104TH CONGRESS, 1st Session | HOUSE OF REPRESENTATIVES | REPT. 104–33 Part 1

# JOB CREATION AND WAGE ENHANCEMENT ACT OF 1995

FEBRUARY 15, 1995.—Ordered to be printed

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

## REPORT

together with

ADDITIONAL, MINORITY, AND ADDITIONAL DISSENTING VIEWS

[To accompany H.R. 9]

[Including cost estimate of the Congressional Budget Office]

The Committee on Commerce, to whom was referred title III of the bill (H.R. 9) to create jobs, enhance wages, strengthen property rights, maintain certain economic liberties, decentralize and reduce the power of the Federal Government with respect to the States, localities, and citizens of the United States, and to increase the accountability of Federal officials, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

The amendment is as follows:

Strike title III and insert the following:

## TITLE III—RISK ASSESSMENT AND COST/BENEFIT ANALYSIS FOR NEW REGULATIONS

**SEC. 3001. FINDINGS.**

The Congress finds that:

(1) Environmental, health, and safety regulations have led to dramatic improvements in the environment and have significantly reduced human health

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risk; however, the Federal regulations that have led to these improvements have been more costly and less effective than they could have been; too often, regulatory priorities have not been based upon a realistic consideration of risk, risk reduction opportunities, and costs.

(2) The public and private resources available to address health, safety, and environmental concerns are not unlimited; those resources need to be allocated to address the greatest needs in the most cost-effective manner and so that the incremental costs of regulatory options are reasonably related to the incremental benefits.

(3) To provide more cost-effective and cost-reasonable protection to human health and the environment, regulatory priorities should be based upon realistic consideration of risk; the priority setting process must include scientifically sound, objective, and unbiased risk assessments, comparative risk analysis, and risk management choices that are grounded in cost-benefit principles.

(4) Risk assessment has proven to be a useful decision making tool; however, improvements are needed in both the quality of assessments and the characterization and communication of findings; scientific and other data must be better collected, organized, and evaluated; most importantly, the critical information resulting from a risk assessment must be effectively communicated in an objective and unbiased manner to decision makers, and from decision makers to the public.

(5) The public stake holders must be fully involved in the risk-decision making process. They have the right-to-know about the risks addressed by regulation, the amount of risk to be reduced, the quality of the science used to support decisions, and the cost of implementing and complying with regulations. This knowledge will allow for public scrutiny and promote quality, integrity, and responsiveness of agency decisions.

**SEC. 3002. DEFINITION OF COVERED FEDERAL AGENCY.**

As used in this title, the term "covered Federal agency" means each of the following:

(1) The Environmental Protection Agency.

(2) The Occupational Safety and Health Administration.

(3) The Department of Transportation (including the National Highway Transportation Safety Administration).

(4) The Food and Drug Administration.

(5) The Department of Energy.

(6) The Department of the Interior.

(7) The Department of Agriculture.

(8) The Consumer Product Safety Commission.

(9) The National Oceanic and Atmospheric Administration

(10) The United States Army Corps of Engineers.

(11) The Mine Safety and Health Administration.

**SEC. 3003. COVERAGE OF TITLE.**

This title does not apply to any situation that the head of the covered Federal agency concerned considers to be an emergency.

# Subtitle A—Risk Assessment and Communication

**SEC. 3101. SHORT TITLE.**

This subtitle may be cited as the "Risk Assessment and Communication Act of 1995".

**SEC. 3102. PURPOSES.**

The purposes of this subtitle are—

(1) to present the public and executive branch with the most scientifically objective and unbiased information concerning the nature and magnitude of health, safety, and environmental risks in order to provide for sound regulatory decisions and public education;

(2) to provide for full consideration and discussion of relevant data and potential methodologies;

(3) to require explanation of significant choices in the risk assessment process which will allow for better peer review and public understanding; and

(4) to improve consistency within the executive branch in preparing risk assessments and risk characterizations.

**SEC. 3103. EFFECTIVE DATE; APPLICABILITY; SAVINGS PROVISIONS.**

(a) EFFECTIVE DATE.—Except as otherwise specifically provided in this subtitle, the provisions of this subtitle shall take effect 18 months after the date of enactment of this subtitle.

(b) APPLICABILITY.—

(1) IN GENERAL.—Except as provided in paragraph (3), this subtitle applies to all significant risk assessment documents and significant risk characterization documents prepared by, or on behalf of, any covered Federal agency in connection with Federal regulatory programs designed to protect human health, safety, or the environment.

(2) SIGNIFICANT RISK ASSESSMENT DOCUMENT OR SIGNIFICANT RISK CHARACTERIZATION DOCUMENT.—(A) As used in this subtitle, the terms "significant risk assessment document" and "significant risk characterization document" include, at a minimum, risk assessment documents or risk characterization documents prepared by or on behalf of a covered Federal agency

and included by the agency in, or inserted by the agency in the administrative record for, the following:

(i) Any major rule, as defined in subtitle B, promulgated as part of any Federal regulatory program designed to protect human health, safety, or the environment.

(ii) A proposed or final permit placing restrictions on facility siting or operation, or a proposed or final cleanup plan, or Federal guidelines for the issuance of any such permit or plan, under Federal laws administered by the Environmental Protection Agency or the Department of the Interior.

(iii) Any report to Congress.

(iv) Placement of a substance or health effects value on the Integrated Risk Information System Database maintained by the Environmental Protection Agency.

(v) Any regulatory action to place a substance on any official list of carcinogens or toxic or hazardous substances.

Such term also includes any risk assessment or risk characterization that forms the basis of a final risk assessment or risk characterization guideline or protocol of general application.

(B) Within 15 months after the enactment of this Act, each covered Federal agency administering a regulatory program designed to protect human health, safety, or the environment shall promulgate a rule establishing those additional categories, if any, of risk assessment and risk characterization documents the agency will consider significant risk assessment documents or significant risk characterization documents for purposes of this subtitle. In establishing such categories, the agency head shall consider—

(i) the benefits of consistent compliance by documents in the categories concerned with the principles under section 3104 and 3105,

(ii) the administrative burdens of including documents in various categories,

(iii) the need to make expeditious administrative decisions regarding documents in various categories,

(iv) the possible use of a risk assessment or risk characterization in any compilation of risk hazards or health or environmental effects prepared by an agency and commonly made available to, or used by, any Federal, State, or local government agency, and

(v) such other factors as may be appropriate.

(3) EXCEPTIONS.—This subtitle does not apply to risk assessments or risk characterizations performed with respect to:

(A) A situation that the head of the agency considers to be an emergency.

(B) A screening analysis, where appropriately labeled as such, including a screening analysis for purposes of product regulation, product reregistration, or premanufacturing notices.

No analysis shall be treated as a screening analysis for purposes of this subparagraph if the results of such analyses are used as the basis for imposing restrictions on substances or activities.

(4) LABELS.—This subtitle shall not apply to any individual food, drug, or other product label, or to any risk characterization appearing on any such label, if the individual product label is required by law to be approved by a Federal department or agency prior to use.

(c) SAVINGS PROVISIONS.—The provisions of this subtitle shall be supplemental to any other provisions of law relating to risk assessments and risk characterizations, but nothing in this subtitle shall be construed to modify any statutory standard or statutory requirement designed to protect health, safety, or the environment. Nothing in this subtitle shall be interpreted to preclude the consideration of any data or the calculation of any estimate to more fully describe risk or provide examples of scientific uncertainty or variability. Nothing in this title shall be construed to require the disclosure of any trade secret or other confidential information.

**SEC. 3104. PRINCIPLES FOR RISK ASSESSMENT.**

(a) IN GENERAL.—The head of each covered Federal agency shall apply the principles set forth in subsection (b) when preparing any significant risk assessment document in order to assure that such risk assessment documents and all of their components distinguish scientific findings from other considerations and are, to the maximum extent feasible, scientifically objective, unbiased, and inclusive of all relevant data. Discussions or explanations required under this section need not be repeated in each significant risk assessment document as long as there is a reference to the relevant discussion or explanation in another agency document.

(b) PRINCIPLES.—The principles to be applied when preparing significant risk assessment documents are as follows:

(1) When discussing human health risks, a significant risk assessment document shall contain a discussion, to the extent relevant, of both laboratory and epidemiological data of sufficient quality which finds, or fails to find, a correlation between health risks and a potential toxin or activity. Where conflicts among such data appear to exist, or where animal data is used as a basis to assess human health, the significant risk assessment document shall, where feasible or appropriate, include discussion of reconciliation of conflicting information, and as appropriate, differences in study designs, comparative physiology, routes of expo-

sure, bioavailability, pharmacokinetics, and any other relevant factor.

(2) Where a significant risk assessment document involves selection of any significant assumption, inference, or model, the covered Federal agency preparing the document shall, to the extent feasible—

(A) present a representative list and explanation of plausible and alternative assumptions, inferences, or models;

(B) explain the basis for any choices;

(C) identify any policy or value judgments;

(D) fully describe any model used in the risk assessment and make explicit the assumptions incorporated in the model; and

(E) indicate the extent to which any significant model has been validated by, or conflicts with, empirical data.

(3) No covered Federal agency shall automatically incorporate or adopt any recommendation or classification made by a non-United States-based entity concerning the health effects value of a substance without an opportunity for notice and comment, and any risk assessment document or risk characterization document adopted by a covered Federal agency on the basis of such a recommendation or classification shall comply with the provisions of this subtitle.

**SEC. 3105. PRINCIPLES FOR RISK CHARACTERIZATION AND COMMUNICATION.**

In each significant risk characterization document, each covered Federal agency characterizing the risk shall comply with each of the following:

(1) ESTIMATES OF RISK.—The head of such agency shall describe the populations or natural resources which are the subject of the risk characterization. If a numerical estimate of risk is provided, the agency shall, to the extent feasible and scientifically appropriate, provide—

(A) the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization (based on the information available to the agency); and

(B) a statement of the reasonable range of scientific uncertainties.

In addition to such best estimate or estimates, the covered Federal agency may present plausible upper-bound or conservative estimates in conjunction with plausible lower bounds estimates. Where appropriate, the covered Federal agency may present, in lieu of a single best estimate, multiple estimates based on assumptions, inferences, or models which are equally plausible, given current scientific understanding. To the extent practical and appropriate, the covered Federal agency shall provide descriptions of the distribution and probability of risk estimates to reflect dif-

ferences in exposure variability or sensitivity in populations and uncertainties.

(2) EXPOSURE SCENARIOS.—Where relevant, the covered Federal agency shall explain the exposure scenarios used in any risk assessment, and, to the extent feasible, provide a statement of the size of the corresponding population at risk and the likelihood of such exposure scenarios.

(3) COMPARISONS.—To the extent feasible, the covered Federal agency shall provide a statement that places the nature and magnitude of risks to human health in context. Such statement shall include appropriate comparisons with estimates of risks that are familiar to and routinely encountered by the general public as well as other risks and, where appropriate and meaningful, comparisons of those risks with other similar risks regulated by the Federal agency resulting from comparable activities and exposure pathways. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks and the preventability or non preventability of risks.

(4) SUBSTITUTION RISKS.—Each significant risk assessment or significant risk characterization document referred to in clause (i), (ii), or (iii) of section 3103(2)(A) shall include, to the extent feasible, a statement of any significant and clear substitution risks to human health, where information on such risks has been provided to the agency.

(5) SUMMARIES OF OTHER RISK ESTIMATES.—If—

(A) a covered Federal agency provides a public comment period with respect to a significant risk assessment document or a significant risk characterization document,

(B) a commenter provides the covered Federal agency with a risk assessment document or a risk characterization document, and a summary thereof, and

(C) such risk assessment document or risk characterization document is consistent with the principles and the guidance provided under this subtitle,

the agency shall, to the extent feasible, present such summary in connection with the presentation of the agency's risk assessment document or risk characterization document. Nothing in this paragraph shall be construed to limit the inclusion of any comments or material supplied by any person to the administrative record of any proceeding.

**SEC. 3106. GUIDELINES.**

(a) GUIDELINES.—Within 15 months after the date of enactment of this Act, the President shall issue guidelines for Federal agencies consistent with the risk assessment and characterization principles set forth in sections 3104 and

3105 and shall provide a format for summarizing risk assessment results.

(b) REPORT.—Within 3 years after the enactment of this Act, each covered Federal agency shall provide a report to the Congress evaluating the categories of policy and value judgments identified under subparagraph (C) of section 3104(b)(2).

(c) PUBLIC COMMENT AND CONSULTATION.—The guidelines and report under this section, shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State agencies and local governments, and such other departments and agencies, offices, organizations, or persons as may be advisable.

(d) REVIEW.—The President shall review and, where appropriate, revise the guidelines published under this section at least every 4 years.

**SEC. 3107. JUDICIAL REVIEW OF SECTIONS 3104 AND 3105.**

When a significant risk assessment document or a significant risk characterization document subject to this subtitle is part of the administrative record in a final agency action, in addition to any other matters that the court may consider in deciding whether the agency's action was lawful, the court shall consider the agency action unlawful if such significant risk assessment document or a significant risk characterization document does not comply with the requirements of section 3104 or 3105.

**SEC. 3108. DEFINITIONS.**

For purposes of this subtitle:

(1) RISK ASSESSMENT DOCUMENT.—The term "risk assessment document" means a document containing the explanation of how hazards associated with a substance, activity, or condition have been identified, quantified, and assessed or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources.

(2) RISK CHARACTERIZATION DOCUMENT.—The term "risk characterization document" means a document quantifying or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources, but such term does not include a food, drug or other product label.

(3) BEST ESTIMATE.—The term "best estimate" means an estimate which, to the extent feasible and scientifically appropriate, is based on one of the following:

(A) Central estimates of risk using the most plausible assumptions.

(B) An approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario.

(C) Any other methodology designed to provide the most unbiased representation of the most

plausible level of risk, given the current scientific information available to the Federal agency concerned.

(4) SUBSTITUTION RISK.—The term "substitution risk" means a potential risk to human health, safety, or the environment from a regulatory option designed to decrease other risks.

(5) DOCUMENT.—The term "document" includes material stored in electronic or digital form.

## Subtitle B—Analysis of Risk Reduction Benefits and Costs

### SEC. 3201. ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS.

(a) IN GENERAL.—The President shall require each covered agency to prepare the following for each major rule designed to protect human health, safety, or the environment that is proposed or promulgated by the agency after the date of enactment of this Act:

(1) For each such proposed or promulgated rule, an assessment of incremental costs and incremental risk reduction or other benefits associated with each significant regulatory alternative considered by the agency in connection with the rule or proposed rule. Costs and benefits shall be quantified to the extent feasible and appropriate and may otherwise be qualitatively described.

(2) For each such proposed or promulgated rule, to the extent feasible, a statement that places the nature and magnitude of the risk in context. The statement shall, to the extent feasible, provide a comparison of any human health, safety, or environmental risks addressed by the regulatory alternatives to other risks chosen by the head of the agency, including at least 3 other risks regulated by the agency and to at least 3 other risks with which the public is familiar. The statement shall also identify relevant distinctions among categories of risk and limitations to comparisons.

(3) For each final rule, an assessment of the costs and risk reduction or other benefits associated with implementation of, and compliance with, the rule.

(b) DECISION CRITERIA.—No final rule subject to the provisions of this title shall be promulgated unless the agency certifies that—

(1) The assessment under paragraph (3) of subsection (a) is based on an objective and unbiased scientific and economic evaluation of all significant and relevant information and risk assessments provided to the agency by interested parties relating to the costs, risks, and risk reduction or other benefits addressed by the rule.

(2) The incremental risk reduction or other benefits of any regulatory or nonregulatory option chosen will be likely to justify, and be reasonably related to, the incremental costs incurred by local and State governments, the Federal Government, and other public and private entities.

(3) No regulatory or nonregulatory option considered by the agency or proposed during the comment period would be more likely to achieve a substantially equivalent reduction in risk in a more cost-effective manner or would be more likely to provide flexibility to the regulated entities in achieving the objectives of the regulation, along with a brief explanation of why other regulatory or nonregulatory options that were considered by the head of the agency were found to be less cost-effective or less flexible.

(c) EFFECT OF REQUIREMENTS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the requirements of this section shall supplement and, to the extent there is a conflict, supersede the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated.

(2) PROHIBITION.—Notwithstanding any other provision of Federal law, no major rule shall be promulgated by any Federal agency pertaining to the protection of health, safety, or the environment unless the requirements of section 3201 (a) and (b) are met and the certifications required therein are supported by substantial evidence of the rulemaking record.

(d) PUBLICATION.—For each major rule referred to in subsection (a) the head of each covered Federal agency shall publish in a clear and concise manner in the Federal Register along with the proposed or final regulation, or otherwise make publicly available, the information required to be prepared under subsection (a) and subsection (b) of this section.

(e) DEFINITIONS.—For purposes of this subtitle:

(1) COSTS.—The term "costs" includes the reasonably identifiable and significant direct and indirect costs to the United States Government, to State and local governments, and to the private sector prices to wage earners, consumers, and the economy, of implementing and complying with a regulatory action.

(2) BENEFIT.—The term "benefit" means the reasonably identifiable significant benefits, including social and economic benefits, that are expected to result directly or indirectly from implementation of a rule or an alternative to a rule.

(3) MAJOR RULE.—The term "major rule" means any regulation that is likely to result in an annual increase in costs of $25,000,000 or more. Such term does not include any regulation or other action taken by an

agency to authorize or approve any individual substance or product.

## Subtitle C—Peer Review

**SEC. 3301. PEER REVIEW PROGRAM.**

(a) ESTABLISHMENT.—For regulatory programs addressing human health, safety, or the environment, the head of each covered Federal agency shall develop a systematic program for peer review of significant risk assessment documents and economic assessments used by the agency. Such program shall be applicable across the agency and—

(1) shall provide for the creation of peer review panels consisting of independent and external experts and shall be broadly representative and balanced to the extent feasible;

(2) may provide for differing levels of peer review depending on the significance or the complexity of the problems or the need for expeditiousness;

(3) shall not exclude peer reviewers with substantial and relevant expertise merely because they represent entities that may have a potential interest in the outcome, provided that interest is fully disclosed to the agency and in the case of a regulatory decision affecting a single entity no peer reviewer representing such entity may be included on the panel;

(4) may provide specific and reasonable deadlines for peer review panels to submit reports under subsection (c); and

(5) shall provide adequate protections for confidential business information and trade secrets, including requiring peer reviewers to enter into confidentiality agreements.

(b) REQUIREMENT FOR PEER REVIEW.—Each covered Federal agency shall provide for peer review of any significant risk assessment document or cost assessment prepared in connection with any regulation that is likely to result in an annual increase in costs of $100,000,000 or more (other than any regulation or other action taken by an agency to authorize or approve any individual substance or product. In addition, the Director of the Office of Management and Budget may order that peer review be provided for any major risk assessment or cost assessment that is likely to have a significant impact on public policy decisions.

(c) RESPONSE TO PEER REVIEW.—The head of the covered Federal agency shall provide a written response to all significant peer review comments.

(d) AVAILABILITY TO PUBLIC.—All peer review comments or conclusions and the agency's responses shall be made available to the public and shall be made part of the administrative record for purposes of judicial review of any final agency action.

(e) PREVIOUSLY REVIEWED DATA AND ANALYSIS.—No peer review shall be required under this section for any data or analysis which has been previously subjected to peer review or for any component of any evaluation or assessment previously subjected to peer review.

(f) NATIONAL PANELS.—The President shall appoint National Peer Review Panels to annually review the risk assessment and cost assessment practices of each covered Federal agency for programs designed to protect human health, safety, or the environment. The Panel shall submit a report to the Congress no less frequently than annually containing the results of such review.

