106TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
106–980

ICCVAM AUTHORIZATION ACT OF 2000

OCTOBER 16, 2000.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 4281]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "ICCVAM Authorization Act of 2000".

SEC. 2. DEFINITIONS.

In this Act:

(1) ALTERNATIVE TEST METHOD.—The term "alternative test method" means a test method that—

(A) includes any new or revised test method; and

(B)(i) reduces the number of animals required;

(ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(iii) replaces animals with non-animal systems or 1 animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate.

(2) ICCVAM TEST RECOMMENDATION.—The term "ICCVAM test recommendation" means a summary report prepared by the ICCVAM characterizing the results of a scientific expert peer review of a test method.

SEC. 3. INTERAGENCY COORDINATING COMMITTEE ON THE VALIDATION OF ALTERNATIVE METHODS.

(a) IN GENERAL.—With respect to the interagency coordinating committee that is known as the Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in this Act as "ICCVAM") and that was established by the Director of the National Institute of Environmental Health Sciences for purposes of section 463A(b) of the Public Health Service Act, the Director of the Institute shall designate such committee as a permanent interagency coordinating committee of the Institute under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. This Act may not be construed as affecting the authorities of such Director regarding ICCVAM that were in effect on the day before the date of the enactment of this Act, except to the extent inconsistent with this Act.

(b) PURPOSES.—The purposes of the ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, or replace the use of animals in testing, where feasible.

(c) COMPOSITION.—The ICCVAM shall be composed of the heads of the following Federal agencies (or their designees):

(1) Agency for Toxic Substances and Disease Registry.
(2) Consumer Product Safety Commission.
(3) Department of Agriculture.
(4) Department of Defense.
(5) Department of Energy.
(6) Department of the Interior.
(7) Department of Transportation.
(8) Environmental Protection Agency.
(9) Food and Drug Administration.
(10) National Institute for Occupational Safety and Health.
(11) National Institutes of Health.
(12) National Cancer Institute.
(13) National Institute of Environmental Health Sciences.
(14) National Library of Medicine.
(15) Occupational Safety and Health Administration.
(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

(d) SCIENTIFIC ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—The Director of the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in this Act as the "SAC") to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods re-

garding ICCVAM activities. The activities of the SAC shall be subject to provisions of the Federal Advisory Committee Act.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The SAC shall be composed of the following voting members:

(i) At least 1 knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of—

(I) the personal care, pharmaceutical, industrial chemicals, or agriculture industry;

(II) any other industry that is regulated by the Federal agencies specified in subsection (c); and

(III) a national animal protection organization established under section 501(c)(3) of the Internal Revenue Code of 1986.

(ii) Representatives (selected by the Director of the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories.

(B) NONVOTING EX OFFICIO MEMBERS.—The membership of the SAC shall, in addition to voting members under subparagraph (A), include as nonvoting ex officio members the agency heads specified in subsection (c) (or their designees).

(e) DUTIES.—The ICCVAM shall, consistent with the purposes described in subsection (b), carry out the following functions:

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

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

(3) Facilitate and provide guidance on the development of validation criteria, validation studies and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders.

(4) Submit ICCVAM test recommendations for the test method reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (or the designee of the Secretary), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for a test method, including batteries of tests and test screens, for chemicals or class of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods.

(5) Consider for review and evaluation, petitions received from the public that—

(A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and

(B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method.

(6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the responses from the agencies regarding such recommendations.

(7) Prepare reports to be made available to the public on its progress under this Act. The first report shall be completed not later than 12 months after the date of the enactment of this Act, and subsequent reports shall be completed biennially thereafter.

SEC. 4. FEDERAL AGENCY ACTION.

(a) IDENTIFICATION OF TESTS.—With respect to each Federal agency carrying out a program that requires or recommends acute or chronic toxicological testing, such agency shall, not later than 180 days after receiving an ICCVAM test recommendation, identify and forward to the ICCVAM any relevant test method specified in a regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test method for which the ICCVAM test recommendation may be added or substituted.

(b) ALTERNATIVES.—Each Federal agency carrying out a program described in subsection (a) shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens), where appro-

priate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose-response assessment, or risk assessment purposes.

