

109TH CONGRESS
2D SESSION

H. R. 5641

To promote safe and ethical clinical trials of drugs and other test articles
on people overseas.

IN THE HOUSE OF REPRESENTATIVES

JUNE 20, 2006

Mr. LANTOS (for himself and Mr. BROWN of Ohio) introduced the following
bill; which was referred to the Committee on International Relations

A BILL

To promote safe and ethical clinical trials of drugs and
other test articles on people overseas.

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 “Safe Overseas Human
5 Testing Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds the following:

8 (1) Before a manufacturer of a new drug or de-
9 vice can market its new product, the Food and Drug
10 Administration (in this section referred to as the

1 “FDA”) requires that the manufacturer conduct
2 laboratory and clinical trials to ascertain the prod-
3 uct’s safety and effectiveness.

4 (2) Federal regulations mandate that an Insti-
5 tutional Review Board (IRB), which is comprised of
6 scientists, physicians, and lay people, review the pro-
7 tocol or research plan and the informed consent
8 form of the proposed clinical trial to ensure, among
9 other things, that the health and safety of the
10 human participants are not unnecessarily endan-
11 gered.

12 (3) Institutional Review Boards also verify that
13 the manufacturer’s clinical researchers implement
14 appropriate additional safeguards to protect the
15 rights and welfare of potentially vulnerable popu-
16 lations and persons who are economically or educa-
17 tionally disadvantaged.

18 (4) Most importantly, the IRBs help assure the
19 FDA that manufacturers of new drugs and medical
20 devices adequately inform human participants of the
21 anticipated risks and the likelihood of projected ben-
22 efits derived from their participation in the clinical
23 trials, and then secure the voluntary consent of the
24 participants.

1 (5) For the purpose of supporting the safety
2 and efficacy of the test article, the FDA, however,
3 may accept the results of clinical trials with human
4 participants which are conducted outside of the
5 United States and do not meet United States IRB
6 and ethical requirements.

7 (6) Foreign clinical trials involving human par-
8 ticipants only need to conform to either international
9 norms on clinical investigations or the laws and reg-
10 ulations of the country in which the research is to
11 be conducted. However, neither international nor
12 most host-country standards meet the stringent re-
13 quirements of the United States.

14 (7) International and most foreign-country legal
15 protections do not adequately shield participants in
16 clinical investigations of a new drug or device from
17 unethical, dangerous, or unscrupulous research prac-
18 tices.

19 (8) Some researchers exploit the fragile regu-
20 latory systems, high illiteracy rates, and public
21 health failures of developing countries to test their
22 experimental drugs and devices on misinformed and
23 unwilling human participants.

24 (9) On April 30, 2001, the National Bioethics
25 Advisory Commission (NBAC) presented to the

1 President a report, entitled “Ethical and Policy
2 Issues in International Research: Clinical Trials in
3 Developing Countries”, which discussed the ethical
4 issues generated by research on human participants
5 in developing countries and recommended ways to
6 help ensure the health and safety of these human
7 participants. The NBAC highlighted the inadequate
8 regulatory protections which are afforded to human
9 participants in many clinical trials abroad.

10 (10) In September 2001, the Office of the In-
11 spector General of the Department of Health and
12 Human Services released the report entitled “The
13 Globalization of Clinical Trials: A Growing Chal-
14 lenge in Protecting Human Subjects”. In the report,
15 the Inspector General acknowledged that key entities
16 which oversee or study foreign research, including
17 United States regulatory agencies and the World
18 Health Organization, have raised concerns about the
19 lack of experience and insufficient monitoring prac-
20 tices of many foreign IRBs.

21 (11) The Inspector General also recommended,
22 among other things, that the FDA collect more in-
23 formation on the performance of foreign IRBs and
24 the growth and location of foreign clinical investiga-
25 tions.

1 (12) While Federal regulation should accelerate,
2 whenever possible, the delivery from laboratory to
3 patients of new drugs which are designed to treat
4 devastating illnesses, existing law permits manufac-
5 turers to profit from the misery and pain of uni-
6 formed, misinformed, and unwilling patients in de-
7 veloping countries.

8 (13) On June 10, 2004, the FDA issued a pro-
9 posed rule that would, among other things, replace
10 the existing requirement that foreign clinical studies
11 be conducted in accordance with the ethical prin-
12 ciples which are contained in the Declaration of Hel-
13 sinki (described in section 312.120(c) of title 21,
14 Code of Federal Regulations), with a requirement
15 that such studies comply with good clinical practice
16 (GCP).

17 (14) Although pharmaceutical and bio-
18 technology companies and their lobbyists, in sub-
19 mitted public comment, generally support the pro-
20 posed rule, other organizations, such as the AIDS
21 Vaccine Advocacy Coalition and Public Citizen, have
22 objected to the proposed deletion of the Declaration
23 of Helsinki from applicable regulations because the
24 removal may result in the use of placebos or other
25 drugs which are less effective than established treat-

1 ments in control groups facing life-threatening med-
2 ical conditions.

3 (15) As of June 15, 2006, the FDA has not
4 promulgated a final version of the June 2004 pro-
5 posed rule.