## Subtitle D—Agency Priorities

**SEC. 3401. PETITION PROCESS**

(a) IN GENERAL.—(1) Within 1 year after the date of enactment of this Act the head of each covered agency shall establish procedures for accepting and considering petitions for—

(A) reviewing and revising any health or environmental effects value, such as those values in the Integrated Risk Information System (IRIS) database or any other compilation of risk, hazard or health or environmental effects information prepared by the agency that is made commonly available or is used by any Federal department, agency, or instrumentality, the States or local governments as a scientific basis for regulatory action;

(B) reviewing a risk assessment that supports a major rule, as defined in section 3201(e)(3), and revising it to take into consideration new information or methodologies or to comply with the requirements of subtitle A;

(C) requiring that a risk assessment that supports a major rule, as defined in section 3201(e)(3), or other agency scientific or technical document supporting a regulatory action be peer reviewed; or

(D) reviewing any major rule, as defined in section 3201(e)(3), promulgated prior to the effective date of this title and revising it to comply with the requirements of this title.

(2) Such procedures be consistent with each of the following:

(A) Any person may petition.

(B) Such petitions shall include adequate supporting documentation, including, where appropriate, new studies or other relevant information that provide the basis for a proposed revision or modified health effects value and where appropriate a summary characterization of the risk complying with the requirements of section 3105 of this title.

(3) The agency head shall respond to the petition in the Federal Register within 90 days from receipt.

(4) The agency shall accept the petition if the new information or methodologies or the application of the provisions of this title would significantly alter the result of the existing risk assessment, health effects value or regulation. If the agency head rejects the petition, the agency head shall state the reasons for doing so. If the agency head accepts the petition, he shall publish a notice in the Federal Register for comment on the substantive issues raised in the petition. The agency head shall accept and consider any relevant data of sufficient quality submitted in response to the notice.

(b) FINAL AGENCY ACTION.—(1) Within 1 year following the submission of a petition under subsection (a), the agency head shall take final action either—

(A) initiating the action requested in the petition; or

(B) denying the petition by determining that the risk assessment, health effects value or regulation should not be changed, stating in the Federal Register the reasons therefor.

(2) Rejection or denial of a petition by an agency head shall constitute final agency action and be subject to review as provided in section 700 and following of title 5 of the United States Code (the Administrative Procedures Act). Any person whose petition was rejected or denied and who can establish that—

(A) the petition included adequate supporting evidence, and

(B) the agency failed or refused to comply with this section

may bring an action in the appropriate United State district court for judicial review of such rejection or denial.

## Subtitle E—Plan

**SEC. 3501. PLAN FOR ASSESSING NEW INFORMATION.**

(a) PLAN.—Within 18 months after the date of enactment of this subtitle, each covered Federal agency shall publish a plan to review and, where appropriate revise any significant risk assessment document or significant risk characterization document published prior to the expiration of such 18-month period if, based on information available at the time of such review, the agency head determines that the application of the principles set forth in sections 3104 and 3105 would be likely to significantly alter the results of the prior risk assessment or risk characterization. The plan shall provide procedures for receiving and considering new information and risk assessments from the public. The plan may set priorities for review and, where appropriate, revision of risk assessment documents and risk characterization documents based on the potential to more efficiently focus national economic re-

sources within Federal regulatory programs designed to protect human health, safety, or the environment on the most important priorities and on such other factors as such Federal agency considers appropriate.

(b) PUBLIC COMMENT AND CONSULTATION.—The plan under this section, shall be developed after notice and opportunity for public comment, and after consultation with representatives of appropriate State agencies and local governments, and such other departments and agencies, offices, organizations, or persons as may be advisable.

## Subtitle F—Priorities

**SEC. 3601. PRIORITIZATION.**

(a) IDENTIFICATION OF OPPORTUNITIES.—In order to assist in the public policy and regulation of risks to public health, the President shall identify opportunities to reflect priorities within existing Federal regulatory programs designed to protect human health in a cost-effective and cost-reasonable manner. The President shall identify each of the following:

(1) The likelihood and severity of public health risks addressed by current Federal programs.

(2) The number of individuals affected.

(3) The incremental costs and risk reduction benefits associated with regulatory or other strategies.

(4) The cost-effectiveness of regulatory or other strategies to reduce risks to public health.

(5) Intergovernmental relationships among Federal, State, and local governments among programs designed to protect public health.

(6) Statutory, regulatory, or administrative obstacles to allocating national economic resources based on the most cost-effective, cost-reasonable priorities considering Federal, State, and local programs.

(b) ANNUAL REPORT.—The President shall annually issue a report to Congress, after notice and opportunity for public comment, to recommend priorities, modifications, elimination, or strategies among existing Federal regulatory programs designed to protect public health. Within 6 months after the issuance of the report, the President shall notify the Congress in writing of the recommendations which can be implemented without further legislative changes and the agency shall consider the priorities set forth in the report when preparing a strategic plan for any regulatory program.

### PURPOSE AND SUMMARY

Title III of H.R. 9 seeks to improve the Federal risk assessment and regulatory decisions in programs designed to protect human health and the environment. Subtitle A provides for minimum standards of disclosure, objectivity and informativeness for the assessment and presentation of risk information in significant Fed-

eral risk assessment and risk characterization documents. Subtitle B requires analysis and consideration of costs, benefits, and flexibility among regulatory options when promulgating major rules. Subtitle C requires independent peer review of certain major risk or economic assessments. Subtitle D provides criteria to petition Federal agencies to revise risk assessments in light of significant new information and under certain circumstances. Subtitle E requires covered Federal agencies to provide an additional plan outlining any additional processes for receiving new information and setting priorities for revising prior risk assessments. Finally, Subtitle F requires the President to identify and report on priorities among Federal regulatory programs to protect human health, consider a number of criteria to provide for recommendations to Congress, and to incorporate such priorities into strategic planning.

## BACKGROUND AND NEED FOR THE LEGISLATION

### I. PERCEIVED PROBLEMS WITH THE STATUS QUO

#### *A. General concerns over excess regulatory costs and inappropriate priorities*

The general problem as perceived by many in State and local government and in the business community is that Federal regulatory costs are too often out of proportion to the problems that the regulations are designed to address. The concern in the area of health, safety and environmental regulations is that the Federal programs require expenditures of substantial economic resources on reductions in risk which are either too hypothetical, exaggerated or small. The overall perception from many quarters is that a significant portion of Federal health, safety or environmental regulatory costs reflect unwise priorities for national economic resources. While estimates vary, many estimates project annual compliance costs of environmental regulations alone at well above $185 billion by the year 2000. Thus, many argue that, while such an amount may not be too high, $185 billion is too high to spend unwisely.

As part of the general problem, there is particular concern over the Federal practice of risk assessment, characterization and communication.[1] There is also concern that Federal agencies do not consider the incremental costs and benefits or regulatory alternatives that are, in some instances, not even measured and, in other instances, not sufficiently considered. These two concerns formed the basis for substantial controversies during the 103rd Congress and are the central issues addressed in Title III of H.R. 9.

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[1] There are a number of terms and relationships that are useful for understanding the general issues concerning Title III. As related to Title III, risk assessment is a science/policy tool to synthesize available scientific information on risk to human health, safety or natural resources. Risk managers consider information on risks, as well as policy, value, and often political judgments, to design and implement strategies to address those risks. Risk managers hire risk assessors to analyze information and answer questions relevant to the risk managers. Risk characterization is the final step in the risk assessment process and constitutes the summary of the analysis which states the nature and magnitude of the risk. Risk communication is the practice of reporting the risks or otherwise placing risks in context.

*B. Concerns over Federal risk assessment, characterization and communication*

The concern with Federal risk assessment practices is the perception among many that Federal risk assessment, characterization and communication is biased and based on a series of hypothetical assumptions which are designed to overstate the risks. Others argue that Federal risk assessments fail to consider important factors and, thus, understate risks in critical ways. Many on both sides argue that the Federal practice of risk assessment, characterization, and communication is not sufficiently transparent or informative. The concern is greatest in situations where there are the fewest facts. Statistics on automobile accidents, for example, are generally considered to be reliable from year to year and likely to reflect the number of projected automobile accidents the next year. Risks to human health from low levels of chemicals, however, are much more subtle and difficult to measure.

The uncertainties, themselves, are not the fault of risk management or assessment practices—they simply reflect the lack of ability to prove or disprove the many assumptions needed to fill in the facts for a given risk assessment. However, the resulting controversies are difficult to address or manage.

In many contexts, Federal agencies explicitly state that their risk assessment process is designed to produce estimates that "err on the side of safety" because of scientific uncertainties and to ensure that the broadest range of the public is protected, consistent with Federal statutory intent. It is generally believed that these "upper bound estimates" are highly improbable and differ from the most plausible level of risk by many orders of magnitude. Moreover, the practice of only calculating upper bound or worst case estimates of risk is criticized as inappropriately collapsing scientific findings with a preconceived policy judgment or bias. The perceived overstatement of risk is a serious concern among the regulated community. Many argue there should also be "best estimates" or estimates of expected value in addition to upper-bound estimates to provide a more realistic benchmark.

*C. Concerns over the costs and benefits of regulatory programs*

Some Federal provisions require consideration of the costs and benefits of regulatory alternatives, although the specific language authorizing such consideration differs greatly among statutes. The resulting regulatory decisions are judicially reviewable. The general standard of review is for courts to be deferential to Federal agencies concerning the analysis of factual issues, especially where Congress has not specifically stated a course of action. On the other hand, many Federal statutes prohibit or do not explicitly authorize consideration of costs and benefits for determining regulatory requirements.

The Reagan Administration issued Executive Order 12291 in order to encourage agencies to at least try to assess the costs and benefits of regulatory options where statutes did not otherwise compel such an assessment. As an executive order, the assessment was not judicially reviewable. The Clinton Administration has replaced Executive Order 12291 with Executive Order 12866 which, more or less, continues the requirements of 12291.

Following is a chart from the section on Risk Management Budgeting in the Fiscal Year 1992 Budget of the United State Government which is a summary of some of the assessments performed under Executive Order 12291. The chart illustrates the perceived problem. For some regulations, the costs per theoretical life saved are in the thousands of dollars. In other cases, the costs per theoretical life saved or cancer incidence avoided are in the millions or billions. Many of the costs associated with the reduction of perceived risks from chemicals are also upper bound estimates and, thus, the true risk reduction is even less cost-effective—possibly by several orders of magnitude. Accordingly, many advocate giving more prominence to the consideration of the relationship between costs and benefits and setting regulatory priorities to both save money and increase protection by focusing resources on the greatest risk reduction opportunities.

RISKS AND COST-EFFECTIVENESS OF SELECTED REGULATIONS

| Regulation [1] | Year issued | Health or safety? | Agents | Baseline mortality risk per million exposed | Cost per premature death averted ($ millions 1990) |
|---|---|---|---|---|---|
| Unvented Space Heater Ban | 1980 | S | CPSC | 1,890 | 0.1 |
| Aircraft Cabin Fire Protection Standard | 1985 | S | FAA | 5 | 0.1 |
| Auto Passive Restraint/Seat Belt Standards | 1984 | S | NHTSA | 6,370 | 0.1 |
| Steering Column Protection Standard [2] | 1967 | S | NHTSA | 385 | 0.1 |
| Underground Construction Standards [3] | 1989 | S | OSHA–S | 38,700 | 0.1 |
| Trihalomethane Drinking Water Standards | 1979 | H | EPA | 420 | 0.2 |
| Aircraft Seat Cushion Flammability Standard | 1984 | S | FAA | 11 | 0.4 |
| Alcohol and Drug Control Standards [3] | 1985 | H | FRA | 81 | 0.4 |
| Auto Fuel-System Integrity Standard | 1975 | S | NHTSA | 343 | 0.4 |
| Standards for Servicing Auto Wheel Rims [3] | 1984 | S | OSHA–S | 630 | 0.4 |
| Aircraft Floor Emergency Lighting Standard | 1984 | S | FAA | 2 | 0.6 |
| Concrete & Masonry Construction Standards [3] | 1988 | S | OSHA–S | 630 | 0.6 |
| Crane Suspended Personnel Platform Standard [3] | 1988 | S | OSHA–S | 81,000 | 0.7 |
| Passive Restraints for Trucks & Buses (Proposed) | 1989 | S | NHTSA | 6,370 | 0.7 |
| Side-Impact Standards for Autos (Dynamic) | 1990 | S | NHTSA | NA | 0.8 |
| Children's Sleepwear Flammability Ban [4] | 1973 | S | CPSC | 29 | 0.8 |
| Auto Side Door Support Standards | 1970 | S | NHTSA | 2,520 | 0.8 |
| Low-Altitude Windshear Equipment & Training Standards. | 1988 | S | FAA | NA | 1.3 |
| Electrical Equipment Standards (Metal Mines) | 1970 | S | MSHA | NA | 1.4 |
| Trenching and Excavation Standards [3] | 1989 | S | OSHA–S | 14,310 | 1.5 |
| Traffic Alert and Collision Avoidance (TCAS) Systems | 1988 | S | FAA | NA | 1.5 |
| Hazard Communication Standard [4] | 1983 | S | OSHA–S | 1,800 | 1.6 |
| Side-Impact Stds for Trucks, Buses and MPVs (Proposed). | 1989 | S | NHTSA | NA | 2.2 |
| Grain Dust Explosion Prevention Standards [3] | 1987 | S | OSHA–S | 9,450 | 2.8 |
| Rear Lap/Shoulder Belts for Autos | 1989 | S | NHTSA | NA | 3.2 |
| Standards for Radionuclides in Uranium Mines [3] | 1984 | H | EPA | 6,300 | 3.4 |
| Benzene NESHAP (Original: Fugitive Emissions) | 1984 | H | EPA | 1,470 | 3.4 |
| Ethylene Dibromide Drinking Water Standard | 1991 | H | EPA | NA | 5.7 |
| Benzene NESHAP (Revised: Coke By-Products) [3] | 1988 | H | EPA | NA | 6.1 |
| Asbestos Occupational Exposure Limit [3] | 1972 | H | OSHA–H | 3,015 | 8.3 |
| Benzene Occupational Exposure Limit [3] | 1987 | H | OSHA–H | 39,600 | 8.9 |
| Electrical Equipment Standards (Coal Mines) [3] | 1970 | S | MSHA | NA | 9.2 |
| Arsenic Emission Standards for Glass Plants | 1986 | H | EPA | 2,660 | 13.5 |
| Ethylene Oxide Occupational Exposure Limit [3] | 1984 | H | OSHA–H | 1,980 | 20.5 |
| Arsenic/Copper NESHAP | 1986 | H | EPA | 63,000 | 23.0 |
| Haz Waste Listing for Petroleum Refining Sludge | 1990 | H | EPA | 210 | 27.6 |
| Cover/Move Uranium Mill Tailings (Inactive Sites) | 1983 | H | EPA | 30,100 | 31.7 |
| Benzene NESHAP (Revised: Transfer Operations) | 1990 | H | EPA | NA | 32.9 |
| Cover/Move Uranium Mill Tailings (Active Sites) | 1983 | H | EPA | 30,100 | 45.0 |
| Acrylonitrile Occupational Exposure Limit [3] | 1978 | H | OSHA–H | 42,300 | 51.5 |

RISKS AND COST-EFFECTIVENESS OF SELECTED REGULATIONS—Continued

| Regulation [1] | Year issued | Health or safety? | Agents | Baseline mortality risk per million exposed | Cost per premature death averted ($ millions 1990) |
|---|---|---|---|---|---|
| Lockout/Tagout [3] | 1989 | S | OSHA–S | 4 | 70.9 |
| Asbestos Occupational Exposure Limit [3] | 1986 | H | OSHA–H | 3,015 | 74.0 |
| Arsenic Occupational Exposure Limit [3] | 1978 | H | OSHA–H | 14,800 | 106.9 |
| Asbestos Ban | 1989 | H | EPA | NA | 110.7 |
| Diethylstilbestrol (DES) Cattlefeed Ban | 1979 | H | FDA | 22 | 124.8 |
| Benzene NESHAP (Revised: Waste Operations) | 1990 | H | EPA | NA | 168.2 |
| 1,2–Dichloropropane Drinking Water Standard | 1991 | H | EPA | NA | 653.0 |
| Haz Waste Land Disposal Ban (1st 3rd) | 1988 | H | EPA | 2 | 4,190.4 |
| Municipal Solid Waste Landfill Standards (Proposed) | 1988 | H | EPA | <1 | 19,107.0 |
| Formaldehyde Occupational Exposure Limit [3] | 1987 | H | OSHA–H | 31 | 86,201.8 |
| Atrazine/Alachlor Drinking Water Standard | 1991 | H | EPA | NA | 92,069.7 |
| Haz Waste Listing for Wood Preserving Chemicals | 1990 | H | EPA | <1 | 5,700,000.0 |

[1] 70-year lifetime exposure assumed unless otherwise specified.
[2] 50-year lifetime exposure.
[3] 45-year lifetime exposure.
[4] 12-year exposure period.
NA=Not available.

Agency abbreviations.—CPSC: Consumer Product Safety Commission; MSHA: Mine Safety and Health Administration; EPA: Environmental Protection Agency; NHTSA: National Highway Traffic Safety Administration; FAA: Federal Aviation Administration; FRA: Federal Railroad Administration; FDA: Food and Drug Administration; OSHA–H: Occupational Safety and Health Administration, Health Standards; OSHA–S: Occupational Safety and Health Administration, Safety Standards.

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Others fear that poorly written cost-benefit provisions could (1) create computer-like reliance on information that is often highly subjective and difficult to quantify; (2) create administrative burdens that would slow the issuance or enforcement of regulations necessary to the Nation's commitment to protecting health, safety, and the environment; and, (3) fail to reflect a value system where some degree of protection is a right and not a value to be traded away by regulatory decisions.

## II. REPORTED PROBLEMS WITH FEDERAL RISK ASSESSMENT, CHARACTERIZATION, AND COMMUNICATION PRACTICES

In 1983 the National Academy of Sciences made recommendations concerning risk assessments which included the statement that:

> Regulatory agencies should take steps to establish and maintain a clear conceptual distinction between assessments of risks and the consideration of risk management alternatives; that is, scientific findings and policy judgements embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.

Despite these recommendations, the practice across most Federal agencies has often been simply to analyze and communicate a single ''upper-bound,'' conservative, or ''worst case'' estimate of risk. Generally, this practice has evolved where there is limited actual information and the agencies must choose a default assumption to fill the gaps of actual information. In many of these situations, the assumption chosen is not designed to be the assumption which is the most scientifically plausible, given the information available, but rather a ''conservative'' assumption which is more likely to overstate than understate the actual risk. Because risk assess-

ments often involve multiplying the values of assumptions and data together, Federal risk assessors often compound the conservative assumptions yielding numerical estimates that can be improbable and differ by many orders of magnitude from a best estimate of the risk. This practice has recently been described as "plausible conservatism."

Federal agencies, often see this practice of "erring on the side of safety" as consistent with their statutory missions. Under this practice, Federal agencies sometimes ignore relevant data because it may not fit into simple models or would require changes in agency analyses. This can result in understatement or overstatement of risks and also tends to inhibit advancements in scientific analyses. Finally, Federal agencies often fail to explain significant choices among significant scientific models or assumptions. The result of these tendencies is poor information concerning the most likely nature and magnitude of the risk; stagnation in development of more accurate risk assessments; inconsistency between programs; and, ultimately, regulatory policy that fails to address serious risks, while requiring the expenditure of billions of dollars on hypothetical and very low levels of risk.