(c) TEST METHOD VALIDATION.—Each Federal agency carrying out a program described in subsection (a) shall ensure that any new or revised acute or chronic toxicity test method, including animal test methods and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test method.

(d) REVIEW.—Not later than 180 days after receipt of an ICCVAM test recommendation, a Federal agency carrying out a program described in subsection (a) shall review such recommendation and notify the ICCVAM in writing of its findings.

(e) RECOMMENDATION ADOPTION.—Each Federal agency carrying out a program described in subsection (a), or its specific regulatory unit or units, shall adopt the ICCVAM test recommendation unless such Federal agency determines that—

(1) the ICCVAM test recommendation is not adequate in terms of biological relevance for the regulatory goal authorized by that agency, or mandated by Congress;

(2) the ICCVAM test recommendation does not generate data, in an amount and of a scientific value that is at least equivalent to the data generated prior to such recommendation, for the appropriate hazard identification, dose-response assessment, or risk assessment purposes as the current test method recommended or required by that agency;

(3) the agency does not employ, recommend, or require testing for that class of chemical or for the recommended test endpoint; or

(4) the ICCVAM test recommendation is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.

SEC. 5. APPLICATION.

(a) APPLICATION.—This Act shall not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases or impairments of humans or animals.

(b) USE OF TEST METHODS.—Nothing in this Act shall prevent a Federal agency from retaining final authority for incorporating the test methods recommended by the ICCVAM in the manner determined to be appropriate by such Federal agency or regulatory body.

(c) LIMITATION.—Nothing in this Act shall be construed to require a manufacturer that is currently not required to perform animal testing to perform such tests. Nothing in this Act shall be construed to require a manufacturer to perform redundant endpoint specific testing.

(d) SUBMISSION OF TESTS AND DATA.—Nothing in this Act precludes a party from submitting a test method or scientific data directly to a Federal agency for use in a regulatory program.

Amend the title so as to read:

"A bill to establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid 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.".

PURPOSE AND SUMMARY

H.R. 4281, the ICCVAM Authorization Act of 2000, as amended, authorizes the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to function as a standing interagency coordinating committee under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. H.R. 4281 directs ICCVAM to review and evaluate new and revised and alternative test methods for regulatory acceptance and use.

The purposes of ICCVAM are to (1) increase the efficiency and effectiveness of Federal agency test method review; (2) eliminate unnecessary duplicative efforts and share expertise between Fed-

eral regulatory agencies; (3) optimize the utilization of scientific expertise outside the Federal government; (4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and (5) to reduce, refine, or replace the use of animals in testing, where feasible.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 4281, the ICCVAM Authorization Act of 2000 was introduced by Representative Ken Calvert on April 13, 2000. H.R. 4281 provides statutory authorization and standing for ICCVAM to establish, wherever feasible, guidelines and recommendations that promote the regulatory acceptance of scientifically valid new and revised and alternative toxicological test methods.

ICCVAM was established by the Director of the National Institute of Environmental Health Sciences (NIEHS) in response to Public Law 103–43, which directed NIEHS to establish criteria and processes for the validation and regulatory acceptance of toxicological test methods. ICCVAM is comprised of representatives from various Federal agencies and programs and is intended to facilitate cross-agency communication and coordination on issues relating to validation, acceptance, and harmonization of toxicological test methods.

Section 1301 of the National Institutes of Health Revitalization Act (P.L. 103–43) directed the National Institute of Environmental Health Sciences (NIEHS) to establish a research program to conduct applied research and testing, including establishing criteria for the validation and regulatory acceptance of alternative test methods; and recommending a process through which scientifically validated alternative methods can be accepted for regulatory use. In response to that mandate, on a discretionary basis, NIEHS established ICCVAM to develop recommendations relating to the validation and acceptance of new and revised and alternative testing methods that would be useful to Federal agencies. The initial objective of ICCVAM was to draft a report (NIH Publication, No. 97–3981, March 1997) to recommend criteria and processes for validation and regulatory acceptance of toxicological test methods. The following Federal regulatory or research agencies, with input through public meetings and comments, drafted that report, "Validation and Regulatory Acceptance of Toxicological Methods—A Report of the ad hoc Interagency Coordinating Committee for the Validation of Alternative Methods": Agency for Toxic Substances and Disease Registry; Consumer Product Safety Commission; Department of Agriculture; Department of Defense; Department of Energy; Department of the Interior; Department of Transportation; Environmental Protection Agency; Food and Drug Administration; National Institute for Occupational Safety and Health; National Institutes of Health; National Cancer Institute; National Institute of Environmental Health Sciences; National Library of Medicine; and Occupational Safety and Health Administration.

