

107TH CONGRESS  
2D SESSION

# H. R. 5249

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

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## IN THE HOUSE OF REPRESENTATIVES

JULY 26, 2002

Mr. LANTOS (for himself, Mr. BROWN of Ohio, Mr. SMITH of New Jersey, Mr. HILLIARD, Ms. WATSON of California, Ms. LEE, Mr. PALLONE, Mr. STUPAK, Mrs. NAPOLITANO, Mr. BERMAN, Mr. ACKERMAN, Mr. PAYNE, Mr. MEEKS of New York, Mr. HOEFFEL, Mr. SHERMAN, Ms. WOOLSEY, Ms. BERKLEY, Ms. MCKINNEY, and Ms. ROS-LEHTINEN) introduced the following bill; which was referred to the Committee on International Relations

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## 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:

1           (1) Before a manufacturer of a new drug or de-  
2 vice can market its new product, the Food and Drug  
3 Administration (FDA) requires that the manufac-  
4 turer conduct laboratory and clinical trials to ascer-  
5 tain the product's safety and effectiveness.

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

14           (3) Institutional Review Boards also verify that  
15 the manufacturer's clinical researchers implement  
16 appropriate additional safeguards to protect the  
17 rights and welfare of potentially vulnerable popu-  
18 lations, such as women, children, the elderly, the  
19 physically or mentally disabled, and persons who are  
20 economically or educationally disadvantaged.

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

1 trials, and then secure the voluntary consent of the  
2 participants.

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

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

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

21 (8) According to the Department of Health and  
22 Human Services (HHS), the number of countries in  
23 which clinical investigators conduct drug research  
24 for FDA-approval purposes mushroomed from 29 in  
25 1990 to 79 in 1999. Russia and countries in East-

1 ern Europe and Latin America experienced the larg-  
2 est growth of clinical research.

3 (9) Some researchers exploit the fragile regu-  
4 latory systems, high illiteracy rates, and public  
5 health failures of developing countries to test their  
6 experimental drugs and devices on misinformed and  
7 unwilling human participants.

8 (10) On December 17, 2000, the *Washington*  
9 *Post* began a six-part series of articles which docu-  
10 mented the abuses and unethical practices of some  
11 United States-based pharmaceutical companies con-  
12 ducting clinical investigations of drugs and other  
13 test articles on human participants overseas.

14 (11) The *Washington Post* articles chronicled  
15 numerous cases where individuals in clinical trials  
16 had not given informed consent, researchers did not  
17 follow protocols for investigation and falsified re-  
18 sults, and poor people were paid to participate in  
19 trials without fully understanding the risks of their  
20 participation.

21 (12) On April 30, 2001, the National Bioethics  
22 Advisory Commission (NBAC) presented to the  
23 President a report, entitled “Ethical and Policy  
24 Issues in International Research: Clinical Trials in  
25 Developing Countries”, which discussed the ethical

1 issues generated by research on human participants  
2 in developing countries and recommended ways to  
3 help ensure the health and safety of these human  
4 participants. The NBAC highlighted the inadequate  
5 regulatory protections which are afforded to human  
6 participants in many clinical trials abroad.

7 (13) In September 2001, the Office of the In-  
8 spector General within HHS released the report  
9 “The Globalization of Clinical Trials: A Growing  
10 Challenge in Protecting Human Subjects”. In the  
11 report, the Inspector General acknowledged that key  
12 entities which oversee or study foreign research, in-  
13 cluding United States regulatory agencies and the  
14 World Health Organization, have raised concerns  
15 about the lack of experience and insufficient moni-  
16 toring practices of many foreign IRBs.

17 (14) Also, the Inspector General recommended,  
18 among other things, that the FDA collect more in-  
19 formation about the performance of foreign IRBs,  
20 and the growth and location of foreign clinical inves-  
21 tigations.

22 (15) While Federal regulation should accelerate,  
23 whenever possible, the delivery from laboratory to  
24 patients of new drugs which are designed to treat  
25 devastating illnesses, existing law permits manufac-

1       turers to profit from the misery and pain of uni-  
2       formed, misinformed, and unwilling patients in de-  
3       veloping countries.

4       **SEC. 3. STATEMENT OF POLICY.**

5       It is the policy of Congress to control the export of  
6       test articles which are intended for clinical investigations  
7       involving human participants in order to—

8               (1) foster public health and safety;

9               (2) prevent injury to the foreign policy of the  
10       United States; and

11              (3) preserve the credibility of the United States  
12       as a responsible trading partner.

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

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

22       (b) CRITERIA FOR EXPORT LICENSE.—In addition to  
23       any other requirements that may apply, including under  
24       the Federal Food, Drug, and Cosmetic Act, the Public  
25       Health Service Act, and regulations issued under either

1 such Act, the President shall require, as a prerequisite for  
2 approval of an export license for a test article required  
3 by subsection (a) of this section, that an applicant for such  
4 license—

5           (1) identify each clinical investigation for which  
6           the test article is intended; and

7           (2) submit proof that each of the protocols for  
8           every clinical investigation identified under para-  
9           graph (1) has been reviewed by an institutional re-  
10          view board and has, at a minimum, met substan-  
11          tially the same standards for the protection of the  
12          rights and welfare of human subjects as the stand-  
13          ards that would be required for IRB approval of the  
14          protocol if the protocol were for a clinical investiga-  
15          tion of such test article pursuant to the Federal  
16          Food, Drug, and Cosmetic Act.

17          (c) REPORTING REQUIREMENT.—Not later than one  
18          year after the date of the enactment of this Act, and annu-  
19          ally thereafter, the President shall prepare and submit to  
20          the appropriate congressional committees a report regard-  
21          ing the approval of export licenses required by subsection  
22          (a). Such report shall include—

23                 (1) the names of the applicants for such export  
24                 licenses;

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

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

5 (d) DEFINITIONS.—In this section:

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

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

17           (3) CLINICAL INVESTIGATION.—

18           (A) IN GENERAL.—The term “clinical in-  
19 vestigation” means any experiment that in-  
20 volves a test article and one or more human  
21 subjects, and that either must meet the require-  
22 ments for prior submission to the Food and  
23 Drug Administration under section 505(i),  
24 507(d), or 520(g) of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 355(i), 357(d), or

1           360j(g)), or need not meet the requirements for  
2           prior submission to the Food and Drug Admin-  
3           istration under those sections, but the results of  
4           which are intended to be later submitted to, or  
5           held for inspection by, the Food and Drug Ad-  
6           ministration as part of an application for a re-  
7           search or marketing permit.

8           (B) EXCLUSION.—The term “clinical in-  
9           vestigation” does not include experiments that  
10          must meet the provisions of part 58 of title 21,  
11          Code of Federal Regulations, or successor regu-  
12          lations, regarding nonclinical laboratory studies.

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

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

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

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

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

16           (9) TEST ARTICLE.—The term “test article”  
17 means any drug for human use, biological product  
18 for human use, medical device for human use,  
19 human food additive, color additive, electronic prod-  
20 uct, or any other article that would be subject to  
21 regulation under the Federal Food, Drug, and Cos-  
22 metic Act if introduced into interstate commerce.

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