

106TH CONGRESS  
2D SESSION

# H. R. 4281

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

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## IN THE HOUSE OF REPRESENTATIVES

APRIL 13, 2000

Mr. CALVERT (for himself, Mr. LANTOS, Mr. BROWN of Ohio, Mr. CAMPBELL, Mrs. CAPPES, Mr. COSTELLO, Mr. DELAHUNT, Mr. DEUTSCH, Ms. ESHOO, Mr. FRANK of Massachusetts, Mr. GILCHREST, Mr. GILMAN, Mr. GOSS, Mr. HORN, Mr. HYDE, Mr. MARKEY, Mr. GARY MILLER of California, Mr. PALLONE, Mr. PORTER, Mr. QUINN, Ms. RIVERS, Mr. SENBRENNER, Mr. SHAYS, Mr. SMITH of New Jersey, Mr. TOWNS, Mr. UDALL of Colorado, Mr. WAXMAN, Mr. WELDON of Pennsylvania and Ms. WOOLSEY) introduced the following bill; which was referred to the Committee on Commerce

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## A BILL

To establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new and revised toxicological tests that protect human and animal health and the environment while reducing, refining, or replacing animal tests and ensuring human safety and product effectiveness.

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 “ICCVAM Authoriza-  
3 tion Act of 2000”.

4 **SEC. 2. INTERAGENCY COORDINATING COMMITTEE ON THE**  
5 **VALIDATION OF ALTERNATIVE METHODS.**

6 (a) IN GENERAL.—The Interagency Coordinating  
7 Committee on the Validation of Alternative Methods (re-  
8 ferred to in this Act as “ICCVAM”) shall be sustained  
9 as a permanent standing committee and continued to be  
10 administered by the National Institute of Environmental  
11 Health Sciences. The purposes of ICCVAM shall be to—

- 12 (1) increase the efficiency and effectiveness of  
13 Federal agency test method review;
- 14 (2) eliminate duplicative efforts and share expe-  
15 riences across Federal regulatory agencies;
- 16 (3) optimize utilization of scientific expertise  
17 outside the Federal Government;
- 18 (4) ensure that new test methods meet the  
19 needs of Federal agencies; and
- 20 (5) reduce, refine, and replace the use of ani-  
21 mals in testing.

22 (b) COMPOSITION.—ICCVAM shall be comprised of  
23 a representative from each of the following agencies and  
24 organizations:

- 25 (1) Agency for Toxic Substances and Disease  
26 Registry.

1 (2) Consumer Product Safety Commission.

2 (3) Department of Agriculture.

3 (4) Department of Defense.

4 (5) Department of Energy.

5 (6) Department of the Interior.

6 (7) Department of Transportation.

7 (8) Environmental Protection Agency.

8 (9) Food and Drug Administration.

9 (10) National Institute for Occupational Safety  
10 and Health.

11 (11) National Institutes of Health.

12 (12) National Cancer Institute.

13 (13) National Institute of Environmental  
14 Health Sciences.

15 (14) National Library of Medicine.

16 (15) Occupational Safety and Health Adminis-  
17 tration.

18 (16) Any other agency that develops, employs,  
19 or regulates the use of animals in toxicity testing.

20 (c) SCIENTIFIC ADVISORY COMMITTEE.—

21 (1) ESTABLISHMENT.—In addition, the Na-  
22 tional Institute of Environmental Health Sciences  
23 shall establish a Scientific Advisory Committee to  
24 assist ICCVAM and the National Institute of Envi-  
25 ronmental Health Sciences. The Committee shall be

1 composed of at least one knowledgeable representa-  
2 tive having a history of expertise, development, or  
3 evaluation in alternatives to animal toxicological  
4 tests, from each of the following interests:

5 (A) The personal care, pharmaceutical, in-  
6 dustrial chemicals, agriculture, and any other  
7 regulated industry.

8 (B) A national animal protection organiza-  
9 tion established under section 501(c)(3) of the  
10 Internal Revenue Code of 1986.

11 (2) MEMBERSHIP.—The National Institute of  
12 Environmental Health Sciences shall also invite to  
13 be members of the Scientific Advisory Committee  
14 representatives from other stakeholder organizations  
15 such as:

16 (A) An academic institution.

17 (B) A State government agency.

18 (C) An international regulatory body.

19 (D) A corporation developing or marketing  
20 alternative test methodologies including con-  
21 tract laboratories.