After publication of the report, the ad hoc ICCVAM moved to standing status under the NIEHS under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Representatives from Federal regulatory and research agencies and programs have continued to meet, with advice from a scientific advisory committee, to assess the validation of

new, revised and alternative toxicological methods. Since then, two methods have undergone rigorous assessment and are deemed scientifically valid and acceptable. The first method, Corrositex, is a replacement for animal-based dermal corrosivity tests for some chemicals. The second, the Local Lymph Node Assay, is a reduction and refinement of animal use method for the skin irritation endpoint. The open public comment process, input by interested stakeholders and the continued commitment by the Federal agencies has led to ICCVAM's success. It has resulted in a more coordinated review process for rigorous scientific assessment of the validation of new, revised, and alternative toxicological test methods.

H.R. 4281 is needed to formally provide standing status for the ad hoc ICCVAM within NIEHS in order to ensure that this interagency coordinating group receives the appropriate attention, staffing and resources to fully carry out its duties. In addition to statutorily authorizing ICCVAM, this legislation is needed to more clearly delineate ICCVAM's purposes and duties, in order to ensure that ICCVAM's efforts are properly directed and focused. The legislation also includes additional mandates that apply to relevant Federal agencies that are needed to ensure that ICCVAM's test recommendations are not disregarded, but rather that such test recommendations are given appropriate consideration.

The Administration has not provided the Committee with an official position on the legislation; however, both the Environmental Protection Agency (EPA) and the National Institute of Environmental Health Sciences (NIEHS) have submitted to the Committee, in writing, policy and technical changes to the bill. H.R. 4281, as amended addresses these concerns and incorporates appropriate changes.

The bill's principal sponsor has received letters of support for H.R. 4281 from the following organizations: Doris Day Animal League and Humane Society of the United States, American Humane Society; the Massachusetts Society for the Prevention of Cruelty to Animals; The Gillette Company, Proctor and Gamble, Colgate-Palmolive Company, American Chemistry Council, American Crop Protection Association, Chemical Specialties Manufacturers Association, Synthetic Organic Chemical Manufacturers Association and the Soap and Detergent Association.

HEARINGS

The Committee on Commerce has not held hearings on this legislation.

COMMITTEE CONSIDERATION

On October 5, 2000, the Subcommittee on Health and Environment was discharged from the further consideration of H.R. 4281. On October 5, 2000, the Full Committee met in open markup session and approved H.R. 4281, as amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 4281 reported.

A motion by Mr. Bliley to order H.R. 4281 reported to the House, without amendment, was agreed to by a voice vote.

The following amendment was agreed to by a voice vote:

> An amendment in the nature of a substitute by Mr. Bilbray, No. 1, making technical and other changes in order to address issues raised by the Administration and others, and including an additional savings clause.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4281, the ICCVAM Authorization Act of 2000, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 13, 2000

Hon. TOM BLILEY,
Chairman, Committee on Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed estimate for H.R. 4281, the ICCVAM Authorization Act of 2000.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Christopher J. Topoleski.

Sincerely,

BARRY B. ANDERSON
(For Dan L. Crippen, Director).

Enclosure.

H.R. 4281—ICCVAM Authorization Act of 2000

Summary: H.R. 4281 would designate the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) as a permanent standing committee administered by the National Institute of Environmental Health Sciences (NIEHS). The legislation would establish objectives for ICCVAM, including increasing the efficiency of reviewing methods of animal testing across federal agencies, and reducing reliance on animal testing. In addition, the bill would direct the NIEHS to establish a Scientific Advisory Committee to assist the ICCVAM in making recommendations.

The bill also would require federal agencies to identify and forward to ICCVAM their guidelines or regulations requiring or recommending animal testing. The ICCVAM would examine alternatives to traditional animal testing and promote the use of those alternatives whenever possible. Agencies would be required to adopt ICCVAM recommendations unless such recommendations are inadequate or unsatisfactory.

