(4) **FORFEITURE.**—Section 303 of the Federal Food, Drug, and Cosmetic Act, as amended by paragraph (3), is amended by adding at the end the following:

“(i) Any property, real or personal, derived from or used to commit a violation of section 301(bb), or any property traceable to such property, shall be subject to forfeiture to the United States.”.

SEC. 3. STUDY BY INSTITUTE OF MEDICINE.

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

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

(2) evaluate the current state of knowledge about biological differences among stem cells obtained from embryos, fetal tissues, and adult tissues and the consequences for research and medicine; and

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

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

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