6 **SEC. 3. STATEMENT OF POLICY.**

7 It is the policy of the United States to control the
8 export of test articles which are intended for clinical inves-
9 tigations involving human participants in order to—

10 (1) foster public health and safety;

11 (2) prevent injury to the foreign policy of the
12 United States; and

13 (3) preserve the credibility of the United States
14 as a responsible trading partner.

15 **SEC. 4. MEASURES TO PROTECT THE PUBLIC HEALTH.**

16 (a) IN GENERAL.—In order to carry out the policy
17 set forth in section 3, test articles intended for clinical
18 investigations may be exported only pursuant to an export
19 license approved by the President. The President may ex-
20 ercise the authorities of the Export Administration Act of
21 1979, as continued in effect pursuant to the International
22 Emergency Economic Powers Act, to carry out this sec-
23 tion.

24 (b) CRITERIA FOR EXPORT LICENSE.—In addition to
25 any other requirements that may apply, including under

1 the Federal Food, Drug, and Cosmetic Act, the Public
2 Health Service Act, and regulations issued under either
3 such Act, the President shall require, as a prerequisite for
4 approval of an export license for a test article required
5 by subsection (a) of this section, that an applicant for such
6 license—

7 (1) identify each clinical investigation for which
8 the test article is intended;

9 (2) secure a certification from an institutional
10 review board that each of the protocols for every
11 clinical investigation identified under paragraph (1)
12 has been reviewed by the institutional review board
13 and has, at a minimum, met substantially the same
14 standards for the protection of the rights and wel-
15 fare of human subjects as the standards that would
16 be required for IRB approval of the protocol if the
17 protocol were for a clinical investigation of the test
18 article pursuant to the Federal Food, Drug, and
19 Cosmetic Act ; and

20 (3) submit the certification secured under para-
21 graph (2) to the President.

22 (c) REPORTING REQUIREMENT.—Not later than one
23 year after the date of the enactment of this Act, and annu-
24 ally thereafter, the President shall prepare and submit to
25 the appropriate congressional committees a report regard-

1 ing the approval of export licenses required by subsection

2 (a). Such report shall include—

3 (1) the names of the applicants for such export
4 licenses;

5 (2) the names of approved applicants for such
6 export licenses; and

7 (3) the destination country or countries for
8 each application for such export licenses.

9 (d) DEFINITIONS.—In this section:

10 (1) APPLICATION FOR RESEARCH OR MAR-
11 KETING PERMIT.—The term “application for re-
12 search or marketing permit” has the meaning given
13 that term in section 56.102(b) of title 21, Code of
14 Federal Regulations, or successor regulations.

15 (2) APPROPRIATE CONGRESSIONAL COMMIT-
16 TEES.—The term “appropriate congressional com-
17 mittees” means the Committee on International Re-
18 lations of the House of Representatives and the
19 Committee on Banking, Housing, and Urban Affairs
20 of the Senate.

21 (3) CLINICAL INVESTIGATION.—

22 (A) IN GENERAL.—The term “clinical in-
23 vestigation” means any experiment that—

24 (i) involves a test article and one or
25 more human subjects; and

1 (ii)(I) the results of which are in-
2 tended to be later submitted to, or held for
3 inspection by, the Secretary of Health and
4 Human Services as part of an application
5 for research or marketing permit; or

6 (II) must meet the requirements for
7 prior submission to such Secretary under
8 section 505(i) or 520(g) of the Federal
9 Food, Drug, and Cosmetic Act (21 U.S.C.
10 355(i) or 360j(g)).

11 (B) EXCLUSION.—The term “clinical in-
12 vestigation” does not include experiments that
13 must meet the requirements of part 58 of title
14 21, Code of Federal Regulations, or successor
15 regulations, regarding nonclinical laboratory
16 studies.

17 (4) DESTINATION COUNTRY.—The term “des-
18 tination country” means the country into which test
19 articles are being exported.

20 (5) HUMAN SUBJECT.—The term “human sub-
21 ject” means an individual who is or becomes a par-
22 ticipant in research, either as a recipient of a test
23 article or as a control. A subject may be either a
24 healthy individual or a patient.

1 (6) INSTITUTION.—The term “institution”
2 means any public or private entity or agency (includ-
3 ing Federal, State, and other agencies), either in the
4 United States or other country.

5 (7) INSTITUTIONAL REVIEW BOARD; IRB.—The
6 terms “institutional review board” and “IRB” mean
7 any board, committee, or other group formally des-
8 ignated by an institution to review, to approve the
9 initiation of, and to conduct periodic review of, bio-
10 medical research involving human subjects. The pri-
11 mary purpose of such review is to assure the protec-
12 tion of the rights and welfare of the human subjects.

13 (8) IRB APPROVAL.—The term “IRB approval”
14 means the determination of an IRB made pursuant
15 to part 56 of title 21, Code of Federal Regulations,
16 or successor regulations, that a clinical investigation
17 has been reviewed and may be conducted at an insti-
18 tution within the constraints set forth by the IRB
19 and by other institutional and Federal requirements.

20 (9) TEST ARTICLE.—The term “test article”
21 means any drug for human use, biological product
22 for human use, medical device for human use,
23 human food additive, color additive, electronic prod-
24 uct, or any other article that would be subject to

1 regulation under the Federal Food, Drug, and Cos-
2 metic Act if introduced into interstate commerce.

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