Assuming the appropriation of the necessary amounts, CBO estimates that implementing H.R. 4281 would cost $1 million in 2001 and $9 million over the 2001–2005 period, assuming annual adjustments for inflation for those activities without specified authorization levels. The five-year total would be $8 million if such inflation adjustments are not made. The legislation would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply.

H.R. 4281 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 4281 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2000	2001	2002	2003	2004	2005
SPENDING SUBJECT TO APPROPRIATION						
Spending under current law:						
Estimated authorization level [1]	445	445	464	473	483	493
Estimated Outlays	384	426	443	456	466	475
Proposed changes: [2]						
Estimated authorization level	0	2	2	2	2	2
Estimated Outlays	0	1	2	2	2	2
Spending under H.R. 4281:						
Estimated authorization level	445	457	466	475	485	495
Estimated Outlays	384	427	445	458	468	477

[1] The 2000 level is the amount appropriated for that year for the agencies that would be affected by H.R. 4281. The 2001–2005 levels are CBO baseline projections, including adjustments for anticipated inflation.

[2] The amounts shown reflect adjustments for anticipated inflation. Without such inflation adjustments. The five-year changes in authorization levels would total $10 million (instead of $11 million) and the changes in outlays would total $8 million (instead of $9 million).

Basis of estimate: For this estimate, CBO assumes that the bill will be enacted early in fiscal year 2001 and that the estimated amounts will be appropriated for each year. We also assume that outlays will follow historical spending rates for the NIEHS for the authorized activities. CBO based its estimates on amounts spent in the past for similar types of activities.

In addition to making the ICCVAM a standing committee, the bill would require federal agencies to identify and forward to ICCVAM their guidelines or regulations requiring or recommending animal testing. Agencies would be required to adopt ICCVAM recommendations unless such recommendations are inadequate or unsatisfactory. The agencies that would most likely be affected by this provision include the Agency for Toxic Substances and Disease Registry, the Department of Agriculture, the Department of Defense, the Department of Energy, the Environmental Protection Agency, the Food and Drug Administration, various institutes within the National Institutes of Health, and any other agency that develops or employs tests or test data using animals or regulates the use of animals in toxicity testing. Based on information from the NIH, it appears that most agencies currently comply with the findings of the ICCVAM on evaluations of research methods. Thus, CBO estimates that the provision would not have a significant impact on federal spending.

Pay-as-you-go considerations: None.

Intergovernmental and private-sector impact: H.R. 4281 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal costs: Christopher J. Topoleski; impact on State, local, and tribal governments: Leo Lex; impact on the private sector: Jennifer Bullard Bowman.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

Section 3(d) of H.R. 4281 creates a scientific advisory committee to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods regarding ICCVAM activities. Pursuant to the requirements of subsection 5(b) of the Federal Advisory Committee Act, the Committee finds that the functions of the proposed advisory committee are not and cannot be performed by an existing Federal agency or advisory commission or by enlarging the mandate of an existing advisory committee.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or

accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section provides the short title of the bill, the "ICCVAM Authorization Act of 2000."

Section 2. Definitions

This section defines an "alternative test method" to include new or revised methods that reduce, refine or replace the use of animals in toxicological testing. This section also defines an "ICCVAM test recommendation" as a summary report prepared by ICCVAM characterizing the results of a scientific expert peer review of a test method. ICCVAM test recommendations are intended to reflect formalized recommendations by ICCVAM that are transmitted through the Department to other Federal agencies, and are not intended to include less formal declarations or statements of position by individual representatives to ICCVAM or to ICCVAM's scientific advisory committee. In addition, the Committee notes that although this bill defines "alternative test method," the ICCVAM's statutory mandates direct it to review, evaluate and make recommendations about new or revised toxicological test methods as well as alternative test methods.

Section 3. Interagency Coordinating Committee on the Validation of Alternative Methods

Subsection (a) designates ICCVAM as a permanent interagency coordinating committee under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (the Center). The Committee recognizes that prior to the date of enactment of this legislation, the ICCVAM is already in operation on a discretionary ad hoc basis within NIEHS, and nothing in this bill is intended to disrupt its ongoing operation.