The practices of only presenting upper-bound estimates and plausible conservatism have been criticized for the past 15 years by the Office of Management and Budget, a number of scientific organizations, and the regulated community. Moreover, risks that regulators set their sites on today are increasingly subtle, difficult to document, and entail greater costs relative to the incremental benefits. This has intensified the concerns over Federal risk assessment, characterization and communication practices over the last five years. The following reports outline a number of the salient criticisms.

The 1983 Regulatory Policy Guidelines from the Presidential Task Force on Regulatory Relief includes the following among its statements of principles:

> Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.

The report included the following discussion about cost-benefit analysis and the need for objective, unbiased risk assessments based on best estimates rather than hypothetical situations:

> All decisions involving risk—public and private—have costs as well as benefits, and excessive costs in any one area can be counterproductive on the whole, reducing resources or incentives for increased health and safety in other areas. * * * To be useful in determining overall benefits and costs, risk assessments must be scientifically objective and include all relevant information. In particular, risk assessments must be unbiased best estimates, not hypothetical "worst cases" or "best cases." Extreme "best" or "worst" safety or health results should be weighted (along with intermediate results) by the probability of their occurrence to estimate the expected result implied by the available evidence. In addition, the distribution of probabilities

> for various possible results should be presented separately, so as to allow for an explicit "margin of safety" in final decisions.

The 1987–88 Regulatory Program of the United States made similar points, decrying the inefficiency of misallocating resources to address hypothetical costs.

> [T]here is a pressing need to improve Federal risk assessment and risk management activities used to assess potential health and safety regulatory actions. Often these risk assessments so overstate risks that the chance that they approximate actual risks is remote. This overstatement—and the uncertainty as to the degree of overstatement—are likely to cause policymakers to overestimate the benefits of regulatory action. As a result, they often select what are, in fact, the wrong targets for reducing risks to society and apply stringent and costly regulatory measures that may actually have little or no risk-reducing benefits, but that may impose significant costs. * * * This nation can ill afford to commit limited resources to the wrong targets. * * * Spending these scarce resources inefficiently will preclude us from pursuing better opportunities to reduce risks and to improve the Nation's standard of living.

The 1990–91 version of this document was even more blunt:

> Unfortunately, risk assessment practices continue to rely on conservative models that effectively intermingle important policy judgements within the scientific assessments of risk. * * * This policy environment makes it difficult to discern serious hazards from trivial ones, and distorts the ordering of the Government's regulatory priorities. In some cases, the distortion of priorities may actually increase health and safety risks.
>
> These "upper-bound" estimates are often useful as a screening device, to exclude from regulatory concern potential hazards that are insignificant even under worst-case conditions. Unfortunately, upper-bound risk estimates are routinely employed for altogether different purposes, such as estimating the likely benefits of regulatory actions.
>
> To the extent that risk assessments differ in the degree to which they adopt conservative assumptions, it is difficult to determine which activities pose the greatest risks and hard to establish reasonable priorities for regulatory action. Because conservatism in risk assessment is especially severe with respect to carcinogens, it is reasonable to expect that other health and safety risks tend to receive relatively less attention and weight. As a result, society may actually incur greater total risk, because of misordered priorities caused by conservative biases in cancer risk assessment.
>
> The public and affected parties also benefit from knowing both the expected risk and the margin of safety rather than being given upper-bound estimates that are probably very different from actual risks * * * providing informa-

> tion in this way should help improve public confidence in quantitative risk assessment as the basis for decisionmaking.

In the case of some agencies, there is evidence that institutional factors may pose a barrier to objective risk presentation and appropriate regard for basing regulatory action on credible science. In a 1992 Report, "Safeguarding the Future: Credible Science, Credible Decisions," an EPA-appointed panel of experts found a "climate and culture" within the EPA that cast serious doubt on the quality of science used by the Agency to justify its programs. Even many agency personnel perceived that EPA science was "adjusted to fit policy." Among the specific findings are:

> EPA's science activities to support regulatory development * * * do not always have adequate, credible quality assurance, quality control, or peer review. EPA has not always ensured that contrasting, reputable scientific views are well explored and well documented from the beginning to the end of the regulatory processes. Instead, studies are frequently carried out without the benefit of peer review or quality assurance. They sometimes escalate into regulatory proposals with no further science input, leaving EPA initiatives on shaky scientific ground.

In 1994, the National Research Council's report on the EPA entitled, Science and Judgment in Risk Assessment, cited the following observations and problems with the failure to communicate relevant information by only reporting upper-bound point estimates:

> EPA does not adequately communicate to its own decision-makers, to Congress, or to the public the variabilities that are and are not accounted for in any risk assessment and the implications for the conservatism and representativeness of the resulting number.
>
> EPA often reports only a single point estimate of risk as a final output. * * * Use of a single point estimate suppresses information about sources of error that result from choices of model, data sets, and techniques for estimating values of parameters from data.
>
> When EPA reports estimates of risks to decisionmakers and the public, it should present not only point estimates of risk, but also the sources and magnitudes of uncertainty associated with those estimates.

The report also cited support for applying uniform risk assessment processes and procedures:

> Without uniform guidelines, there is a danger that the models used in risk assessments will be selected on an ad hoc basis, according to whether regulating a substance is thought to be politically feasible or according to other parochial concerns.
>
> EPA does not always provide a method by which industry, environmental groups, or the general public can raise questions regarding the scientific basis of a decision * * * [and] does not have a procedural mechanism that allows

those outside EPA to petition for departures from default options.

## III. COMMITTEE HEARINGS IN THE 103D CONGRESS

On November 17, 1993, the Subcommittee on Transportation and Hazardous Materials held a hearing on Federal risk assessment practices and review of risk legislation, including H.R. 2910, The Risk Communication Act of 1993. While the scope of Title III of H.R. 9, the Job Creation and Wage Enhancement Act, is broader than in the last Congress, the principles of disclosure providing best estimates and comparisons from H.R. 2910 form the basis for Subtitle A of Title III.

Testimony relevant to Federal risk assessment, characterization, and communication practices and H.R. 2910 is highlighted below:

### *A. Excerpts from the testimony of the Honorable Thomas Grumbly, Assistant Secretary for Environmental Restoration and Waste Management, Department of Energy*

[Y]ou want to be sure that as you are going forward to clean up, to spend large sums of money, that the regulators * * * aren't letting their policy choices about what we think we ought to do * * * influence the actual assessments of risk * * * I think that frankly is something I think our colleagues in all of the regulatory agencies in the land need to keep a little more paramount in their consideration.

EPA contractors come in, turn the crank, use a lot of assumptions that * * * tends to cascade conservative assumption upon conservative assumption, and then hit a particular hazardous waste site with a risk, an estimated risk that simply doesn't bear any relationship to what anybody who is knowledgeable actually thinks is a real risk at the site.

[O]ne of your former colleagues used to say $1 billion here, $1 billion there, pretty soon it is real money. We are going to spend $14 billion next year cleaning up hazardous waste in this country. And I think that often there are large questions in a lot of people's mind whether we are getting the benefits for that. The only way to really assess the benefits better is to make some investments in assessing the risks. * * * I think we really need to grapple with this and make sure they have the resources that are necessary, because the costs to society if not is really tremendous.

### *B. Excerpts from the testimony of Dr. Lynn Goldman, Assistant Administrator for Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency*

I don't think that overall the system is slanted [toward only answering the question of the upper bound risk level as opposed to the most plausible level of risk. I do think that there are differences in the different statutes we use in terms of whether we are instructed to look at upper bounds — or upper bound risk level — as opposed to the

most plausible level of risk] but I don't think that the current practice or policies for doing risk assessment * * * I would not call them slanted.

I do think, though, there is a lot of concern that assumptions may build on each other and that you may end up with impossible assumptions.

*C. Excerpts from the testimony of Dr. Michael Gough, Program Manager, Biology and Behavioral Sciences Program, Office of Technology Assessment*

Better risk communication among researchers, assessors, and managers will inform the rest of government, industry, and citizens about the process, the problems, and the opportunities. It will make little difference if the process works to the satisfaction of experts and the decisionmakers, and leaves the public uneasy and wary.

I think that it is fair [to ask for a best estimate]. I think also it fits in with what the OTA report says that it would be directing people—direct research in those directions.

*D. Excerpts from the testimony of Dr. John Graham, senior scientist, Center for Risk Analysis, Harvard School of Public Health*

We have done at the Harvard Center for Risk Analysis a systematic study of the way EPA does risk assessment. And here is the news: The various EPA program and regional offices do not report risk estimates in a consistent fashion * * * usually only one number is reported. Some of these numbers are worst-case figures. Some are conservative yet plausible numbers. Some are central estimates. And some are simply impossible to interpret how conservative the number is. So as Dr. Goldman told you, risk assessors don't always do worst-case estimates. The problem is we are doing different things in different places. Few programs report the desired lower-bound estimate, central estimate, and upper-bound estimate that would be helpful.

There are many decisionmakers outside of EPA—States and localities, environmental advocacy groups, industry groups and international bodies, that do not appreciate the single risk number that EPA is generally reporting. Yet they use this number oftentimes in making their decisions about risk assessment and risk management.

Practices have emerged in different parts of the agencies and different fiefdoms based upon influences, people, history, and institutional history and the laws per se, while they regulate risk management, do not regulate risk assessment in any particularly strong way.

While EPA is making efforts to correct this problem, I would characterize the progress as slow and there are clear institutional reasons why particular program offices and particular regions won't necessarily benefit from a more consistent way of reporting risks, and they are going to put up institutional barriers to making this process move forward.

H.R. 2910, the Risk Communication Act, is a very unique initiative at fostering more accurate, complete, and consistent reporting of risk estimates.

It is a widely misunderstood point among people who think they are advocating on behalf of public health and the environment that in fact the worst-case estimate of risk will not do the most with our scarce resources for environmental and public health protection.

I am having conversations with EPA scientists and risk managers about the bills that we are talking about today. It is interesting, the kind of reactions you get. On the one hand, you hear the argument that we are already doing all these things, why are you requiring us to do what we are already doing? On the other hand, they will argue to you that these things add enormous layers of extra expensive analytical requirements, they are going to drag out decisions for two or three years.

*E. Excerpts from the testimony of Dr. John Moore, president, Institute for Evaluating Health Risks, former Assistant Administrator, Office of Pesticides and Toxic Substances*

Well, if you make a cascading series of default assumptions in trying to put together a risk assessment, you can end up with an outcome that when you step back and take a hard look at it, it almost doesn't pass the laugh test. I guess what bothers me is that when a risk assessment is brought to a decision-maker that is replete with these cascading assumptions, that the fact that those cascading assumptions have been used is not made apparent to the decision-maker, I think is wrong.

I think H.R. 2910 comes close to achieving the positive results that we all maybe would like to see, without creating undue administrative burdens. I think it remains focused on the main issue which is the systematic development and communication of the scientific basis for identifying and characterizing health risks. I don't think it is proscriptive in detailing how it is to be done.

*F. Excerpts from the testimony of Mr. Ben Maiden, vice president, Battelle Operations [accompanying Greg Lashutka, mayor of Columbus, Ohio]*

I think one of the major policy issues that the committee must look at is the full disclosure provision which is a key element of the Risk Communication Act, as I understand it, and I tend to endorse the testimony of previous individuals, including Dr. Graham, who indicated that not only will the Nation save considerable money and have a better set of results for limited dollar investments, looking at the best-estimate case rather than the worst case. It is a win-win situation all around when it comes to that.

But focusing on the central estimates of risk rather than on the worst case while disclosing the worst case, in my judgment, would substantially reduce the unfunded man-

date problem and improve the performance of the results, the return on our investment.

## IV. REPORTED PROBLEMS WITH FAILURE OF FEDERAL REGULATORY PROGRAMS TO PROVIDE A REASONABLE RELATIONSHIP OF COSTS AND BENEFITS, SUFFICIENT FLEXIBILITY, AND REALISTIC RISK REDUCTION PRIORITIES

### *A. General Problems*

In a 1992 article, the New York Times summed up the prevailing criticism of Congress' and the Environmental Protection Agency's choice of priorities:

> In the last 15 years, environmental policy has too often evolved largely in reaction to popular panics, not in response to sound scientific analysis of which environmental hazards present the greatest risks. As a result * * * billions of dollars are wasted each year in battling problems that are no longer considered especially dangerous, leaving little money for others that cause far more harm.

A 1990 report by EPA's Science Advisory Board, "Reducing Risk: Setting Priorities and Strategies for Environmental Protection," agrees with this general analysis and states: "There are heavy costs involved if society fails to set environmental priorities." The Center for Resource Economics in a report released May 1992 points out that this failure is currently affecting EPA programs and estimates that EPA spends just 20% of its own budget on the most serious risks.

While estimates do vary, many of the estimates place Federal regulatory costs at over $540 billion per year—a figure that will grow through the year 2000 even without any additional legislative mandates. In the area of health, safety, and the environment, regulation is particularly expensive. Federal environmental mandates drained over $115 billion of national economic resources in 1993 alone.

The health and environmental benefits of Federal environmental programs vary dramatically in terms of the cost-effectiveness of reducing health and environmental risks. The previous chart from the FY 1992 Budget document which described the cost efficiency of several recent regulations is indicative of the wide range in cost-effectiveness.

The Committee specifically began to address these concerns in the context of Superfund and Safe Drinking Water Act legislation in the 103rd Congress.

### *B. EPA, States, municipalities, and the General Accounting Office call for more realistic priorities for the expenditure of limited national economic resources for reducing risks to human health, safety, and the environment.*

#### 1. EPA

In 1990, former EPA Administrator Bill Reilly released a statement entitled, "Aiming Before We Shoot: The 'Quiet Revolution' in Environmental Policy." Mr. Reilly stated that "we have to find a better way of setting environmental priorities * * * Risk is a com-

mon metric that lets us distinguish the environmental heart attacks from broken bones or indigestion or bruises." These principles lead to a report from EPA's Science Advisory Board titled "Reducing Risk: Setting Priorities and Strategies for Environmental Protection." The first recommendation in the report is that EPA should target its environmental protection efforts on the basis of opportunities for greatest risk reduction.

2. National Governors Association

In two major policy statements on the cumulative impact of environmental regulations, the National Governors Association noted:

> Under funded and inflexible environmental regulations often exceed the financial and technical capabilities of the governing agencies * * * Resources are finite, but current regulatory practices—which may not include the flexibility to adapt to distinctive, specific characteristics of individual areas—often preclude the intelligent application of resources to problems * * * As recommended by the Science Advisory Board of the Environmental Protection Agency (EPA), EPA should set risk-based priorities for environmental protection. EPA should target its efforts to reducing the most serious remaining risks to the environment and public health. Risk identification and resulting environmental regulation should be the product of scientific study.
>
> National Governor's Association Policy, NR–8 Environmental Priorities and Unfunded Mandates.
>
> 8.2.1 Federal environmental laws and regulations must recognize the need to set priorities and focus on the most important environmental objectives at the national, State, and local levels. In order to promote risk-based priority setting, environmental requirements should be based upon sound science and risk-reduction principles, including the appropriate use of cost-benefit analysis that considers both quantifiable and qualitative measures. Such analyses will ensure that funds expended on environmental protection and conservation address the greatest risks first and provide the greatest possible return on investment.

3. Mayors of cities and municipalities

A bipartisan group of 114 mayors from towns and cities across the United States sent a letter to President Clinton warning of an "impending fiscal crisis" in trying to pay for the costs of unfunded Federal environmental mandates. The letter also urges Congress to assure that environmental protection investments are made where they accomplish the greatest good.

The report accompanying the letter entitled, "Paying for Federal Environmental Mandates: a Looming Crisis for Cities and Counties," found major shortcomings in the way Congress and Federal agencies make decisions on environmental protection. These include:

> Environmental issues are addressed in a vacuum without examining the impacts new mandates have on local

government costs, personal incomes, private property rights, and the economy.

Mandates sometimes are not scientifically justified, and respond to preconceived rather than real risks.

4. National League of Cities

The National League of Cities has adopted a resolution calling on Congress and the Administration to "review, evaluate, and calculate the total burden unfunded mandates place on State and local governments * * * and to authorize and fund significant efforts to assess real and scientifically verifiable risk prior to requiring any action." The League also called on Congress and the Administration to "develop guidelines based on the results of scientifically verifiable risk assessment which would authorize regional authorities, states, and local governments to prioritize the implementation of national environmental mandates based on the actual regional, State and/or local environmental problems."

5. General Accounting Office

In a June 1991 report titled, "Environmental Protection: Meeting Public Expectations with Limited Resources," the General Accounting Office recommended that the Administrator of EPA work with Congress to shift resources from problems of less severe risk to problems whose risks are greater and to educate the public about relative environmental risks. The report further stated that in authorizing and appropriating funds the Congress should take into account EPA's effort to reorder budget priorities so they incorporate the concept of relative risks to human health and the environment, including the costs and feasibility of reducing these risks.

## V. LEGISLATIVE BACKGROUND ON TITLE III OF H.R. 9

### *A. Efforts in the 103rd Congress*

1. Legislation related to subtitles A—risk assessment and communication

Proposals for risk assessment reform and cost-benefit were a dominant part of the legislative agenda of the 103rd Congress. Subtitle A of Title III is largely based on H.R. 2910, the Risk Communication Act of 1993, which was introduced by Representatives Moorhead, Brown, Bliley, Oxley, Hayes, Lloyd, Walker, and Zimmer. The most significant difference between H.R. 2910 and Title III is that H.R. 2910 applies only to the Environmental Protection Agency whereas Title III as reported by the Committee on Commerce applies to a broader list of covered Federal agencies to the extent they have regulatory programs designed to protect human health, safety or the environment. An oversight hearing related to H.R. 2910 was conducted by the Subcommittee on Hazardous Materials and Transportation on November 17, 1993, but there was no subsequent legislative action. Nonetheless, H.R. 2910 attracted a significant amount of support and created political pressure for related legislation and amendments.

The Science Committee held a number of hearings on related issues and reported H.R. 4306, the Risk Assessment Improvement Act. H.R. 4306 also only applied to EPA and contained provisions designed to address the same perceived problems with Federal risk

assessment and characterization practices. H.R. 4306 was not brought up for a vote on the floor. Representative Walker, now Chairman of the Science Committee, did offer a subset of H.R. 4306 as an amendment to H.R. 3870, the Environmental Technologies Act of 1994. The Walker amendment was approved 286 to 139.

During the 103rd Congress, the Energy and Commerce Committee adopted several Republican amendments requiring unbiased presentation of risk information during markups of H.R. 3800, The Superfund Reform Act of 1994; H.R. 3392, the Safe Drinking Water Act Amendments of 1994; H.R. 2448, The Radon Awareness and Disclosure Act, and H.R. 2919, the Indoor Air Act of 1994. The Safe Drinking Water and Radon legislation were both approved on the House floor but did not become law. These provisions reflected requirements for transparency and objectivity similar to those in Subtitle A. H.R. 3800, the Superfund bill, also contained provisions for a National Risk Protocol designed, in part, to address the perceived problems of unrealistic and probably exaggerated risk estimates in the Superfund program.

2. Legislation Related to Subtitle B—Cost-Benefit Analysis

Based on concerns over both risk assessments at EPA and the perceived failure of EPA regulations to reflect costs and benefits, the Senate also approved risk and cost-benefit language in the Johnston amendment by a vote of 95–3 during floor consideration of legislation to elevate EPA to Cabinet status in early 1993. A less demanding version of the Johnston amendment was also attached to legislation reauthorizing the Safe Drinking Water Act in the Senate. The Johnston amendment basically required: (1) cost-benefit analysis for major rules; (2) comparative risk analysis to place the risk reduction into perspective; and (3) certifications that the science used the best reasonably available scientific information and that the benefits of the rule justified the costs.