22 (d) DUTIES.—ICCVAM shall carry out the following  
23 duties consistent with the protection of public health and  
24 the environment and for the purpose of reducing, refining,

1 and replacing the use of animals in acute and chronic toxicological tests:

3 (1) Review and evaluate existing and new alternative methods, including batteries of tests and test screens, which may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised test methods of interagency interest.

9 (2) Facilitate interagency and international harmonization of acute chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal tests.

13 (3) Facilitate, promote, and provide guidance on development of validation criteria and processes for new methods and help promote the acceptance of such methods and awareness of accepted methods by Federal agencies and other stakeholders.

18 (4) File formal recommendations with each appropriate Federal agency identifying specific agency guidelines, recommendations, or regulations for each new test, battery of tests, test screen, or end point reviewed by ICCVAM that may be appropriate for the reduction, refinement, or replacement of an animal test required or recommended by that Federal agency for compliance with that agency's specific

1 statutes, regulations, or guidelines. Tests may be  
2 recommended for a certain class of chemicals within  
3 that regulatory framework.

4 (5) Consider for review and evaluation petitions  
5 received from the public which identify a specific  
6 regulation, recommendation, or guideline, and which  
7 recommend alternatives and provide scientific evi-  
8 dence of the acceptability of the alternatives for the  
9 purpose of carrying out the regulatory mandate in  
10 question.

11 (6) Make final recommendations to agencies  
12 and responses from agencies available to the public.

13 (7) Make an annual report to be made available  
14 to the public on its progress to promote the regu-  
15 latory acceptance of new and revised toxicological  
16 tests.

17 **SEC. 3. APPLICATION.**

18 This Act shall not apply to regulations, guidelines,  
19 or recommendations related to medical research. The term  
20 “medical research” means research, including research  
21 performed using biotechnology, related to the causes, diag-  
22 nosis, treatment, or control of physical or mental impair-  
23 ments of humans or animals. The term does not include  
24 the testing of a product to determine its toxicity for the  
25 purpose of complying with protocols, recommendations, or

1 guidelines for testing required, recommended, or accepted  
2 by a Federal regulatory agency for a product introduced  
3 in commerce.

4 **SEC. 4. FEDERAL AGENCY ACTION.**

5 (a) IDENTIFICATION OF TESTS.—Within 180 days  
6 after the date of enactment of this Act, each Federal agen-  
7 cy authorized to carry out a regulatory program which re-  
8 quires or recommends acute or chronic toxicological test-  
9 ing shall identify any regulation or industry-wide guideline  
10 which specifically or in practice requires, recommends, or  
11 encourages the use of an animal acute or chronic toxicological  
12 test and shall forward to ICCVAM a list of these  
13 regulations, guidelines, and recommendations along with  
14 the test or tests recommended or required.

15 (b) ALTERNATIVES.—Each Federal agency shall pro-  
16 mote and encourage the development and use of alter-  
17 natives to animal tests, including batteries of tests and  
18 test screens, where appropriate, for the purpose of com-  
19 plying with Federal regulations, guidelines, or rec-  
20 ommendations, in each instance, and for each chemical  
21 class, for which such tests are found to be effective for  
22 generating data at least equivalent for hazard identifica-  
23 tion or dose-response assessment purposes to the method  
24 established under the current regulatory scheme.

1 (c) TEST VALIDATION.—Each Federal agency shall  
2 ensure that any new acute or chronic toxicity test, includ-  
3 ing animal tests and alternatives, is determined to be valid  
4 for its proposed use prior to requiring, recommending, or  
5 encouraging its application.

6 (d) REVIEWS.—Each Federal agency shall review any  
7 formal recommendations from ICCVAM to promulgate  
8 new regulations or draft new guidelines or recommenda-  
9 tions to promote the ICCVAM recommendations and no-  
10 tify ICCVAM in writing of its findings within 180 days  
11 of receipt of the recommendations.

12 (e) RECOMMENDATION ADOPTION.—Each Federal  
13 agency shall adopt the ICCVAM recommendations unless  
14 each individual Federal agency determines that—

15 (1) the alternative is not adequate in terms of  
16 biological relevance for the regulatory goal author-  
17 ized by that agency;

18 (2) the alternative does not generate data at  
19 least equivalent for the appropriate hazard identi-  
20 fication or dose-response assessment purpose as the  
21 method recommended by that agency;

22 (3) that agency does not employ, recommend,  
23 or require testing for that class of chemical or for  
24 the recommended end point; or

1           (4) the new test method is unacceptable for sat-  
2           isfactorily fulfilling the test needs for that particular  
3           agency and its respective congressional mandate.

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