Subsection (b) delineates the purposes of ICCVAM to: (1) increase the efficiency and effectiveness of Federal agency test method review; (2) eliminate unnecessary duplicative efforts and share expertise between Federal regulatory agencies; (3) optimize utilization of scientific expertise outside the Federal government; (4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and (5) to reduce, refine, or replace the use of animals in testing, where feasible. The Committee intends that ICCVAM, in carrying out its duties described in subsection (e) of this section, should perform those duties in accordance with these purposes.

Subsection (c) identifies the Federal agencies who may provide representatives to participate on the ICCVAM. ICCVAM will be comprised of representatives from fifteen Federal regulatory and/or research agencies and representatives from other Federal agencies that develop or employ tests or test data using animals or that regulate on the basis of the use of animals in toxicity testing. The Committee encourages such Federal agencies to participate as part of this interagency coordinating committee; however, participation on ICCVAM is not mandatory.

Subsection (d) creates a Scientific Advisory Committee (SAC) to provide scientific advice to ICCVAM and to the Center. The Committee intends that the SAC will be operated in accordance with the Federal Advisory Committee Act in order to ensure that affected parties, including researchers, corporations, and other interested members of the public have access to the proceedings of the SAC and of ICCVAM, and that the process employed for operating the SAC is both open and transparent. The SAC will include representatives with expertise in the development or evaluation of new, revised, and alternative test methods from various sectors of regulated industries, national animal protection organizations, and other representatives chosen by the National Institute of Environmental Health Sciences from academia, State government agencies, international regulatory bodies, and corporations developing or marketing new or revised or alternative test methods. In addition, representatives from agencies participating in ICCVAM are included as non-voting members of the SAC to ensure that those representatives are invited to the SAC deliberations.

Subsection (e) identifies the duties and functions of ICCVAM, including the responsibility of reviewing and evaluating new and revised and alternative test methods to assess their scientific validity. In addition, ICCVAM will coordinate the necessary technical reviews for those proposed methods, and it will facilitate communication regarding interagency and international harmonization of scientifically valid alternative test methods. This subsection requires that ICCVAM facilitate and provide guidance on the development of validation criteria, studies and processes for new and revised and alternative test methods, and will help to promote awareness of the acceptance of such scientifically validated test methods by Federal agencies and other stakeholders. This subsection further requires that ICCVAM submit its test recommendations through expeditious transmittal by the Secretary of HHS to each appropriate Federal agency providing specific identification of the guidelines, recommendations, or regulations for each test, battery of tests, test screen or endpoint reviewed by the ICCVAM that may be appropriate for scientific improvement, while seeking, where feasible, to reduce, refine or replace the use of animals. In addition, this subsection requires that ICCVAM consider petitions from the public to the extent that those petitions recommend new or revised or alternative test methods and provide valid scientific evidence in support of the new or revised or alternative test method. It is the Committee's expectation that once ICCVAM has delivered a test recommendation to the Secretary of HHS, the Secretary's sole role is to expeditiously transmit that recommendation to the relevant Federal agencies without delay. The ICCVAM test recommendations and the agency's responses will be made available to the public. The Committee intends that the proceedings of ICCVAM and the SAC should be conducted in a manner that is open and transparent. This subsection requires ICCVAM to prepare reports to be made available to the public on its progress under this Act. The first report shall be due no later than 12 months after the date of enactment of this Act, and additional reports shall be prepared every two years thereafter.

The Committee intends that nothing in this subsection restricts the ongoing efforts of ICCVAM to undertake efforts to foster great-

er awareness and acceptance of scientifically valid alternative test methods. Moreover, the Committee notes that this subsection is consistent with the stated goal of ICCVAM identified by NIEHS on page 45 of its report "Validation and Regulatory Acceptance of Toxicological Test Methods," NIH Publication, No. 97–3981, March 1997, in which the NIEHS states "The Committee [ICCVAM] will seek to promote toxicological test methods that (1) enhance agencies ability to assess risks and make decisions; and (2) where feasible and practical, reduce animal use, refine animal procedures to make them less stressful, or replace animals in toxicological tests (the 3Rs)." The ICCVAM recommendation is a statement of objective science, not policy, or a statement that a given method fits a specific regulatory context. ICCVAM will review test methods that will reduce, refine or replace animal test methods, but the ICCVAM test recommendation itself must be a scientifically objective statement characterizing the results of a scientific expert review of a test method. ICCVAM shall identify regulatory areas where the test may be relevant, but ICCVAM would not make a finding that a test method must fit a specific regulatory context for an agency. That decision is left up to the relevant Federal agencies in carrying out their respective mandates. Moreover, ICCVAM is making no recommendation on the use of existing test methods. ICCVAM test recommendations may be useful as an adjunct to help modify the scientific interpretation of the mode of action of a chemical.