Subtitle B of Title III is patterned after the Johnston amendment with at least three substantial modifications. First, Subtitle B applies to health, safety or environmental regulations regardless of the Federal agency, whereas the Senate versions of the Johnston amendment applied only to EPA. Second, Subtitle B applies requirements to all rules whose projected annual compliance cost exceeds $25 million dollars, whereas the Johnston amendment defined major rules at $100 million dollars annual compliance cost. Finally, the Johnston amendment contained explicit exclusions from judicial review, whereas Subtitle B does not.

Despite the lopsided votes in the Senate, the amendment sparked controversy—with both the Administration and environmental groups expressing concerns. The then chairmen of four House committees and one Subcommittee, in a letter to President Clinton, stated that the Johnston amendment would overturn "carefully considered judgements which Congress designed to fit the specifics of the problems in question" and complained that the amendment imposed "insidious and burdensome new mandates designed to undermine [EPA's] efforts to protect our nation's health and environment." Environmental groups, in letters to President Clinton dated May 20, 1993, stated that the Johnston amendment:

> * * * intrudes into the carefully crafted analyses already mandated by numerous substantive environmental laws. In doing so it clearly treads upon the expertise and jurisdiction of committees that have, over the past two decades, fine tuned EPA's numerous statutory duties * * *

The environmental groups also stated that the amendment:

> * * * fails to explain whether the life of a person with a low income or an elderly person should be worth less than someone with a high income who is young. It does not resolve whether a risk imposed on someone involuntarily and unnecessarily by a polluter is different from an avoidable risk a person has voluntarily and knowingly accepted. In other words, the Johnston Amendment requires the agency to give detailed answers to essentially unanswerable questions before the agency acts * * *

On the other hand, Dr. John Graham, Director of Harvard's Center for Risk Analysis has said:

> [The Johnston Amendment] is necessary and appropriate because bureaucratic politics does not naturally produce scientific candor about the extent of various risks and the costs of achieving varying amounts of risk reduction. By injecting such information into environmental rulemaking, this bill will raise the level of public debate about the proper course of environmental policy.

Based on this controversy, the Democratic leadership in the House sought to avoid votes on analogues to the Johnston amendment through a combination of germaneness rules and by proposing a restricted rule for consideration on the House floor. The proposed restrictive rule was defeated by a vote of 227 to 191, and the House version of EPA Cabinet legislation, H.R. 3425, was never taken up on the House floor. A less demanding version of the Johnston amendment, however, was adopted as part of H.R. 3171, the Department of Agriculture Reauthorization bill. Mr. Tauzin also introduced H.R. 3395 which was referred to the Committee on Energy and Commerce and essentially matched the Johnston amendment.

In the Committee on Energy and Commerce, the major cost-benefit issues were considered in the context of specific statutes. For example, in reathorization of both H.R. 3800, The Superfund Reform Act, and H.R. 3392, The Safe Drinking Water bill, the Committee modified statutory cleanup and drinking water standards to include consideration of incremental costs and benefits in more situations. When costs and benefits are part of standard setting, there is generally no dollar threshold for applicability, and there is judicial review of the administrative decisions.

### 3. Legislation Related to Subtitle E—Setting Priorities

Mr. Zimmer and Mr. Slattery introduced H.R. 3111, the Risk Reduction Act of 1993. The bill is essentially the analogue to S. 110 introduced by Senator Moynihan. The bill creates three advisory committees: one, to identify and rank the relative environmental risks; the second, to quantify the benefits of reducing risks; and the

third, to develop and implement strategies for communicating risk information to the public. All of these advisory committees would provide reports to Congress by 1995 and every two years thereafter. Section 6 of the bill requires EPA to provide general risk assessment guidelines. Section 7 sets out areas for further research. Section 9 would establish an Interagency Panel on Risk Assessment and Reduction. Finally, section 10 sets out a biennial Report to Congress which sets priorities for health and environmental risks, provides options for addressing these risks and corresponding estimates of costs and benefits. The bill was not marked up, although a version of the bill was adopted as part of Safe Drinking Water legislation on the Senate Floor.

*B. History of Title III of the Job Creation and Wage Enhancement Act and "Contract With America"*

The Job Creation and Wage Enhancement Act generally embodies the principles addressed in "Contract with America." The Contract is a political and policy document, intended to serve as a blueprint for legislative action in the House of Representatives during the first 100 days of the first session. The political commitment of the Contract with respect to Title III is to bring risk assessment reform and cost-benefit legislation for a vote on the House floor in the first 100 days. This commitment does not freeze legislative language in place and fully encompasses the need to modify and improve the policy positions and workability in the Title and to gain greater political consensus where possible.

As discussed previously, Subtitle A of Title III, as introduced, is patterned after H.R. 2910, the Risk Communication Act of 1993. The major difference is an expansion of the applicability of Title III to more Federal agencies than the Environmental Protection Agency.

As discussed above Subtitle B, as introduced, is patterned after the Johnston amendment with at least three substantial modifications. First, Subtitle B applies to health, safety or environmental regulations across a number of agencies, not just the EPA. Second, Subtitle B applies requirements to all rules whose projected annual compliance cost exceeds $25 million dollars, whereas the Johnston amendment defined major rules at $100 million annual compliance cost. Finally, Subtitle B does not contain explicit exclusions from judicial review as did the Johnston amendment.

Draft copies of the Job Creation and Wage Enhancement Act were publicly available in September and October of 1994. After the November 1994 election, the draft became subject to public scrutiny and discourse. On this basis a number of changes were made between the September 1994 draft of Title III and the bill as introduced on January 4, 1995, to improve the workability of the Title and, in part, to address a number of concerns from the Administration. These included (1) reducing the scope of the bill from all Federal agencies to regulatory programs addressing health, safety and the environment; (2) changing the numerical threshold for applicability of Subtitle B from rules imposing $1 million in annual compliance cost to $25 million; (3) reducing the prescriptiveness of Subtitle C generally; (4) changing the numerical threshold peer review requirements to rules imposing annual com-

pliance costs of $100 million; (5) eliminating the provision affording peer review panels an effective veto in the rulemaking process and (6) eliminating a citizen suit provision which would have added a number of new causes of action.

## VI. COMMITTEE HEARINGS ON TITLE III OF H.R. 9

On February 1 and 2, 1995, the Subcommittee on Commerce, Trade and Hazardous Materials and the Subcommittee on Health and Environment held joint hearings on Title III of H.R. 9.

As a general matter, many groups representing State and local governments and a wide range of businesses appear to support statutory risk assessment reform and provisions for elevating the status and consideration of costs and benefits in Federal regulatory programs. The Administration stated a willingness to work on such legislation, but has a number of concerns with Title III specifically and H.R. 9 generally. A number of environmental or public interest groups have also taken issue with H.R. 9 generally. A cross-section of these parties was represented at the hearing along with a number of scientists and professional organizations with expertise on risk assessment.

The regulated community generally considers Title III, as drafted, to be a modest "down payment" on regulatory reform. While these groups appear willing to support modifications to improve the workability of Title III, many have expressed concerns that the title contains too many loopholes. Several in the business community also discussed more far reaching amendments. There was strong support among the regulated community for maintaining requirements which are enforceable against the Federal agencies in court.

The Administration has expressed a desire to craft appropriate risk legislation which is "fair, effective, and affordable" but believes Title III as drafted does not meet these tests. Moreover, the Administration notes that Title III is interrelated to other provisions in H.R. 9, such as Title V's paper work reduction requirements and Title VI and VII's requirements for regulatory impact analyses. Thus, the Administration argues that the cumulative impact on Federal agencies is too broad, too prescriptive, too costly, and creates too many avenues for excessive review and opportunities for legal challenge.

The issue of scope is of great concern and was one of the important topics during the hearing. By expanding the applicability of these provisions beyond EPA, the Administration argued that there are a potentially greater number of unintended consequences and areas which, one could argue, are not part of the political or policy problems. The hearing also highlighted the need to redefine terms in Subtitle A to avoid application of new requirements for risk characterization to reports or documents stemming from minor inspection activities such as food inspections or other actions which (1) are unlikely to affect actions to impose further regulatory costs and (2) unlikely to affect public understanding or discourse on risk issues the way major Federal reports might.

Many of the witnesses stated that the general provisions of Title III would provide substantial benefits in terms of greater public confidence in the Federal risk information system; consistency; con-

sideration of costs and benefits; and more informed decisionmaking. Administration witnesses, the Environmental Defense Fund, OMB Watch, and a representative from the United Auto Workers generally expressed concerns over greater administrative burdens on Federal agencies, potential delays in rulemakings, and the negative consequences of adding new areas of law for parties challenging administrative actions to litigate.

All of the testimony from the hearing helped shape the legislation reported out of Committee. The following excerpts highlight a number of significant points of witnesses that encouraged the Committee to report comprehensive risk assessment and cost-benefit legislation.

## STATE AND LOCAL GOVERNMENTS

*A. Excerpts from the testimony of Governor Benjamin Nelson, State of Nebraska*

> The science of risk assessment may never be perfect, but the time has come to fully incorporate consideration of risks, priorities, public health benefits, and cost-effectiveness into Federal decisionmaking.
>
> Governors strongly support risk reduction principles in the development of environmental regulations and commend your pursuit of this legislation. However, we believe it is essential that such analyses focus on cost effectiveness by requiring agencies to identify the least costly regulatory alternatives that achieve risk reductions.
>
> Requirements established under existing laws and regulations are increasingly burdensome, less that cost-effective, and imbalanced in terms of addressing priority problems first. The governors believe that the days when we could afford to ″do it all″ have long gone, if they ever existed. Today we have to set priorities, choose among many competing demands for our resources, and spend the public's money—or use regulations to make the public spend its own money—more carefully.
>
> Investments on priority needs will optimize the amount of environmental protection ″bought″ with the finite resources available by promoting adoption of regulatory alternatives that effectively reduce risks at the least cost. A comprehensive perspective based upon the best obtainable scientific, technical, economic, and other information will better enable Federal and State policymakers to determine how much, if any, new regulation is appropriate for environmental programs.

*B. Excerpts from the testimony of Randy Johnson, county commissioner, Hennepin County, Minnesota*

> We spend a great deal of our taxpayers money solving problems that, if left to our own decisions, would be placed much lower on the priority list. We divert resources and attention from serious local health threats to comply with Federal laws and regulations that are stapled together and called national environmental policies.

The National Association of Counties believes that Congress should adopt legislation which requires Federal agencies to provide fair, scientifically sound, and consistent assessments of purported health, safety, or environmental risks prior to the imposition of new regulations. It is just plain wrong to regulate without at least an attempt to make a scientifically-based assessment of the risk that is sought to be abated, its relationship to other risks, and the costs involved.

At a minimum, all regulations imposing costs on local governments should be peer-reviewed. Risk assessments should be scientifically objective and should include data that argues against the need to regulate as well as for it.

Risks should also be compared with those that people understand and to which they can readily relate. It is also important to give us the tools to explain to our citizens why some of these regulations are necessary.

*C. Excerpts from the testimony of Barbara Wheeler, the National School Boards Association*

The formulation of public policy on the asbestos issue was ahead of the scientific evidence to establish an accurate risk assessment; the result was that millions of scarce educational dollars were wasted. Schools cannot afford to abate questionable environmental hazards, abate them in an unnecessary way, or abate them down to a level that is beyond a meaningful risk.

Inaccurate risk assessment on asbestos has diverted billions of dollars from schools.

Developing a firm scientific basis for knowing that we have an environmental hazard and the degree to which it should be abated are critical to ensuring that educational dollars are spent wisely—either to protect the health of children or to educate them.

On asbestos, the public policy was made ahead of the scientific evidence. The result was that billions of scarce educational dollars were wasted.

*D. Excerpts from the testimony of Donald Schregardus, Director, Ohio Environmental Protection Agency, Columbus, Ohio*

As the larger sources of pollution have been controlled, environmental laws have shifted to focus on smaller and more numerous pollution sources and minute quantities of natural and man-made chemicals in the environment. As this occurs, the cost of meeting and administering environmental laws has skyrocketed * * * compliance costs are growing exponentially as the law of diminishing returns takes over.

In Ohio, for example, Ohio EPA found that of the 52 synthetic organic chemical pesticides that US EPA requires water systems to test for, only 9 were used in the State in quantities that might be detected. The State and communities were forced to spend thousands of dollars and significant time providing to US EPA that those pesticides

were not a problem instead of using resources to solve real drinking water concerns.

The provisions in HR 9 will help to ensure that the Federal Superfund program sets priorities according to the risks posed by individual sites and the cost effectiveness of the solutions.

Federal law must include the flexibility to recognize State and local risk-based priorities because the critical environmental problems in one area may be of little risk in another area.

## EXPERTS IN RISK ASSESSMENT AND MANAGEMENT POLICY

*A. Excerpts from the testimony of Lester B. Lave, university professor, Carnegie Mellon University*

Congress should instruct regulatory agencies to use the best scientific knowledge, not "conservative" decision rules. Agencies should explore all plausible alternative scientific theories and explain why they chose a particular theory and data set as the basis of the risk estimates it is relying on. They should take care to spell out the uncertainties in the analysis.

There have been far too many instances in which a plausible sounding regulation was adopted and later discovered to have excess costs, give little or no reduction in risks, or to be ineffective. Far too often the attention of regulators and Congress is focused on what turn out to be minor issues, diverting attention from major problems.

Title III is good in pressing regulators to use the best scientific understanding and to estimate risks based on this understanding. A major contribution to risk analysis policy and providing decision-makers and the public with information is this insistence on using best scientific understanding and not simply calculating conservative estimates.

Title III mandates benefit-cost analysis as well as risk analysis. I support this requirement based on the same reason: good decisions require good information.

I stress again that these [benefit-cost] value judgements should not be made by bureaucrats and hidden in the analysis; the analyses ought to be open and permit others to supply the value judgments that they deem appropriate.

*B. Excerpts from the testimony of Dr. Gilbert S. Ommen, Chair, Commission on Risk Assessment and Risk Management*

The Commission supports the flexibility that Section 3105, Principles for Risk Characterization and Communication, provides * * * Section 3105(1) provides enough flexibility to avoid being prescriptive and enough guidance to be useful in the treatment of numerical estimates; however, this section misses a critical element of risk characterization, namely a qualitative assessment of the nature of the adverse effects and the strength of the evidence. * * *

The Commission supports the provision of Section 3104, Principles for Risk Assessment, that would distinguish scientific findings from other considerations. This provision would make risk assessments clearer and more relevant both to risk managers and to stakeholders.

Using of risk comparisons in partnership with the public and all levels of government is consistent with the current legislative goal of achieving the maximal reduction of overall health and environmental risks with whatever expenditures are made. * * * we invoke the Committee to consider encouraging more widespread priority setting exercises and implementation of the results of those exercises to improve environmental health in this era of decreasing public funds.

*C. Excerpts from the testimony of John A. Moore, president, Institute for Evaluating Health Risks, Washington, D.C.*

The preoccupation with theoretical cancer risk that has dominated regulatory activity, diverted attention from other adverse effects that may be of equal or greater public health importance.

The greatest impediment to the development of a strong base of support for risk assessment within the scientific community has been the procedures many Federal agencies use to derive quantitative estimates of cancer risk. The risk characterization language in HR 9, including estimates of risk and the requirement to discuss other plausible alternate assumptions, will result in a more balanced presentation of information and foster reconciliation of current differences.

Throughout my career peer review, when properly used, has consistently demonstrated its value. Peer review can provide a dispassionate analysis as to the quality and balance of the risk assessment and economic assessment that are key components of risk management decisions.

*D. Excerpts from the testimony of Dr. John D. Graham, Harvard Center for Risk Analysis*

New legislation can help in numerous ways but the two most urgent needs are (1) a statutory requirement that Federal agencies report realistic estimates of risk based on the best available science, and (2) a statutory requirement that regulators explain how their decisions reflect a reasonable balance between the benefits of reducing risk and the costs ( and unintended risks) of regulation.

In fact, the choice of regulatory priorities is rarely informed by formal analysis. EPA, for example, now openly acknowledges that its budgetary priorities are not in synch with the seriousness of risks and only modest reallocations from overblown (e.g., pesticides residues) to neglected (e.g., indoor air pollution) dangers have occurred since EPA acknowledged this perversity in 1987. Former EPA Administrator William Reilly commented in a recent speech at Harvard that the fraction of EPA's budget devoted to

"high-risk" threats increased from 15% to 30% during his four-year tenure at EPA.

When scientific information about risk is uncertain, some agencies are inclined to publish "worst-case" estimates of risk without providing any realistic indication of what the actual risk is likely to be.

The important practice of subjecting agency analyses to independent peer review by qualified experts is sporadic in some agencies and absent entirely in other agencies.

*E. Excerpts from the testimony of Dr. Roger O McClellan, president, Chemical Industry Institute of Toxicology, Research Triangle Park, N.C.*

Risk assessments must make maximum use of available scientific data, with default options utilized only in the absence of specific scientific information. The use of default options in the risk assessment process should be clearly documented and the scientific rationale provided for their use.

Scientifically sound risk characterizations should be used to compare and prioritize risks for subsequent action and to assure consistency across legislative and agency boundaries.

Provision must be make for public comment and external peer review of risk assessments. The principal criteria for selection of peer reviewers must be their scientific competence and knowledge of the risk assessment process. All peer review comments, including minority views, should be documented and forwarded to the risk manager.

*F. Excerpts from the testimony of Jeremiah Lynch, president, American Industrial Hygiene Association*

To the extent practical and appropriate, agencies should provide descriptions of the distribution and probability of risk estimates to reflect differences in exposure variability in populations and uncertainties. The priority setting process must include scientifically sound, objective, and unbiased risk assessments.

AIHA has reviewed the proposed requirements for risk assessment found in HR 9. AIHA supports the use of human health risk assessment techniques in regulatory decision making, in the making of public health policy, and in the allocation of government resources to environmental issues. AIHA believes risk assessment should be conducted with the best available scientific data. In the absence of scientific data, AIHA supports the use of health protective but reasonable default values which are selected using well-defined principles.

*G. Excerpts from the testimony of Don Ritter, chairman, National Environmental Policy Institute*

We have also wasted vast media-sensitive resources chasing down infinitesimally small amounts of high profile substances; resources that might have been used more ef-

fectively or used to boost jobs and American competitiveness here and abroad, when applied to other environmental problems and opportunities.

Risk assessment that is open, transparent, rigorously peer reviewed, democratized and demystified can go a long way to changing a broken system.

One of the main policy conclusions of our work is that the risk assessment process should be transparent and peer-reviewed so that Congress, policy makers in agencies, and the public can easily understand the risks we are protecting against.

## THE REGULATED COMMUNITY

### *A. Excerpts from the testimony of Kenneth W. Farber, Food Industry Environmental Council*

Federal agencies should be required to use sound risk assessment methodologies, including appropriate best estimate analyses, when conducting and reviewing risk assessments. Whenever possible, policy and value considerations should be separated from scientific analyses and should be articulated clearly. Subtitle A of Title III of H.R. 9 accomplishes these objectives.

The Federal Government treats risk inconsistently within and across agencies. Agencies do not always base policy decisions on sound science, and in some instances, they blur the underlying science with other policy and value considerations in making regulatory decisions.

In many government decisions, policy and value considerations are left vague or are mixed inappropriately with the scientific rationale of a decision. This bill will help to ensure the scientific basis for risk-based decisions is founded on current and reliable scientific principles and assumptions, and that policy and value considerations are articulated clearly.

EPA's means of addressing risk should be consistent with that of FDA and the U.S. Department of Agriculture. This is not necessarily the case today. Specifically, the way EPA may make a "weight of the evidence" determination is not consistent in many cases with FDA's approach.

