

106TH CONGRESS
1ST SESSION

H. R. 2700

To require that United States supported clinical research that is conducted in sub-Saharan African countries be conducted in accordance with the most protective ethical standards regarding the use of human research subjects, and to prohibit the revocation or revision of intellectual property or competition laws or policies of sub-Saharan African countries that are designed to promote access to pharmaceuticals or other medical technologies.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 4, 1999

Mr. JACKSON of Illinois introduced the following bill; which was referred to the Committee on International Relations

A BILL

To require that United States supported clinical research that is conducted in sub-Saharan African countries be conducted in accordance with the most protective ethical standards regarding the use of human research subjects, and to prohibit the revocation or revision of intellectual property or competition laws or policies of sub-Saharan African countries that are designed to promote access to pharmaceuticals or other medical technologies.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Highly Essential Life-
3 saving Pharmaceuticals for Africa Act” or the “HELP for
4 Africa Act”.

5 **SEC. 2. ETHICAL STANDARDS REGARDING USE OF HUMAN**
6 **SUBJECTS IN UNITED STATES SUPPORTED**
7 **RESEARCH IN SUB-SAHARAN AFRICAN COUN-**
8 **TRIES.**

9 No funds appropriated or otherwise made available
10 to any Federal department or agency may be expended
11 for the conduct in a sub-Saharan African country of clin-
12 ical research unless the following conditions are met:

13 (1) The research is conducted in accordance
14 with the same ethical standards regarding the use of
15 human research subjects as apply to clinical research
16 in the United States that is conducted or supported
17 by the National Institutes of Health.

18 (2) The research is conducted in accordance
19 with the International Ethical Guidelines for Bio-
20 medical Research Involving Human Subjects (pre-
21 pared by the Council for International Organizations
22 of Medical Sciences and the World Health Organiza-
23 tion), as in effect on the date of the enactment of
24 this Act.

25 (3) The research is conducted in accordance
26 with the World Medical Association’s Declaration of

1 Helsinki, as in effect on the date of the enactment
2 of this Act.

3 (4) With respect to a particular issue regarding
4 the protection of human subjects (including the issue
5 of informed consent), if there are inconsistencies
6 among the ethical standards or guidelines referred to
7 in paragraphs (1) through (3), the standard or
8 guideline that is most protective of human subjects
9 is applied.

10 (5) Before the research is conducted, the Fed-
11 eral department or agency involved negotiates an
12 agreement with the entity that will conduct the re-
13 search, the purpose of which negotiation is to pro-
14 vide, to the greatest extent practicable, that if pur-
15 suant to the research the medical treatment involved
16 is determined to be safe and effective, the entity will,
17 in accordance with the law of the sub-Saharan Afri-
18 can country in which the research is conducted,
19 make the treatment available to the individuals who
20 participated as subjects in the research, and to other
21 individuals in such country who have a medical need
22 for the treatment, for a price that gives such individ-
23 uals reasonable access to the treatment.

1 **SEC. 3. INTELLECTUAL PROPERTY OR COMPETITION LAWS**
2 **OR POLICIES OF SUB-SAHARAN AFRICAN**
3 **COUNTRIES.**

4 No funds appropriated or otherwise made available
5 to any Federal department or agency may be used to seek,
6 through negotiation or otherwise, the revocation or revi-
7 sion of any intellectual property or competition law or pol-
8 icy of a sub-Saharan African country that is designed to
9 promote access to pharmaceuticals or other medical tech-
10 nologies if such law or policy, as the case may be, complies
11 with the Agreement on Trade-Related Aspects of Intellec-
12 tual Property Rights referred to in section 101(d)(15) of
13 the Uruguay Round Agreements Act (19 U.S.C.
14 3511(d)(15)).

15 **SEC. 4. SUB-SAHARAN AFRICAN COUNTRY DEFINED.**

16 In this Act, the term “sub-Saharan African country”
17 means any of the following:

- 18 Republic of Angola (Angola)
- 19 Republic of Botswana (Botswana)
- 20 Republic of Burundi (Burundi)
- 21 Republic of Cape Verde (Cape Verde)
- 22 Republic of Chad (Chad)
- 23 Democratic Republic of Congo
- 24 Republic of the Congo (Congo)
- 25 Republic of Djibouti (Djibouti)
- 26 State of Eritrea (Eritrea)

- 1 Gabonese Republic (Gabon)
- 2 Republic of Ghana (Ghana)
- 3 Republic of Guinea-Bissau (Guinea-Bissau)
- 4 Kingdom of Lesotho (Lesotho)
- 5 Republic of Madagascar (Madagascar)
- 6 Republic of Mali (Mali)
- 7 Republic of Mauritius (Mauritius)
- 8 Republic of Namibia (Namibia)
- 9 Federal Republic of Nigeria (Nigeria)
- 10 Democratic Republic of Sao Tomé and Príncipe
- 11 (Sao Tomé and Príncipe)
- 12 Republic of Sierra Leone (Sierra Leone)
- 13 Somalia
- 14 Kingdom of Swaziland (Swaziland)
- 15 Republic of Togo (Togo)
- 16 Republic of Zimbabwe (Zimbabwe)
- 17 Republic of Benin (Benin)
- 18 Burkina Faso (Burkina)
- 19 Republic of Cameroon (Cameroon)
- 20 Central African Republic
- 21 Federal Islamic Republic of the Comoros
- 22 (Comoros)
- 23 Republic of Côte d'Ivoire (Côte d'Ivoire)
- 24 Republic of Equatorial Guinea (Equatorial
- 25 Guinea)

- 1 Ethiopia
- 2 Republic of the Gambia (Gambia)
- 3 Republic of Guinea (Guinea)
- 4 Republic of Kenya (Kenya)
- 5 Republic of Liberia (Liberia)
- 6 Republic of Malawi (Malawi)
- 7 Islamic Republic of Mauritania (Mauritania)
- 8 Republic of Mozambique (Mozambique)
- 9 Republic of Niger (Niger)
- 10 Republic of Rwanda (Rwanda)
- 11 Republic of Senegal (Senegal)
- 12 Republic of Seychelles (Seychelles)
- 13 Republic of South Africa (South Africa)
- 14 Republic of Sudan (Sudan)
- 15 United Republic of Tanzania (Tanzania)
- 16 Republic of Uganda (Uganda)
- 17 Republic of Zambia (Zambia)

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