Section 4. Federal agency action

Subsection (a) requires relevant Federal agencies with programs requiring toxicological testing, within 180 days of receiving an ICCVAM recommendation, to provide a response to ICCVAM. The response should identify test requirements in regulations or guidelines that currently require, recommend or encourage acute or chronic toxicological test methods for which the ICCVAM test method may be relevant.

Subsection (b) requires relevant Federal agencies to encourage, where appropriate, the development of scientifically valid alternative test methods.

Subsection (c) requires relevant Federal agencies to ensure that any new or revised or alternative test method must be validated prior to requiring, recommending or encouraging use of the test. The Committee intends that in order for the new or revised or alternative test method to be valid, at a minimum, it must be capable of producing results that are reliable, relevant and reproducible.

Subsection (d) requires relevant Federal agencies to review each ICCVAM test recommendation and respond within 180 days regarding its review.

Subsection (e) requires relevant Federal agencies to adopt the ICCVAM recommendation unless the Federal agency determines that: (1) the ICCVAM test recommendation is not adequate in terms of biological relevance to the Federal agency's regulatory goal; (2) the ICCVAM test recommendation does not generate data of sufficient scientific value; (3) the Federal agency does not employ, recommend or require testing for the recommended test endpoint or relevant class of chemicals; or (4) the Federal agency

deems the ICCVAM test recommendation unacceptable for satisfactorily fulfilling the needs for that Federal agency or its respective congressional mandates. The Committee intends that relevant Federal agencies review, evaluate, and adopt the ICCVAM test recommendations pertaining to scientifically valid new, revised and alternative test methods, where such test recommendations are acceptable for meeting the agency's regulatory objectives. However, the Committee does not intend for this subsection to require any Federal agency to adopt an ICCVAM test recommendation that such Federal agency determines is unacceptable for that particular Federal agency or is outside the purview of its respective congressional mandates. During the ICCVAM review process it is important for Federal agencies to make their scientific views known. In responding this subsection, Federal agencies should present separate explanations concerning the extent to which a method is scientifically valid and the appropriate means for incorporating or rejecting the use of such test methods. Nothing in this Act changes any existing requirement for a Federal agency to respond to scientific information presented to it during a regulatory process.

Section 5. Application

Subsection (a) excludes from coverage of this bill any research, including research performed using biotechnology, techniques, or research relating to the causes, diagnosis, treatment, control or prevention of physical or mental diseases or impairments. As a result, the Committee intends that this legislation should not apply to medical research or research using biotechnology techniques, but rather should only apply to research relating to new or revised or alternative toxicological test methods.

Subsection (b) provides that Federal agencies will retain final authority for incorporating ICCVAM test recommendations in the manner determined to be appropriate by the Federal agency or regulatory body. Nothing in the bill is intended to prevent a Federal agency from retaining the final authority to adopt an ICCVAM test recommendation in the manner determined to be appropriate by that Federal agency. Furthermore, this legislation only applies to new, revised and alternative test methods; the Committee does not intend for this legislation to address existing test methods.

Subsection (c) provides that nothing in the bill is intended to require a manufacturer to perform toxicological testing that would otherwise not already be required.

Subsection (d) provides that this bill is not intended to prevent an agency from considering, nor prevent a company from submitting directly to an agency, any test method, test, test data or other scientific information for use in a regulatory program. The Committee does not intend for ICCVAM, or the process established for ICCVAM review of new, revised and alternative test methods to preclude, limit, hamper or impede, in any way, the ability of any party to provide any scientific information pertaining to a test, test method, or test data to any Federal agency for use by that Federal agency in a regulatory context or program as determined to be appropriate by such Federal agency.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

This legislation does not amend any existing Federal statute.

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