### *B. Excerpts from the testimony of Jerry J. Jasinowski, Alliance for Reasonable Regulation*

Risk assessments, when they are conducted at all, tend to be unrealistic, overly conservative, and reflective of unstated policy choices or default assumptions which, if they must be included in the risk assessment at all, should be explicitly acknowledged and fully explained.

In most cases, health and environmental risks are inadequately characterized and communicated to decisionmakers and interested members of the public.

In most cases, the scientific and technical assessments on which regulations are based are not subjected to independent external peer review. As a result, the scientific

and technical underpinnings of agency actions that may have enormous consequences often are not adequately tested.

Environmental regulations sometimes are set at a level of stringency that imposes exceedingly large costs but achieves little, if any, incremental environmental or public health benefit.

The economic and other adverse impacts of agency rules (including the creation of what H.R. 9 refers to as "substitution risks") frequently are not evaluated adequately or are not factored into the ultimate regulatory decision.

Agency rules tend to be relatively inflexible, reflecting a penchant for command-and-control specification, rather than a performance-based orientation. This results in regulations that are far less cost-effective than they could be, and it frequently precludes the adoption of environmental management practices that would actually be more protective and less costly than the actions required under the rule.

Alternatives to proposed regulatory actions (whether they be non-regulatory, voluntary, market-based, or regulatory in nature) frequently do not receive the attention they deserve.

In order to ensure that risk-based decisions have a sound scientific and technical underpinning, any risk assessment that may potentially serve as the basis for a major rule should be subjected to independent, external peer review.

## COMMITTEE CONSIDERATION

On February 8, 1995, the Committee on Commerce met in open session and ordered reported the bill H.R. 9 with an amendment by a recorded vote of 27 to 16, a quorum being present.

## ROLL CALL VOTES

Pursuant to clause 2(l)(2)(B) of rule XI of the Rules of the House of Representatives, following are listed the recorded votes on the motion to report H.R. 9 and on amendments offered to the measure, including the names of those Members voting for and against.

### ROLL CALL VOTE #3

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Markey re: level of protection.

Disposition: Not agreed to, by a roll call vote of 16 ayes to 30 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | ..... | X | ..... | Mr. Dingell | X | ..... | |
| Mr. Moorhead | ..... | X | ..... | Mr. Waxman | X | ..... | |
| Mr. Fields | ..... | X | ..... | Mr. Markey | X | ..... | |
| Mr. Oxley | ..... | X | ..... | Mr. Tauzin | ..... | X | |

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bilirakis | ..... | X | ..... | Mr. Wyden | X | ..... | |
| Mr. Schaefer | ..... | X | ..... | Mr. Hall | ..... | X | |
| Mr. Barton | ..... | X | ..... | Mr. Bryant | X | ..... | |
| Mr. Hastert | ..... | X | ..... | Mr. Boucher | X | ..... | |
| Mr. Upton | ..... | X | ..... | Mr. Manton | X | ..... | |
| Mr. Stearns | ..... | X | ..... | Mr. Towns | X | ..... | |
| Mr. Paxon | ..... | X | ..... | Mr. Studds | X | ..... | |
| Mr. Gillmor | ..... | X | ..... | Mr. Pallone | X | ..... | |
| Mr. Klug | ..... | X | ..... | Mr. Brown | X | ..... | |
| Mr. Franks | ..... | X | ..... | Mrs. Lincoln | ..... | X | |
| Mr. Greenwood | ..... | X | ..... | Mr. Gordon | ..... | X | |
| Mr. Crapo | ..... | X | ..... | Ms. Furse | X | ..... | |
| Mr. Cox | ..... | X | ..... | Mr. Deutsch | ..... | X | |
| Mr. Burr | ..... | X | ..... | Mr. Rush | X | ..... | |
| Mr. Bilbray | ..... | X | ..... | Ms. Eshoo | X | ..... | |
| Mr. Whitfield | ..... | X | ..... | Mr. Klink | X | ..... | |
| Mr. Ganske | ..... | X | ..... | Mr. Stupak | X | ..... | |
| Mr. Frisa | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. Norwood | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. White | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. Coburn | ..... | X | ..... | ..... | ..... | ..... | |

ROLL CALL VOTE #4

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Motion: Motion by Mr. Stearns to move the previous question on the Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Brown re: exceptions for "imminent endangerment."

Disposition: Agreed to, by a roll call vote of 24 ayes to 21 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | X | ..... | ..... | Mr. Dingell | ..... | X | |
| Mr. Moorhead | X | ..... | ..... | Mr. Waxman | ..... | X | |
| Mr. Fields | X | ..... | ..... | Mr. Markey | ..... | X | |
| Mr. Oxley | X | ..... | ..... | Mr. Tauzin | ..... | X | |
| Mr. Bilirakis | X | ..... | ..... | Mr. Wyden | ..... | X | |
| Mr. Schaefer | X | ..... | ..... | Mr. Hall | ..... | X | |
| Mr. Barton | X | ..... | ..... | Mr. Bryant | ..... | X | |
| Mr. Hastert | X | ..... | ..... | Mr. Boucher | ..... | X | |
| Mr. Upton | X | ..... | ..... | Mr. Manton | ..... | X | |
| Mr. Stearns | X | ..... | ..... | Mr. Towns | ..... | X | |
| Mr. Paxon | X | ..... | ..... | Mr. Studds | ..... | X | |
| Mr. Gillmor | X | ..... | ..... | Mr. Pallone | ..... | X | |
| Mr. Klug | X | ..... | ..... | Mr. Brown | ..... | X | |
| Mr. Franks | X | ..... | ..... | Mrs. Lincoln | ..... | X | |
| Mr. Greenwood | X | ..... | ..... | Mr. Gordon | ..... | X | |
| Mr. Crapo | X | ..... | ..... | Ms. Furse | ..... | X | |
| Mr. Cox | X | ..... | ..... | Mr. Deutsch | ..... | X | |
| Mr. Burr | X | ..... | ..... | Mr. Rush | ..... | X | |
| Mr. Bilbray | X | ..... | ..... | Ms. Eshoo | ..... | X | |
| Mr. Whitfield | X | ..... | ..... | Mr. Klink | ..... | X | |
| Mr. Ganske | X | ..... | ..... | Mr. Stupak | ..... | X | |
| Mr. Frisa | X | | | | | | |
| Mr. Norwood | X | | | | | | |
| Mr. White. | | | | | | | |
| Mr. Coburn | X | | | | | | |

ROLL CALL VOTE #5

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Brown re: exceptions for "imminent endangerment".

Disposition: Not agreed to, by a roll call vote of 20 ayes to 25 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | | X | | Mr. Dingell | X | | |
| Mr. Moorhead | | X | | Mr. Waxman | X | | |
| Mr. Fields | | X | | Mr. Markey | X | | |
| Mr. Oxley | | X | | Mr. Tauzin | | X | |
| Mr. Bilirakis | | X | | Mr. Wyden | X | | |
| Mr. Schaefer | | X | | Mr. Hall | X | | |
| Mr. Barton | | X | | Mr. Bryant | X | | |
| Mr. Hastert | | X | | Mr. Boucher | X | | |
| Mr. Upton | | X | | Mr. Manton | X | | |
| Mr. Stearns | | X | | Mr. Towns | X | | |
| Mr. Paxon | | X | | Mr. Studds | X | | |
| Mr. Gillmor | | X | | Mr. Pallone | X | | |
| Mr. Klug | | X | | Mr. Brown | X | | |
| Mr. Franks | | X | | Mr. Lincoln | X | | |
| Mr. Greenwood | | X | | Mr. Gordon | X | | |
| Mr. Crapo | | X | | Ms. Furse | X | | |
| Mr. Cox | | X | | Mr. Deutsch | X | | |
| Mr. Burr | | X | | Mr. Rush | X | | |
| Mr. Bilbray | | X | | Ms. Eshoo | X | | |
| Mr. Whitfield | | X | | Mr. Klink | X | | |
| Mr. Ganske | | X | | Mr. Stupak | X | | |
| Mr. Frisa | | X | | | | | |
| Mr. Norwood | | X | | | | | |
| Mr. White | | | | | | | |
| Mr. Coburn | | X | | | | | |

ROLL CALL VOTE #6

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Bryant re: exceptions for product/substance approvals, certifications, and for enforcement

Disposition: Not agreed to, by a roll call vote of 19 ayes to 27 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | | X | | Mr. Dingell | X | | |
| Mr. Moorhead | | X | | Mr. Waxman | X | | |
| Mr. Fields | | X | | Mr. Markey | X | | |
| Mr. Oxley | | X | | Mr. Tauzin | | X | |
| Mr. Bilirakis | | X | | Mr. Wyden | X | | |
| Mr. Schaefer | | X | | Mr. Hall | | X | |
| Mr. Barton | | X | | Mr. Bryant | X | | |
| Mr. Hastert | | X | | Mr. Boucher | X | | |
| Mr. Upton | | X | | Mr. Manton | X | | |
| Mr. Stearns | | X | | Mr. Towns | X | | |
| Mr. Paxon | | X | | Mr. Studds | X | | |
| Mr. Gillmor | | X | | Mr. Pallone | X | | |

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Klung | | X | | Mr. Brown | X | | |
| Mr. Franks | | X | | Mrs. Lincoln | X | | |
| Mr. Greenwood | | X | | Mr. Gordon | X | | |
| Mr. Crapo | | X | | Ms. Furse | X | | |
| Mr. Cox | | X | | Mr. Deutsch | X | | |
| Mr. Burr | | X | | Mr. Rush | X | | |
| Mr. Bilbray | | X | | Ms. Eshoo | X | | |
| Mr. Whitfield | | X | | Mr. Klink | X | | |
| Mr. Ganske | | X | | Mr. Stupak | X | | |
| Mr. Frisa | | X | | | | | |
| Mr. Norwood | | X | | | | | |
| Mr. White | | X | | | | | |
| Mr. Coburn | | X | | | | | |

ROLL CALL VOTE #7

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Ms. Eshoo re: level of protection relative to women's health issues.

Disposition: Not agreed to, by a roll call vote of 14 ayes to 24 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | | X | | Mr. Dingell | X | | |
| Mr. Moorhead | | X | | Mr. Waxman | X | | |
| Mr. Fields | | X | | Mr. Markey | X | | |
| Mr. Oxley | | X | | Mr. Tauzin | | | |
| Mr. Bilirakis | | X | | Mr. Wyden | X | | |
| Mr. Schaefer | | X | | Mr. Hall | | | |
| Mr. Barton | | X | | Mr. Bryant | | | |
| Mr. Hastert | | X | | Mr. Boucher | | | |
| Mr. Upton | | X | | Mr. Manton | X | | |
| Mr. Stearns | | X | | Mr. Towns | X | | |
| Mr. Paxon | | X | | Mr. Studds | | | |
| Mr. Gillmor | | X | | Mr. Pallone | X | | |
| Mr. Klug | | X | | Mr. Brown | X | | |
| Mr. Franks | | X | | Mrs. Lincoln | | | |
| Mr. Greenwood | | X | | Mr. Gordon | X | | |
| Mr. Crapo | | X | | Ms. Furse | | | |
| Mr. Cox | | | | Mr. Deutsch | X | | |
| Mr. Burr | | X | | Mr. Rush | X | | |
| Mr. Bilbray | | X | | Ms. Eshoo | X | | |
| Mr. Whitfield | | X | | Mr. Klink | X | | |
| Mr. Ganske | | X | | Mr. Stupak | X | | |
| Mr. Frisa | | X | . | | | | |
| Mr. Norwood | | X | . | | | | |
| Mr. White | | X | . | | | | |
| Mr. Coburn | | X | . | | | | |

ROLL CALL VOTE #8

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Markey re: peer review.

Disposition: Not agreed to, by a roll call vote of 17 ayes to 25 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | ..... | X | ..... | Mr. Dingell | X | | |
| Mr. Moorhead | ..... | X | ..... | Mr. Waxman. | | | |
| Mr. Fields | ..... | X | ..... | Mr. Markey | X | | |
| Mr. Oxley | ..... | X | ..... | Mr. Tauzin | ..... | X | |
| Mr. Bilirakis | ..... | X | ..... | Mr. Wyden | X | | |
| Mr. Schaefer | ..... | X | ..... | Mr. Hall. | | | |
| Mr. Barton | ..... | X | ..... | Mr. Bryant | X | | |
| Mr. Hastert | ..... | X | ..... | Mr. Boucher | X | | |
| Mr. Upton | ..... | X | ..... | Mr. Manton | X | | |
| Mr. Stearns | ..... | X | ..... | Mr. Towns | X | | |
| Mr. Paxon | ..... | ..... | ..... | Mr. Studds. | | | |
| Mr. Gillmor | ..... | X | ..... | Mr. Pallone | X | | |
| Mr. Klug | ..... | X | ..... | Mr. Brown | X | | |
| Mr. Franks | ..... | X | ..... | Mrs. Lincoln | X | | |
| Mr. Greenwood | ..... | X | ..... | Mr. Gordon | X | | |
| Mr. Crapo | ..... | X | ..... | Ms. Furse | X | | |
| Mr. Cox | ..... | X | ..... | Mr. Deutsch | X | | |
| Mr. Burr | ..... | X | ..... | Mr. Rush | X | | |
| Mr. Bilbray | ..... | X | ..... | Ms. Eshoo | X | | |
| Mr. Whitfield | ..... | X | ..... | Mr. Klink | X | | |
| Mr. Ganske | ..... | X | ..... | Mr. Stupak | X | | |
| Mr. Frisa | ..... | X | | | | | |
| Mr. Norwood | ..... | X | | | | | |
| Mr. White | ..... | X | | | | | |
| Mr. Coburn | ..... | X | | | | | |

ROLL CALL VOTE #9

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mrs. Lincoln re: relationship of Title III requirements to small business.

Disposition: Not agreed to, by a roll call vote of 21 ayes to 22 nays.

| Representtive | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | ..... | X | ..... | Mr. Dingell | X | ..... | |
| Mr. Moorhead | ..... | X | ..... | Mr. Waxman | ..... | ..... | |
| Mr. Fields | ..... | X | ..... | Mr. Markey | X | ..... | |
| Mr. Oxley | ..... | X | ..... | Mr. Tauzin | X | ..... | |
| Mr. Bilirakis | X | ..... | ..... | Mr. Wyden | X | ..... | |
| Mr. Schaefer | X | ..... | ..... | Mr. Hall | X | ..... | |
| Mr. Barton | X | ..... | ..... | Mr. Byrant | X | ..... | |
| Mr. Hastert | ..... | X | ..... | Mr. Boucher | X | ..... | |
| Mr. Upton | ..... | X | ..... | Mr. Manton | X | ..... | |
| Mr. Stearns | ..... | X | ..... | Mr. Towns | ..... | ..... | |
| Mr. Paxon | ..... | X | ..... | Mr. Studds | ..... | ..... | |
| Mr. Gillmor | ..... | X | ..... | Mr. Pallone | X | ..... | |
| Mr. Klug | ..... | X | ..... | Mr. Brown | X | ..... | |
| Mr. Franks | ..... | X | ..... | Mrs. Lincoln | X | ..... | |
| Mr. Greenwood | ..... | X | ..... | Mr. Gordon | X | ..... | |
| Mr. Crapo | ..... | X | ..... | Ms. Furse | X | ..... | |
| Mr. Cox | ..... | X | ..... | Mr. Deutsch | X | ..... | |
| Mr. Burr | ..... | X | ..... | Mr. Rush | X | ..... | |
| Mr. Bilbray | ..... | X | ..... | Ms. Eshoo | X | ..... | |
| Mr. Whitfield | ..... | X | ..... | Mr. Klink | X | ..... | |
| Mr. Ganske | ..... | X | ..... | Mr. Stupak | X | ..... | |
| Mr. Frisa | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. Norwood | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. White | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. Coburn | ..... | X | ..... | ..... | ..... | ..... | |

ROLL CALL VOTE #10

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mrs. Lincoln re: unfunded mandates and State laws.

Disposition: Not agreed to, by a roll call vote of 17 ayes to 27 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | | X | | Mr. Dingell | X | | |
| Mr. Moorhead | | X | | Mr. Waxman | | | |
| Mr. Fields | | X | | Mr. Markey | X | | |
| Mr. Oxley | | X | | Mr. Tauzin | | X | |
| Mr. Bililrakis | | X | | Mr. Wyden | X | | |
| Mr. Schaefer | | X | | Mr. Hall | | X | |
| Mr. Barton | | X | | Mr. Bryant | X | | |
| Mr. Hastert | | X | | Mr. Boucher | X | | |
| Mr. Upton | | X | | Mr. Manton | X | | |
| Mr. Stearns | | X | | Mr. Towns | X | | |
| Mr. Paxon | | X | | Mr. Studds | | | |
| Mr. Gillmor | | X | | Mr. Pallone | X | | |
| Mr. Klug | | X | | Mr. Brown | X | | |
| Mr. Franks | | X | | Mrs. Lincoln | X | | |
| Mr. Greenwood | | X | | Mr. Gordon | X | | |
| Mr. Crapo | | X | | Ms. Fuse | X | | |
| Mr. Cox | | X | | Mr. Deutsch | X | | |
| Mr. Burr | | X | | Mr. Rush | X | | |
| Mr. Bilbray | | X | | Ms. Eshoo | X | | |
| Mr. Whitfield | | X | | Mr. Klink | X | | |
| Mr. Ganske | | X | | Mr. Stupak | X | | |
| Mr. Frisa | | X | | | | | |
| Mr. Norwood | | X | | | | | |
| Mr. White | | X | | | | | |
| Mr. Coburn | | X | | | | | |

ROLL CALL VOTE #11

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Substitute Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Brown.

Disposition: Not agreed to, by a roll call vote of 16 ayes to 26 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | | X | | Mr. Dingell | X | | |
| Mr. Moorhead | | X | | Mr. Waxman | | | |
| Mr. Fields | | X | | Mr. Markey | X | | |
| Mr. Oxley | | X | | Mr. Tauzin | | X | |
| Mr. Bilirakis | | X | | Mr. Wyden | X | | |
| Mr. Schaefer | | X | | Mr. Hall | | X | |
| Mr. Barton | | X | | Mr. Bryant | X | | |
| Mr. Hastert | | X | | Mr. Boucher | X | | |
| Mr. Upton | | X | | Mr. Manton | X | | |
| Mr. Stearns | | X | | Mr. Towns | X | | |
| Mr. Paxon | | X | | Mr. Studds | | | |
| Mr. Gillmor | | X | | Mr. Pallone | X | | |
| Mr. Klug | | X | | Mr. Brown | X | | |

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Franks | ..... | X | ..... | Mrs. Lincoln | ..... | ..... | |
| Mr. Greenwood | ..... | X | ..... | Mr. Gordon | X | ..... | |
| Mr. Crapo | ..... | X | ..... | Ms. Furse | X | ..... | |
| Mr. Cox | ..... | X | ..... | Mr. Deutsch | X | ..... | |
| Mr. Burr | ..... | X | ..... | Mr. Rush | X | ..... | |
| Mr. Bilbray | ..... | X | ..... | Ms. Eshoo | X | ..... | |
| Mr. Whitfield | ..... | X | ..... | Mr. Klink | X | ..... | |
| Mr. Ganske | ..... | X | ..... | Mr. Stupak | X | ..... | |
| Mr. Frisa | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. Norwood | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. White | ..... | X | ..... | ..... | ..... | ..... | |
| Mr. Coburn | ..... | X | ..... | ..... | ..... | ..... | |

ROLL CALL VOTE #12

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment in the Nature of a Substitute by Mr. Oxley and Mr. Bilirakis for Title III.

Disposition: Agreed to, as amended, by a roll call vote of 26 ayes to 16 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | X | ..... | ..... | Mr. Dingell | ..... | X | |
| Mr. Moorhead | X | ..... | ..... | Mr. Waxman | ..... | ..... | |
| Mr. Fields | X | ..... | ..... | Mr. Markey | ..... | X | |
| Mr. Oxley | X | ..... | ..... | Mr. Tauzin | X | ..... | |
| Mr. Bilirakis | X | ..... | ..... | Mr. Wyden | ..... | X | |
| Mr. Schaefer | X | ..... | ..... | Mr. Hall | X | ..... | |
| Mr. Barton | X | ..... | ..... | Mr. Bryant | ..... | X | |
| Mr. Hastert | X | ..... | ..... | Mr. Boucher | ..... | X | |
| Mr. Upton | X | ..... | ..... | Mr. Manton | ..... | X | |
| Mr. Stearns | X | ..... | ..... | Mr. Towns | ..... | X | |
| Mr. Paxon | X | ..... | ..... | Mr. Studds | ..... | ..... | |
| Mr. Gillmor | X | ..... | ..... | Mr. Pallone | ..... | X | |
| Mr. Klug | X | ..... | ..... | Mr. Brown | ..... | X | |
| Mr. Franks | X | ..... | ..... | Mrs. Lincoln | ..... | ..... | |
| Mr. Greenwood | X | ..... | ..... | Mr. Gordon | ..... | X | |
| Mr. Crapo | X | ..... | ..... | Ms. Furse | ..... | X | |
| Mr. Cox | X | ..... | ..... | Mr. Deutsch | ..... | X | |
| Mr. Burr | X | ..... | ..... | Mr. Rush | ..... | X | |
| Mr. Bilbray | X | ..... | ..... | Ms. Eshoo | ..... | X | |
| Mr. Whitfield | X | ..... | ..... | Mr. Klink | ..... | X | |
| Mr. Ganske | X | ..... | ..... | Mr. Stupak | ..... | X | |
| Mr. Frisa | X | ..... | ..... | ..... | ..... | ..... | |
| Mr. Norwood | X | ..... | ..... | ..... | ..... | ..... | |
| Mr. White | X | ..... | ..... | ..... | ..... | ..... | |
| Mr. Coburn | X | ..... | ..... | ..... | ..... | ..... | |

ROLL CALL VOTE #13

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Motion: Motion by Mr. Oxley to order H.R. 9 reported to the House, as amended.

Disposition: Agree to, by a roll call vote of 27 ayes to 16 nays.

| Representative | Aye | Nay | Present | Representative | Aye | Nay | Present |
|---|---|---|---|---|---|---|---|
| Mr. Bliley | X | ..... | ..... | Mr. Dingell | ..... | X | |
| Mr. Moorhead | X | ..... | ..... | Mr. Waxman | ..... | ..... | |
| Mr. Fields | X | ..... | ..... | Mr. Markey | ..... | X | |
| Mr. Oxley | X | ..... | ..... | Mr. Tauzin | X | ..... | |
| Mr. Bilirakis | X | ..... | ..... | Mr. Wyden | ..... | X | |
| Mr. Schaefer | X | ..... | ..... | Mr. Hall | X | ..... | |
| Mr. Barton | X | ..... | ..... | Mr. Byrant | ..... | X | |
| Mr. Hastert | X | ..... | ..... | Mr. Boucher | ..... | X | |
| Mr. Upton | X | ..... | ..... | Mr. Manton | ..... | X | |
| Mr. Stearns | X | ..... | ..... | Mr. Towns | ..... | X | |
| Mr. Paxon | X | ..... | ..... | Mr. Studds | ..... | ..... | |
| Mr. Gillmor | X | ..... | ..... | Mr. Pallone | ..... | X | |
| Mr. Klug | X | ..... | ..... | Mr. Brown | ..... | X | |
| Mr. Franks | X | ..... | ..... | Mrs. Lincoln | ..... | ..... | |
| Mr. Greenwood | X | ..... | ..... | Mr. Gordon | ..... | X | |
| Mr. Crapo | X | ..... | ..... | Ms. Furse | ..... | X | |
| Mr. Cox | X | ..... | ..... | Mr. Deutsch | ..... | X | |
| Mr. Burr | X | ..... | ..... | Mr. Rush | ..... | X | |
| Mr. Bilbray | X | ..... | ..... | Ms. Eshoo | ..... | X | |
| Mr. Whitfield | X | ..... | ..... | Mr. Klink | ..... | X | |
| Mr. Ganske | X | ..... | ..... | Mr. Stupak | ..... | X | |
| Mr. Frisa | X | ..... | ..... | ..... | ..... | ..... | |
| Mr. Norwood | X | ..... | ..... | ..... | ..... | ..... | |
| Mr. White | X | ..... | ..... | ..... | ..... | ..... | |
| Mr. Coburn | X | ..... | ..... | ..... | ..... | ..... | |

VOICE VOTES

Bill: Title III, Risk Assessment and Cost/Benefit Analysis of New Regulations, of H.R. 9, the Job Creation and Wage Enhancement Act.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Fields re: definition of covered Federal agencies.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Barton re: principles for risk assessment.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Rush re: judicial review.

Disposition: Not Agreed to, by a voice vote.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Barton re: judicial review of Sections 3104 and 3105.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Stupak re: risk comparison.

Disposition: Agreed to, by a voice vote.

Amendment: Amendment to the Oxley-Bilirakis Amendment in the Nature of a Substitute by Mr. Barton re: petition process.

Disposition: Agreed to, by a voice vote.

## COMMITTEE OVERSIGHT FINDINGS

Clause 2(1)(3)(A) of Rule XI requires each committee report to contain oversight findings and recommendations required pursuant

to Clause 2(b)(1) of Rule X. The committee has had several hearings on the subject matter of Title III of H.R. 9, including a hearing on November 17, 1993, in the Subcommittee on Transportation and Hazardous Materials. The findings of these hearings are reflected in the committee report.

## COMMITTEE ON GOVERNMENT OVERSIGHT AND REFORM

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Oversight and Reform.

## COMMITTEE COST ESTIMATE

Pursuant to clause 7(a) of rule XIII of the rules of the House of Representatives, the Committee is required to estimate the costs that would be incurred in carrying out Title III of H.R. 9. The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office, pursuant to section 403 of the Congressional Budget Act of 1974, with the following concerns.

First, Title III is drafted to provide covered Federal agencies with flexibility in complying with the requirements of the Title. Specifically, the legislation provides that "[c]osts and benefits shall be quantified to the extent feasible and appropriate and may otherwise be qualitatively described." Section 3201(a)(1). This language provides Federal agencies with flexibility in complying with the requirements of the legislation. It is not apparent that this flexibility has been taken into account in the information provided by the Federal agencies to the Congressional Budget Office for the purpose of its estimate.

Second, it is not apparent that the Congressional Budget Office cost estimates take into account the savings to the Federal government resulting from this legislation. For example, pursuant to Section 3201(b) and (c), this legislation could result in savings in hazardous waste cleanup programs, some of which would accrue to the Federal government.

Finally, the Congressional Budget Office estimate does not purport to identify savings to Federal, state and local governments and the national economy that are expected to occur as a result of improved risk assessment and cost-benefit legislation. The Committee believes it is important to consider these savings when evaluating estimates of costs.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 2(l)(3)(C) of rule XI of the rules of the House of Representatives, following is the cost estimate provided by the Congressional Budget Office pursuant to section 403 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
*Washington, DC, February 15, 1995.*

Hon. THOMAS J. BLILEY, JR.,
*Chairman, Committee on Commerce, House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for Title III of H.R. 9, the Job Creation and Wage Enhancement Act of 1995.

Enactment of Title III of H.R. 9 could affect direct spending or receipts. Therefore, pay-as-you-go procedures would apply to the bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM
(For Robert D. Reischauer, Director).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: Title III of H.R. 9.

2. Bill title: Job Creation and Wage Enhancement Act of 1995.

3. Bill status: As ordered reported by the House Committee on Commerce on February 8, 1995.

4. Bill purpose: This title applies to 12 federal agencies with regulatory programs designed to protect human health, safety, or the environment. The provisions of subtitle A would apply to any risk assessment or risk characterization document prepared in connection with a rule that is expected to have direct or indirect costs to the federal government, state or local governments, or the private sector of at least $25 million annually. Subtitle A also would apply to permits issued by the Environmental Protection Agency (EPA) and the Department of the Interior (DOI). Subtitle B would apply to agency rules expected to have a direct or indirect cost of at least $25 million annually, regardless of whether or not a risk assessment or characterization document is prepared.

Subtitle A would require these 12 agencies to apply specified principles when preparing risk assessments in connection with their regulatory programs. The bill would establish a list of components that agencies must include in risk characterization documents. Within 15 months following enactment, the President is to issue guidelines to agencies that are consistent with the risk assessment and risk characterization principles described in the bill.

Subtitle B would require these agencies to assess the incremental costs and incremental risk reduction or other benefits associated with proposed or promulgated rules designed to protect human health, safety, or the environment. The bill also would require a review and analysis of other regulatory or nonregulatory options considered by the agency. In addition, this subtitle would prohibit the promulgation of any final rule unless the agency certifies that the incremental risk reduction or other benefits of the regulation will be likely to justify, and be reasonably related to, the incremental costs.

Subtitle C would require the specified agencies to establish peer review procedures for risk assessments and economic assessments associated with rules expected to have annual costs to the economy exceeding $100 million. Subtitle D would require these agencies to establish procedures for considering petitions by individuals for reviewing existing rules and revising them to comply with the provisions of this bill.

5. Estimated cost to the Federal Government: We estimate that enactment of this title would increase the cost of issuing and reviewing regulations by affected federal agencies by at least $250 million annually, if the number of federal regulations is not affected by the bill. The title may also lead to additional legal challenges of proposed federal regulatory activities; federal agencies and the courts would incur additional costs to defend and process these cases, but CBO is unable to estimate the increase in the number of legal proceedings or the amount of additional costs. Enacting Title III of H.R. 9 could lead to the delay or loss of federal receipts expected under current law; therefore, pay-as-you-go procedures would apply to the bill. CBO is working with federal agencies to determine the amount of the loss in receipts but cannot now provide an estimate.

Few of the agencies that would be affected by this bill have had time to systematically study the additional costs that its implementation would impose. The risk analysis work, the cost/benefit comparisons, and the peer review provisions are similar to the work most agencies now conduct for some regulations expected to have an economic impact greater than $100 million annually. This estimate assumes that agencies will try to adhere to their current schedules for implementing new regulations and revising existing rules. This estimate does not include any costs for analyzing permits issued by EPA and DOI, nor does it include any funds for carrying out subtitle D of the bill, because we currently have no basis for estimating such impacts. None of the agencies we contacted could predict the number of petitions that they might receive for reviewing and revising current regulations. Several agencies noted, however, that the petition process outlined in the bill could potentially result in significant costs for additional risk assessments and analysis and for increased litigation.

EPA currently spends about $120 million annually on risk assessment and cost/benefit assessments to support rule making efforts for regulations expected to have an economic impact greater than $100 million annually. Based on information from the agency, we estimate that the volume of work that would be added by Title III would double the agency's cost for these studies. Based on its current regulatory workload, the agency estimates that lowering the threshold for detailed risk assessments and cost/benefit analysis from regulations with economic impacts of $100 million annually to $25 million annually would triple the number of regulatory actions requiring detailed study. Because it is not clear how the provisions of the bill would be applied to the permits issued by the agency, this estimate does not include any additional costs for risk assessments and cost/benefit analysis of permits. The agency handles hundreds of permit applications and modifications each year.

The Department of Agriculture (USDA) currently prepares regulatory impact assessments, environmental impact statements, and risk analyses for all regulatory actions affecting human health, safety, or the environment that are expected to result in annual costs to the economy of more than $100 million. Based on information from USDA, we estimate that lowering the threshold for these analyses would increase the number of risk assessments and cost/benefit studies by about 200 each year. The additional costs associated with such assessments and studies range from less than $100,000 for a relatively routine rule to several million dollars for a major regulatory change. CBO estimates that most of the additional work would cost $150,000 to $250,000 per analysis, or an additional $30 million to $50 million annually for the department.

The cost to the Department of Transportation (DOT) of implementing Title III of H.R. 9 also could be large. The agency currently spends about $300 million annually on formal rule-making proceedings. We cannot estimate the additional costs the bill would impose on DOT because the agency is currently unclear about how to implement the legislation. The type of risk assessments and characterizations conducted by DOT are generally quite different from the type defined in Title III.

Based on information from the Food and Drug Administration (FDA), CBO estimates that the requirements in Title III of the bill would add about $20 million annually to the agency's current spending of pre-market regulatory activities. The agency estimates that the additional analysis required by the bill would add an average of about $700,000 to an additional 25 rules each year.

The Department of Energy (DOE) also would incur additional costs to implement Title III of H.R. 9. CBO has been unable to quantify the impact, but we expect that the incremental cost of risk assessment on both the environmental, safety, and health program and the environmental management program would be significant, perhaps hundreds of millions of dollars.

The Department of the Interior (DOI) currently spends about $50 million per year for regulatory analysis. This work is carried out primarily by the Office of Surface Mining, the Minerals Management Service, and the Bureau of Land Management as part of their overall regulatory enforcement activities. DOI estimates that lowering the threshold for regulatory analyses from $100 million to $25 million would significantly increase the number of analyses these agencies would have to prepare, resulting in additional annual costs of about $20 million.

Requirements in H.R. 9 also would increase costs of the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and the Consumer Product Safety Commission (CPSC). Based on information from these agencies, CBO estimates that Title III would result in total additional costs of less than $20 million per year for these agencies.

6. Comparison with spending under current law: CBO estimates enactment of this title would add at least $250 million annually to the cost of issuing regulations.

7. Pay-as-you-go considerations: Section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985 sets up pay-as-you-go procedures for legislation affecting direct spending or re-

ceipts through 1988. Enactment of Title III of H.R. 9 could affect receipts; therefore, pay-as-you-go procedures would apply to the bill.

It is possible, depending on how the provisions of Title III are interpreted and implemented, that enactment of this title could result in a loss of receipts to the federal government, such as those from commercial activities on public lands. CBO estimates that DOI and USDA collect about $1 billion annually from new sales of federal resources that could be affected by Title III. If the leasing and sale activities of these agencies were significantly delayed, some of these receipts would also be delayed.

If provisions of the title are interpreted to apply to agency actions governing the sale of federal resources such as oil, gas, and timber, then additional time would be needed to prepare cost/benefit analyses and environmental impact statements associated with these activities. These additional tasks would probably delay some sales. It is also possible that the requirements of Title III could be the basis for lawsuits against an agency's leasing or sale program, thus delaying some sales and associated receipts to the federal Treasury. At this time, CBO cannot estimate the loss of receipts that could occur if these activities are delayed by enactment of this bill.

8. Estimated cost to State and local governments: How enactment of Title III would affect the budgets of state and local governments is unclear. If regulations that would impose additional requirements on state and local governments are either delayed or precluded by the enactment of these provisions, then costs to these entities would be less. It is also possible, however, that some regulatory actions that would otherwise provide relief to state and local governments could be delayed or precluded, thereby increasing their costs for various activities. CBO has no basis for predicting the direction, magnitude, or timing of such impacts.

9. Estimated comparison: None.

10. Previous CBO estimate: None.

11. Estimate prepared by: Kim Cawley and Connie Takata.

12. Estimate approved by: Paul N. Van de Water, Assistant Director for Budget Analysis.

## INFLATIONARY IMPACT STATEMENT

Clause 2(l)(4) of Rule XI of the Rules of the House of Representatives to include an analytical statement describing what impact enactment of the measure would have on prices and costs in the operation of the national economy. The Committee has determined that Title III of H.R. 9 has no inflationary impact on the nation's economy, because the bill will make Federal regulations more cost-effective and insure that Federal and national resources are used to address the most serious risks to public health and the environment.

## SECTION-BY-SECTION ANALYSIS

### *Section 3001. Findings*

Under this section, Congress finds that environmental, health and safety regulations have dramatically improved the environment and significantly reduced risks to human health, but that

those regulations have been more costly and less effective than they could have been. Too frequently, they have not been based on a realistic consideration of risk. This section further finds that public and private resources are not unlimited, and that resources need to be allocated to address the greatest needs in the most cost-effective manner, and so that incremental regulatory costs are reasonably related to incremental benefits. This section further finds that regulatory priorities should be based upon realistic consideration of risk and sound, objective, and unbiased risk assessments. Risk assessments should be based on better science and must be communicated more effectively and objectively to decision makers and the public. Public stakeholders must be fully involved in the risk decisionmaking process.

*Section 3002. Definition of covered Federal agency*

This section defines the term "covered Federal agencies" to include the following agencies: the Environmental Protection Agency; the Occupational Safety and Health Administration; the Department of Transportation (including the National Highway Traffic Safety Administration); the Food and Drug Administration; the Department of Energy; the Department of the Interior; the Department of Agriculture; the Consumer Product Safety Commission; the National Oceanic and Atmospheric Administration; the United States Army Corps of Engineers; and the Mine Safety and Health Administration.

*Section 3003. Coverage of title*

This section provides that the title does not apply to any situation that the head of the covered Federal agency concerned considers to be an emergency.

In determining whether an emergency exists, an agency head should be guided by applicable statutory definitions and, unless otherwise prohibited, ordinary notions of urgency and necessity constituting an emergency. The mere existence of the usual kind and level of risk which any statute subject to this title is designed to regulate does not constitute an emergency. [Moreover, there are situations where the Federal agency can and should comply with the provisions of the Title after the period of time which constitutes the emergency].

SUBTITLE A—RISK ASSESSMENT AND COMMUNICATION

*Section 3101. Short title*

This section sets forth the short title of Subtitle A, the "Risk Assessment and Communication Act of 1995."

*Section 3102. Purposes*

This section sets forth the following purposes of the subtitle: (1) to present the public and the executive branch with the most scientifically objective and unbiased information about the nature and magnitude of health, safety and environmental risks to provide for sound regulatory decisions and public education; (2) to provide for full consideration and discussion of data and methodologies; (3) to require explanation of significant choices in the risk assessment

process; and (4) to improve consistency in Federal risk assessments and risk characterizations.

*Section 3103. Effective date, applicability, savings provisions*

This section provides that the subtitle shall take effect 18 months after the date of enactment, except as otherwise specified. This section specifies that Subtitle A applies to all significant risk assessment and significant risk characterization documents prepared by covered Federal agencies. It defines "significant risk assessment document" and "significant risk characterization document" to include the following risk documents prepared by or on behalf of a covered Federal agency: (1) any major rule designed to protect human health, safety or the environment; (2) proposed or final permits restricting facility siting or operation, or proposed or final cleanup plans, or guidelines for the issuance of such permits and plans, under laws administered by the Environmental Protection Agency or the Department of the Interior; (3) reports to Congress; (4) inclusion of substances on the Integrated Risk Information System database; (5) regulatory actions placing substances on official lists of carcinogens or toxic or hazardous substances; and (6) any risk assessment or risk characterization forming the basis of a final risk assessment or risk characterization guideline or protocol of general application. The term "regulatory program designed to protect human health, safety or the environment" does not include internal personnel matters or programs regulating the provision of health care services.

Subsection 3103(b) recognizes that agency policy relating to risk assessment and risk management is established not just in formal regulations, but also in final guidances and protocols. All of these forms of documents that are intended to have general application, rather than to be limited to an individual substance, product, or permit, are required to comply with the principles established in subtitle A. Second, Section 3103(b) is intended to exclude any action where an individual substance, product, or permit or its labeling, is reviewed and authorized or approved by an agency for some type of use. For example, FDA licensing of individual new drugs, devices or biologics would be excluded as would EPA approvals for individual pesticides or items under the Toxic Substances Control Act.

The guidance documents or protocols on which such a review is conducted will be subject to subtitle A, but the individual review or individual compliance actions are not themselves actions subject to subtitle A unless otherwise specified in paragraph 3103(b).

Paragraph 3103(b)(2) further requires covered Federal agencies to promulgate a rule within 15 months of the date of enactment listing other risk assessment and risk characterization documents deemed to be significant, and sets forth criteria to be considered in promulgating the rule. It provides that the subtitle does not apply to emergencies, screening analyses, or food, drug and product labels requiring Federal approval prior to their use. It clarifies that the provisions of the subtitle do not modify and are supplemental to existing Federal health, safety and environmental standards. It further clarifies that nothing in the title requires disclosure of trade secrets or confidential information.

In promulgating regulations under section 3103(b)(2)(B), the Committee expects the head of each covered Federal agency to place substantial value on the consistent application of the principles in sections 3104 and 3105 to provide for sound decisionmaking and public discourse. The Committee expects that the more likely a category of documents is to affect significant regulatory decisions or public discourse, the higher the presumption for inclusion.

Decisions under 3103(b)(2)(B) and the minimum documents described in 3103(b)(2)(A) work in conjunction with the several rules of reason, such as the phrases "to the extent feasible" or "where relevant" in sections 3104 and 3105. Moreover, section 3104 states that discussions or explanations required under that section need not be repeated in each significant risk assessment document as long as there is a reference to the relevant discussion in another agency document. Thus, each document category may have somewhat different requirements. However, the phrase "to the extent feasible" means that where it is feasible to comply with one component of a requirement and not another, there must be compliance with the component of the requirement which is feasible.

*Section 3104. Principles for risk assessment*

Subsection 3104(b) provides principles that describe a scientifically objective and unbiased risk assessment. These principles will make risk assessment processes more transparent, allowing risk managers and the public to understand the evaluation and selection of data, models, and assumptions in a risk assessment.

Paragraph 3104(b)(1) requires that significant risk assessment documents contain discussion of certain data where relevant. Federal agencies often use default assumptions when actual data exist. Default assumptions allow risk assessors to make quantitative estimates of risk when available data are incomplete. Often agencies choose default assumptions which, given the available scientific information, tend to overstate risks in the resulting risk estimate. One such default assumption concerning risks to human health is to simply base risk estimates on studies which find a positive correlation. Agencies often persist in using these defaults, even when chemical- or situation-specific data are available. The bill addresses this problem by requiring significant risk assessment documents to include discussions of relevant data. Subparagraph 3104(b)(2) will remove the current disincentive for organizations to develop data that will increase the accuracy of risk assessments.

Paragraph 3104(b)(2) requires that significant risk documents provide or refer to an explanation for certain significant choices made by the agency. The paragraph further requires that the document provides or refers to a description of any significant model and the extent to which such model has been validated by, or conflicts with, empirical data.

Paragraph 3104(b)(3) states that no covered Federal agency shall automatically incorporate or adopt any recommendation or classification made by a non-United States-based entity concerning the health effects value of a substance without an opportunity for notice and comment on such incorporation or adoption.

*Section 3105. Principles for risk characterization and communication*

This section provides for a description in significant risk documents of the populations or natural resources subject to risk characterization, a best estimate and other risk estimates and an explanation of uncertainties in risk assumptions, an explanation of exposure scenarios, comparisons to routinely encountered risks that place the federally addressed risks in context, a statement of significant and clear substitution risks, and a summary of other risk estimates to the extent feasible.

Federal agencies generally do not provide complete characterizations of risk, but rather provide only single-point, upper-bound estimates of risk. This forces risk managers to make decisions with incomplete information and misleads the public into believing that some risks are much larger than they are. This section requires the agency to include several pieces of information in significant risk characterization documents.

Paragraph 3105(1) requires covered Federal agencies to provide, to the extent feasible and scientifically appropriate, the best estimate or estimates for the given populations or natural resources, along with the reasonable range of scientific uncertainty. The agency may present plausible upper bound or conservative estimates in conjunction with plausible lower bound estimates. Indeed, the savings clause in section 3103 makes clear that no calculation is precluded. Best estimates are defined flexibly to include any methodology designed to provide the most plausible level of risk, given the scientific information available to the Administrator. Subtitle A does not opine on which combination of scientific assumptions or methodology are appropriate and, thus, makes no pronouncement on the science itself. Rather, the best estimate requirement is simply a question for the risk assessors to answer. The scientific debate about the answer continues under the current standards of review.

Best estimates will: (1) help provide a more realistic picture of the nature and magnitude of the risks; (2) make the impact of conservative assumptions in an upper-bound estimate clearer to decisionmakers and the public; (3) separate scientific findings from considerations affecting regulatory strategies; (4) provide for more realistic comparisons between risks; and (5) move scientific debate forward by requiring consideration of new, more plausible models and assumptions.

The provision prohibits agencies from simply ignoring more scientifically plausible assumptions and methodologies when they are available. The requirement does not require papering over legitimate scientific disagreements by averaging incompatible estimates. Under such situations, the agency merely needs to state why it is not scientifically appropriate for the given component of the risk assessment. Nor would agencies need to perform new evaluations which are excessively burdensome. This is, however, a narrow exception and the agency would need to explain why a given approach is not "feasible." Moreover, under the language "to the extent feasible," agencies would be required to try to get as close to a best estimate as feasible. For example, it may be feasible to use the most plausible assumptions for some components of a best esti-

mate calculation but not others. Finally, what is feasible and scientifically appropriate will change over time. Certainly, where public comment provides a scientifically sound means of getting a risk estimate which is closer to a best estimate, the agency should utilize this approach. This specifically means that actual information should be used in lieu of default assumptions where the actual information is more scientifically plausible than the information underlying the default assumption.

Paragraph 3105(l) further requires that, where practical, agencies should provide probability distributions for risk estimates that reflect both variability and uncertainty. Presenting the full distribution of risk provides risk managers and the public with the most complete picture of what is and what is not known about the risk.

Paragraph 3105(2) requires agencies to explain the exposure scenarios used and provide a statement of the size of the population and likelihood that an exposure will occur. This information will help assure that the public understands the precise basis of the given risk assessment. Moreover, the requirement will help separate more likely exposure scenarios from unlikely exposure scenarios, such as a child eating dirt from a fenced-in industrial site.

Paragraph 3105(3) requires agencies to provide a statement placing the nature and magnitude of risks in context. Additional information will assist the public in understanding how the risk affects them, and how it relates to other risks with which they are more familiar. This section acknowledges the difficulty in making useful and meaningful risk comparisons by including references to relevant distinctions among categories of risk and limitations to comparisons.

Paragraph 3105(4) requires that each significant risk assessment or significant risk characterization document referred to in Clause(i), (ii) or (iii) of section 3103(2)(A) shall include, to the extent feasible, a statement of any significant and clear substitution risks to human health, where information on such risk has been provided to the agency. The term "substitution risk" is defined in section 3108 to mean potential risks to human health, safety or the environment that arise from a regulatory option designed to decrease other risks. Current risk characterization and communication fail to provide adequate information about the risks that the proposed action will pose. Because they are not currently assessed, those risks are often assumed to be zero. Many risk management actions pose their own risks. The Committee has provided a number of qualifications to this requirement.

First, the requirement only applies to "significant" substitution risks. The Committee expects agencies to look to the magnitude of the substitution risk relative to the risk being addressed by the particular regulatory strategy. If a regulatory strategy is addressing minor risks, then minor substitution risks may be significant. If the strategy is addressing major risks, then minor substitution risks would not be significant.

Second, the requirement only applies to "clear" substitution risks. This language is designed to preclude requiring statements more indirect or hypothetical statements of substitution risks. Indirect risks resulting from loss of economic resources or the inability

to direct such resources to other health or safety requirements would not meet the requirement for a "clear" substitution risk. However, as stated in the savings clause, nothing in the Title prevents agencies from providing information beyond the minimum requirements.

Third, the requirement applies only "where information on such risks has been provided to the agency. Thus, the provision does not require the agencies necessarily to look at all possible consequences, for example, restricting a product or chemical. However, where specific information is provided and reasonably summarized in a comment period, the agencies should make feasible efforts to highlight this information.

Finally, nothing requires the statement to include a numerical measure. Statements should be as informative as the information available but may be quantitative or qualitative. The statement may also be brief with a cross-reference to more extensive discussion in another document.

Paragraph 3105(5) requires agencies to present summaries of other risk estimates if they meet certain requirements. Because risk assessments often require many subjective judgments, risk characterizations conducted by different organizations can vary greatly. Inclusion of other risk estimates, provided that they meet the standards set forth in the amendment, will provide a fuller characterization of risk. The terms "in connection with the presentation of the agency's risk assessment document or risk characterization document" allows for brief summaries along with cross references to other documents.

*Section 3106. Guidelines*

This section requires the President to issue guidelines for Federal agencies consistent with Sections 3104 and 3105 within 15 months of the date of enactment. It requires agencies to evaluate policy and value judgments inherent in their risk assessments and report to Congress within three years. It provides for public comment and consultation with State and local governments and other agencies in the preparation of the guidelines and the reports. It requires the President to review and, where appropriate, revise the guidelines every four years.

The section includes the guidelines requirement to ensure that the bill's principles are implemented consistently throughout the covered Federal agencies and to facilitate comparisons of risks assessed by various Federal agencies. Risk assessment and characterization guidelines should allow for incorporation of new scientific advances and better methods of risk characterization and communication.

*Section 3107. Judicial Review of Sections 3104 and 3105*

This section requires courts to consider unlawful any agency action in which a final agency action does not comply with the requirements of sections 3104 or 3105. When a significant risk assessment document or a significant risk characterization document is prepared in connection with a final agency action (e.g., a final rule), that document will be part of the administrative record that can be considered by the court, if the final agency action is brought

before a court for review. Under the provisions that govern judicial review of most agency actions, such as those codified in Section 10 of the Administrative Procedure Act, 5 U.S.C., Section 706, reviewing courts are directed to hold unlawful and set aside agency action that, among other things, is found to be without observance of procedure required by law or otherwise not in accordance with law. In making these determinations, the APA directs that "due account shall be taken of the rule of prejudicial error."

In the absence of a provision like Section 3107, it may not be fully clear how a court would evaluate an agency's failure to comply with the requirements of sections 3104 and 3105 when it reviews a final agency action in connection with the preparation of a significant risk assessment or risk characterization document.

For example, without section 3107, courts might declare the failure to provide a best estimate under section 3105 a harmless error based on the agency's assertion that the omission did not influence the final rule. Under the language of section 3107, however, courts would consider the final agency action unlawful where the action does not comply with section 3104 or 3105 because the failure to characterize risk in the manner outlined would leave out elements Congress considers critical to the rulemaking process. This ensures the requirements of 3104 or 3105 supplement otherwise applicable statutory requirements and must be followed.

Courts may continue to gauge whether a given violation of sections 3104 or 3105 is de minimus in nature in determining whether to set aside agency actions. Moreover, sections 3104 and 3105 simply require that certain discussions be made a part of documents supporting the final agency actions. Judicial review of the quality of those discussions remains subject to otherwise applicable standards of judicial review.

*Section 3108. Definitions*

This section defines certain terms. The term "risk assessment document" means a document explaining how hazards associated with a substance, activity or condition have been identified, quantified and assessed or describing the degree of toxicity, exposure or other risk they pose for exposed individuals, populations or resources. The term "risk characterization document" means a document quantifying or describing the degree of toxicity, exposure, or other risk they pose for exposed individuals, populations, or resources, but such term does not include a food, drug or other product label. The term "best estimate" means an estimate which, to the extent feasible and scientifically appropriate, is based on central estimates of risk using the most plausible assumptions; an approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario; or any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the Federal agency concerned. The term "substitution risk" means a potential risk to human health, safety or the environment from a regulatory option designed to decrease other risks. The term "document" includes material stored in electronic or digital form.

SUBTITLE B—ANALYSIS OF RISK REDUCTION BENEFITS AND COSTS

*Section 3201. Analysis of risk reduction benefits and costs*

Paragraph 3201(a) directs the President to require covered Federal agencies to prepare the following for major rules proposed or promulgated after the date of enactment and designed to protect human health, safety or the environment: an assessment of incremental costs and incremental benefits for each significant regulatory alternative; a statement placing the nature and magnitude of the risks in context; and for each final rule, an assessment of the costs and benefits of compliance with the rule.

Quantification in cost-benefit analysis and risks assessments is only required to the extent feasible and appropriate, and other factors relevant to the decisionmaking may be qualitatively described. The methodology and level of detail for both risk assessments and cost-benefit analyses should be appropriate to the significance and complexity of decisionmaking on the matter at issue, considering any need for expedition.

Both risk assessments and cost-benefit analyses can be tiered or tailored to fit the decisionmaking process and the decision confronting a particular agency, as long as the basic elements of reasoned decisionmaking and the logic of the cost-benefit and risk assessment methodology are respected. This legislation does not intend to disregard or minimize the application of agency expertise in the decisionmaking process, nor does it mandate a strict recipe for risk assessment or cost-benefit analysis. Rather, it aims to ensure rationality in both the decisionmaking process and the ultimate decisions by Federal agencies, recognizing the wide variance in the types of decisions and types of situations faced by agency officials.

Paragraph 3201(b) prohibits promulgation of any final rule subject to this title unless the final rule cost-benefit assessment is based on an objective, unbiased scientific and economic information; incremental benefits are reasonably related to and justify the incremental costs; and no other proposed or considered options would be more likely to achieve a substantially equivalent risk reduction in a more flexible or cost-effective manner.

The language requiring consideration of "incremental" costs and benefits will ensure that the agencies recognize the role of diminishing returns in addressing regulatory objectives. In many cases, great benefits may be obtained by relatively inexpensive and simple steps. The word "incremental" is used to clarify that the agencies must apply cost-benefit analysis to assess the utility of increments of risk reduction. Existing regulatory statutes may provide criteria by which agencies choose among various cost-benefit justified options providing varying levels of costs and benefits.

Paragraph 3201(c) provides that notwithstanding other provisions of law, the requirements of the bill supplement, and to the extent of any conflict, supersede the decisional criteria of underlying statutes. It prohibits promulgation of any major rule unless the requirements of 3201(a) and 3201(b) are met and supported by substantial evidence of the rulemaking record.

The provisions of 3201(c) make the provisions of 3201(a) and 3201(b) applicable to new regulations promulgated under existing Federal statutes. The Section 3201(b) decisional criteria supple-

ment, and to the extent there is a conflict, supersede the decisional criteria for rulemaking otherwise applicable under the statute pursuant to which a rule is promulgated.

In effect, agencies will continue to follow the instructions provided by Congress in past and future Federal legislation, but shall, in addition, follow the risk assessment principles and procedures, and apply as additional decisional criteria the cost-benefit and cost-effectiveness certification requirements of Section 3201(b). When there is a conflict with or explicit textual language in a Federal statute prohibiting consideration of the criteria set forth in 3201(b), the provisions of 3201(c) state that the decisional criteria in Section 3201(b) shall supersede those in the statute pursuant to which the rule is promulgated, but only to the extent there is a conflict. The decisional criteria otherwise applicable under other statutory authority will continue to apply to the extent not inconsistent with the section 3201(b) criteria. By this means, the language molds the ultimate decisional criteria for rulemaking applied under all such statutes to the requirements of Section 3201(b) with as little disruption as feasible to the otherwise applicable instructions by Congress.

The provisions of paragraphs 3201 (a)–(c) use principles which are not designed to predetermine particular policy or regulatory approaches. For example, where risks need to be regulated and regulation is justified by its benefits, regulation will go forward even if costly or inconvenient to some.

Paragraph 3201(d), for each major rule, requires agencies to publish in the Federal Register or otherwise make available the information required to be prepared under 3201(a) and 3201(b). For the purposes of this subtitle, it defines "costs" to include the direct and indirect costs of compliance to the Federal Government, State and local governments, and private entities; it defines "benefits" to include direct and indirect social and economic benefits; and it defines "major rule" to mean any regulation, other than a regulation or other action to authorize or approve any individual substance or product, that is likely to result in an annual increase in costs of $25 million or more.

For purposes of efficiency, the judicial review of the risk assessment and cost/benefit analyses contained in the regulatory impact analysis required under 3201(a) and (b) should proceed, on the basis of the whole record of the rulemaking (which will include the actions taken under 3201(a) and (b), in conjunction with review of the rule under the statute granting the agency authority to conduct the rulemaking.

The promulgation of rules by agencies, whether major rules under this legislation or not, are already subject to judicial review under the particular statute granting the agency authority to conduct the rulemaking. The language intends that the procedures and decisional criteria of 3201(a) and (b) shall be judicially reviewable, pursuant to the Administrative Procedure Act (APA) or the statute granting the agency authority to conduct the rulemaking. This review should occur at the same time and in the same court that review agency findings under the statute granting the agency authority to conduct the rulemaking.

Under the provisions of 3201(c)(2), the certifications required under 3201(b) must be supported by substantial evidence in the rulemaking record. All other aspects of the rule will be subject to otherwise applicable standards of review.

SUBTITLE C—PEER REVIEW

*Section 3301. Peer review program*

This section requires each covered Federal agency to develop a systematic peer review program for significant risk assessment documents and economic assessments for regulatory programs addressing human health, safety or the environment. The program shall provide for peer review panels of independent and external experts and shall be broadly representative and balanced to the extent feasible; may provide for differing levels of peer review depending on the significance or complexity of the problems and the need for expeditiousness; shall not exclude peer reviewers merely because they represent entities with a potential interest in the outcome, provided that the interest is fully disclosed, but for regulatory decisions affecting a single entity no person representing that entity may be included on the panel; may provide specific and reasonable deadlines for peer review panels to submit reports; and shall provide adequate protections for confidential business information and trade secrets. It requires peer review for any significant risk assessment document or cost assessment prepared for any regulation likely to increase costs by $100 million or more annually (other than actions to approve individual substances or products). It requires covered Federal agencies to respond in writing to significant peer review comments. It requires that all peer review comments and agency responses be made available to the public and part of the administrative record. It excepts from peer review data and analysis which has been previously peer reviewed. It requires the President to appoint peer review panels to annually review the risk and cost assessment practices of each covered Federal agency and requires those panels to report annually to Congress.

SUBTITLE D—AGENCY PRIORITIES

*Section 3401. Petition process*

This section requires each Federal agency to establish procedures within one year for accepting and considering petitions for reviewing and revising any health or environmental effects value, such as those in the Integrated Risk Information System database; reviewing risk assessments supporting major rules and revising them to take into account new information or methodologies or comply with subtitle A; requiring peer review; and reviewing and revising any major rule promulgated prior to the effective date of this title. It requires that the procedures allow any person to petition upon adequate information to demonstrate that a revision is justified. It requires the agency to respond to petitions in the Federal Register within 90 days. It requires the agency to accept petitions if the information on which they are based would significantly alter an existing risk assessment, and requires the agency to explain the reasons for rejecting any petition. The section requires initiation or denial of the action requested in any petition within one year and

deems rejection or denial of a petition to be final agency action, thereby subjecting it to judicial review under the Administrative Procedures Act.

Section 3401 was added to create a petition process that, under certain circumstances, will allow an interested party to revise significant risk assessments connected with existing regulations, certain other risk assessments, and any major rule as defined in section 3201(e)(3).

The petition process empowers ordinary Americans to help find and improve prior risk assessments and, where appropriate, correct past regulatory mistakes, while erecting sufficient safeguards to prevent a flood of meritless petitions. To ensure that the petition process does not place an undue burden on covered agencies, Section 3401 requires the petitioner to include adequate supporting documentation, including, where appropriate, new studies or other information that provides the basis for the change requested in the petition. Where the petition describes a risk, it should include a summary risk characterization that is consistent with the requirements of Title III. Petitioner further carries the burden to document that a rule is a major rule as defined in section 3201(e)(3).

Under 3401(b), the rejection or denial of a petition is deemed to be a final agency action under the Administrative Procedures Act. This provision allows an unsuccessful petitioner to seek judicial review of an agency's refusal to take the action requested by the petitioner. Under this provision, the reviewing court will compel the agency to take the requested action if the petitioner can show that the petition included adequate evidence to support the requested action and that the agency's refusal or denial of the petition is inconsistent with the standards of Section 3401. Subparagraph 3401(b) sets a requirement to either initiate the requested action or deny the petition. There is no requirement concerning the timing to complete the actions. Such time period should be reasonable given the particular task but not so long as to provide a means to escape the purpose of this section.

## SUBTITLE E—PLAN

### *Section 3501. PLAN for assessing new information*

This section requires each covered agency to publish a plan to review and, where appropriate, revise significant risk assessment documents and risk characterization documents with 18 months of the date of enactment if the agency determines that the principles in sections 3104 and 3105 would likely significantly alter the prior results of those documents. It provides that each plan must provide procedures for considering public comment, and may establish priorities for review and revision based on whether economic resources can be more effectively focused. It requires that each plan be developed after notice and an opportunity for public comment, and in consultation with State and local governments and other Federal agencies. The plan must go through public notice and comment and, thus, provide a clear and open set of procedures to supplement the petition process in Subtitle D.

SUBTITLE F—PRIORITIES

*Section 3601. Prioritization*

This section requires the President to identify opportunities for regulatory agencies to reflect public health priorities within their programs. The President must identify the likelihood and severity of the public health risks addressed; the number of persons affected; the incremental costs and benefits; the cost-effectiveness of risk reduction strategies; intergovernmental relationships within regulatory programs; and obstacles to allocating resources cost effectively to serve public health priorities. The President must annually report public health regulatory priorities to Congress.

Too often Federal health risks are not prioritized. Rather than following an established procedure, agencies respond haphazardly, with the result being an overregulation of some risks, under-regulation of others, and reduction of agency effectiveness and credibility. An effective priority setting process incorporates scientifically sound risk assessments, comparative risk analysis based on generally accepted societal values, and risk management choices grounded in cost-benefit principles.

## ADDITIONAL VIEWS OF MESSRS. BLILEY, OXLEY, AND BILIRAKIS

We provide these additional views to state our support for this legislation, which provides a strong measure of regulatory reform, and to comment on some of the proposed amendments that we could not support.

Congress shares responsibility with the Executive Branch, and State and local governments for hundreds of billions of dollars in regulatory costs. At this time, the legislative record of the 103d and 104th Congresses shows that a substantial portion of State and local governments, businesses and the scientific community have lost confidence in Federal risk assessment and characterization processes which form the basis of much of these regulatory costs. These groups, with sufficient reason, believe that too many Federal programs commit national economic resources to reduce risks that are excessively hypothetical or very small. These requirements constitute "unfounded" mandates that drain resources from other priorities at the Federal, State and local level.

Many outside the Washington D.C. beltway further believe, with sufficient reason, that Federal regulatory decisions fail to consider whether the incremental costs of specific regulatory options are justified and reasonably related to the purported risk reduction benefits. The record also reflects that Federal regulatory decisions create inflexible requirements that are not cost-effective in addressing a given level of risk reduction. The Executive Branch, however, can legitimately complain that existing statutory provisions actually restrict it from issuing regulations that are reasonable with respect to the above concerns.

Many Members of the 103d Congress sought to take significant steps to address these concerns. Unfortunately, the Democratic leadership of the 103d Congress and the Clinton Administration opposed these steps. In a number of instances, the Democratic leadership simply would not allow a vote on the floor for fear that significant legislation that would address risk assessment reform and require consideration of costs and benefits would in fact pass. If this Congress does not take enforceable steps to restore the credibility of the regulatory process concerning risk assessments and the costs and benefits of regulations, then there will be an even bigger freshman class elected in 1996 than in 1994. This legislation was reported from the Committee by a recorded vote of 27 to 16. At this time, Republicans on the Committee, along with a small number of like-minded Democrats, again find themselves alone in this effort.

This legislation is a strong first step. We fully support changes to make the bill more effective, eliminate unintended consequences, and minimize unnecessary administrative burdens. However, to follow the mantra of the Administration, the framework of this bill is fair, effective and affordable. We simply disagree, however, with

the Clinton Administration and the minority on what these terms mean.

Title III as reported out of the Committee is fair because it requires that significant Federal risk assessment and risk characterization documents present information in an objective, unbiased and informative manner. The principles of Subtitle A require disclosure that will further promote fairness and greater public understanding. The record clearly shows that the current Federal practice in this area is both misleading and unfair. The legislation is also fair because it requires consideration of both costs and benefits and does not require any particular outcome from the regulatory process. The legislation simply requires careful and objective consideration of alternatives, costs and benefits in individual contexts. On balance, these principles will both save money and focus resources on the most significant risks.

Title III is also effective because the requirements are enforceable. As discussed below, the Executive Branch should abide by the law, subject to judicial review, just as States, local governments and businesses must. There should be no double standard.

Finally, Title III as passed out of the Committee is affordable because careful consideration and objective information will help ensure that hundreds of billions of dollars in annual economic costs are focused on real and substantial risk reduction. We cannot afford to continue to regulate without the information and factors set out in this bill. Informed decisionmaking—doing it right or, as a former Administrator of the Environmental Protection Agency states, aiming before we shoot—carries administrative burdens. The initial estimates of this burden are high but they specifically fail to account for the flexibility provided in the legislation and the boilerplate nature of much of the analyses.

For example, the legislation simply asks that rules which are likely to impose $25 million in annual costs be called major rules subject to Subtitle B. Under Subtitle B, costs and benefits are to be quantified "to the extent feasible and appropriate and may otherwise be qualitatively described." Nothing requires a "Cadillac" analysis. Perhaps the legislation should. Twenty-five million dollars in annual costs is not a small sum of money. Home buyers and car buyers certainly make an effort to acquire objective information and carefully consider alternatives before purchasing. Businesses must do the same before making major investments. State and local governments have been forced to make painful choices concerning education and crime prevention because of unfunded and "unfounded" Federal mandates. Why shouldn't Federal regulatory programs be subject to the same constraints?

During the markup of Title III of H.R. 9, a number of amendments were offered and rejected. We would like to outline our concerns with some of these amendments.

Mr. Rush offered an amendment that would have explicitly prohibited courts from reviewing whether the covered Federal agency had complied with the requirements of Title III. The exact language of the Rush amendment was, in part, as follows:

> Nothing in this title creates any right to judicial review or administrative review, nor creates any right or benefit substantive or procedural, enforceable at law or equity by

> any party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

We voted against this amendment because it would have rendered Title III unenforceable. If the requirements of Title III are not subject to some form of judicial review, the Title stands as little more than a non-binding resolution of mere congressional preference concerning risk assessment practices. Judicial review of the requirements of Title III is essential to ensure that risk management decisions are based on objective and unbiased information.

Mr. Markey also offered an amendment that would have altered the fundamental effect of the legislation. While attractive at first glance, it would have vitiated Title III by preventing Federal agencies from revising their risk assessment and risk management practices to improve the Federal government's overall efficiency in addressing risks and improve cost-effectiveness. Mr. Markey's amendment provided that "[n]othing in this title shall be implemented in a manner that reduces the degree or level of protection of human health or safety or the environment otherwise provided by law."

The Markey amendment fails to recognize the balance between incremental costs and benefits. Title III, as reported out of Committee, is designed to influence change in Federal regulatory programs in a fair and effective manner. The construct of the bill is to provide information to regulators and the public to make wise use of resources. In some instances, this will mean a greater investment of economic resources; in others, it will mean avoiding the expenditure of large amounts of economic resources for marginal and, often, hypothetical levels of risk reduction benefits. The Markey amendment would have eliminated the central construct of the legislation.

Mr. Markey also offered an amendment that would have prohibited individuals with a financial interest in the outcome of a peer review from participating in such peer review unless the financial interest is disclosed to the agency and the agency determines that such interest will not reasonably be expected to create a bias in favor of obtaining an outcome that is consistent with such interest. We opposed this amendment for the following reasons.

First, Mr. Markey's amendment takes a naive and rather unrealistic view of the peer review process. In many instances, few people may be qualified to review the underlying science of Federal regulatory decisions, which are typically very complicated. Many of the people most likely to be qualified with the appropriate expertise are those who have received grant money from a company interested in the outcome. Second, one of the basic ideas behind the bill is to allow for full public participation. To cut off the productive sector from participating in risk assessments, despite provisions in the bill to ensure the disclosure of financial interests, is directly contrary to the open process the Committee is trying to foster.

We also had concerns about two amendments offered by Mrs. Lincoln which may have sounded good on initial review, but ultimately seemed based on a misapprehension of the bill's effects. These amendments stated that nothing in the bill shall force changes in State regulations or require businesses with fewer than 100 employees to conduct more tests. The bill has no application

to State regulations except insofar as State laws tie their scope and standards to Federally adopted standards. Nor does the bill have any requirement that businesses must perform risk assessments. We note that the National Federation of Independent Businesses has stated its support for Title III.

In the case of both amendments, we believe that overall Title III will dramatically lessen Federal regulatory burdens on State and local governments and businesses of all sizes by requiring that Federal regulations be based on sound science and cost-justified. As a result of Title III, individual changes in Federal regulatory programs may increase or decrease regulatory burdens based on context. Title III does not predetermine outcomes, but it does require application of a process which overall will scientifically and economically justify Federal efforts.

Finally, Mr. Brown offered a substitute amendment that rolled together several of these amendments, and added other language that would have prevented the bill from having its intended effect. One provision stated that any agency action taken without conforming to this bill would not be considered a prohibited regulatory action. Another provision would have allowed any agency to avoid the requirements of the legislation any time the agency head deemed the agency was unable to meet them. In essence, such language makes compliance with the bill optional, as the agency head sees fit. We feel that such language demonstrates the basic opposition of the minority to the idea of fir, objective risk assessments and cost-justification of regulatory actions.

Title III is a strong effort toward better Federal regulation. We fully support changes that will make the bill more effective, eliminate unintended consequences and minimize unnecessary administrative burdens. However, we have a strong disagreement with many of the steps the minority proposed in an effort they contend was designed to improve the bill.

Congress must help ensure an effective and workable system of accountability, disclosure, peer-review, and careful analysis of alternatives. In the end, we must ensure that the Federal government can stand behind and justify regulations based on the facts. Title III is the right down payment toward this result.

THOMAS J. BLILEY, Jr.
MICHAEL G. OXLEY.
MICHAEL BILIRAKIS.

## ADDITIONAL VIEWS

The enthusiasm for risk assessment legislation is not new to the 104th Congress. Nor is it limited specifically to the Committee on Commerce or its predecessor the Energy and Commerce Committee. In the last Congress, I was a sponsor of H.R. 2910, the 1993 Risk Communication Act, which set some critical objectives and requirements for our system of communicating risks. H.R. 2910 was meant as a first step to ensure that we could compare and understand information from program to program.

The Committee on Science, Space and Technology also was interested in risk assessments and their use. The Science, Space and Technology subcommittee on Investigations and Oversight held

hearings in 1994 on unfunded environmental mandates and their effects on State and local governments. Speaking before the committee, on behalf of the National Association of Counties (NACo) was the Honorable Tom Davis, Chairman of the Fairfax County, Virginia, Board of Supervisors. Mr. Davis stated:

> One of the biggest problems we have is the environmental regulations and standards we are required to meet most often are not based on scientifically sound assessments of purported health, safety or environmental risk. Before requiring State and local governments to spend billions of dollars, we need to be sure that the standards we're required to meet will significantly reduce the risks. That's why NACo fully supports the Risk Communications Act (H.R. 2910) and we commend you and Chairman George Brown and other Members for sponsoring this legislation. If enacted, it will help promote risk assessment in developing future regulations.

While H.R. 2910 was never passed, Title III does incorporate the language regarding risk assessments.

EPA's Science Advisory Board, The National Governors Association, representatives of local governments and businesses are all asking for simple accountability for Federal regulatory programs. They want to make sure we are spending money based on assessments of real risks, not on assessments of excessively hypothetical and exaggerated risks. Assessing risks is the cornerstone of environmental decisionmaking and is important in other Federal agencies as well.

Everyday human activity produces many risks. For instance, driving 50 miles in a car creates approximately a one-in-a-million risk of a fatality. Similarly, how do we know whether naturally occurring radon gas poses a risk in homes or whether alar on apples or asbestos in schools are really a risk to our children? Almost half a billion dollars was lost on the alar scare along with almost $27 billion dollars on asbestos removal, much of which was not necessary.

These examples are only a few of the reasons that Title III and its language are needed. An unrealistic understanding of the nature and magnitude of risks produces unrealistic expectations, priorities, and programs which themselves cause needless administrative burdens on Federal agencies along with very costly burdens for local governments and businesses.

Unnecessary spending for programs that do little to protect human health and safety must be curbed. Title III sets some critical objectives and requirements for our system of communicating risks. It is a first step to ensure that we can compare and understand information from program to program and agency to agency. Title III will help ensure that each subsequent risk manager and the public shares the same information on risks. This is an important investment and worth the burden of changing to a new set of minimum requirements.

CARLOS J. MOORHEAD.

## ADDITIONAL VIEWS ON TITLE III, H.R. 9 BY MR. BARTON, MR. TAUZIN, MR. CRAPO

### SECTION 3401—PETITION PROCESS TO REVIEW EXISTING RULES AND RISK ASSESSMENTS

We believe the Committee took a very important step toward reform of outdated and mistaken existing regulations when it adopted by a voice vote the "petition process" amendment we sponsored. It is a vital part of Title III and should be included in the bill sent to the President.

The amendment establishes a process whereby interested parties can seek changes in existing regulations and other significant agency documents that are not consistent with the principles of Title III. Title III of H.R. 9 is designed to ensure that federal regulations are based on realistic and understandable estimates of health, safety, and environmental risks, and that federal agencies do not impose significant costs on American businesses and consumers in order to address risks that are trivial compared to the risks of daily life. As originally drafted, the provisions of Title III would have applied only to future regulatory actions.

Members of the Committee were concerned that it did not address existing regulations and other agency documents that support regulatory decisions. Many existing risk assessments supporting major rules should be updated to reflect current science. Therefore, we proposed that Section 3401 be added. We believe that *full* regulatory reform, which certainly must include a review of existing major rules, will not occur without a provision like the petition process in Section 3401.

JOE BARTON.
MIKE CRAPO.
BILLY TAUZIN.

## MINORITY VIEWS ON H.R. 9

We strongly support the goal of improving federal regulatory programs through greater use of risk assessment, cost-benefit analysis, and peer review. These analytical tools can help agencies do their jobs better, limit burdens on private industry, and reduce government waste. We also believe federal agencies must be held to high standards in terms of getting the biggest "bang" for every dollar spent on laws to safeguard health and the environment. The Nation cannot tolerate excessive industry regulation, or excuse sloppy or biased regulatory programs.

We feel just as firmly, however, that environmental, health, and safety laws, which Congress adopted after careful consideration, are on the books for good reasons. While legislation to improve regulatory analysis is desirable, it must not swallow up the larger purpose of protecting health, safety, and the environment. The question is not whether regulatory reform is important—but rather how to achieve it in the most cost-effective and responsible manner.

The bill reported by the Committee is deeply flawed and will undermine important statutory protections. Rather than directing agencies to perform useful analyses as adjuncts to better policy, the bill treats analysis as a goal unto itself. In fact, H.R. 9 as reported will create many new layers of bureaucracy, clog the regulatory process, invite litigation, and impose substantial new costs on the federal treasury while doing little to improve the efficiency of our regulatory agencies.

### THE DEMOCRATIC ALTERNATIVE

During the Committee markup, Mr. Brown of Ohio offered a Democratic alternative that requires covered agencies to conduct risk assessment and cost-benefit analysis for all major rules. It also requires agencies, consistent with other applicable law, to demonstrate that the benefits justify the costs of major rules and to identify the most cost-effective options for carrying out regulatory responsibilities. The amendment directs agencies to develop standards for how and when to conduct scientific peer review. The amendment also requires agencies to establish regulatory priorities based on the seriousness of risk and risk reduction opportunities, taking into account available public and private resources. The amendment, however, does not permit analytical tools to become the masters of the statutes they should serve or to erect a monumental bureaucracy that undermines the goal of protecting public health, safety, and the environment.

We are surprised that, only a few days after the House of Representatives approved a balanced budget amendment to the U.S. Constitution, the Committee is reporting legislation that will dramatically increase the size and staffing needs of the federal government. Under the leadership of Vice-President Gore's "Reinventing

Government" initiative, the Administration is making real progress in streamlining and downsizing government. Since the start of the Clinton Administration the federal government has been reduced by 102,000 employees. By the end of the next fiscal year, it will have been reduced by approximately 170,000.

This bill will reverse that trend. It will demand a much bigger federal government, staffed by more agency employees to carry out its requirements. A Majority of the Committee approved this bill with no consideration of the cost or impact on the size of government. By contrast, the Democratic alternative provides a much less costly, less bureaucratic, and less complicated way to ensure that government regulatory actions are based on sound science.

OVERRIDING EXISTING HEALTH, SAFETY, AND ENVIRONMENT STATUTES

Over many years, Republican and Democratic Presidents alike have proposed, and Congress has enacted, specific laws to protect the American people from identifiable threats to human health, safety, and the environment. These statutes cover a wide range of concerns—protecting women from breast cancer, protecting children from unsafe toys, regulating emissions of hazardous air pollutants, providing for worker safety, and providing for clean rivers and safe food and drinking water, among others. The standards for protection differ from statute to statute. Each was carefully worked out for a particular set of reasons, based on particular circumstances posed by a particular threat.

With little review and no analysis of consequences based on the record, the Majority at the last minute added a provision to H.R. 9 (section 3201(c)) that supplants the standards and decisionmaking criteria of all existing health, safety, and environmental statutes. The bill as reported applies the same decisionmaking criteria to all statutes without regard to the implications for each of the individual threats to our health or safety.

This strict adherence to uniformity is badly misdirected. Indeed, completely contrary to the Majority complaints about "one-size-fits-all" mandates, this bill establishes a "one-size-fits-all" criteria for risk assessment and health and safety standards. We expect, at the outset, protracted litigation over whether the decisionmaking criteria of the cost-benefit subtitle conflict with standards and criteria of current law. No one knows what competitive impacts will result for companies and industries that have undertaken significant investments in new technology or processes to comply with existing legal standards. Delay of ongoing and necessary government actions to protect public health and safety inevitably will occur. There are many examples, but a few will suffice to illustrate the point:

1. *Mammography Quality.* Over 50,000 women each year die from breast cancer. Many of these deaths can be prevented through early detection and treatment. Providing women access to quality mammography services is a key to early detection of breast cancer. The Mammography Quality Standards Act of 1992 required the Secretary, who is acting through the Food and Drug Administration (FDA), to ensure that quality through the regulation of facilities delivering mammography services.

The statute requires that all mammography facilities be accredited and certified and establishes quality standards for accreditation. Under these standards, for example, 1) a medical physicist must survey mammography equipment and oversee quality assurance practices at each facility and 2) mammography facilities must maintain each patient's mammogram in the patient's permanent medical records for a specified period of time.

The statute specifies these requirements. There are no subjective decisional criteria to be applied. Because such regulations likely would exceed the $25 million threshold for application of H.R. 9, however, and because section 3002 of H.R. 9 states clearly that FDA is one of the agencies covered by the bill, the agency will in the future be expected in issuing regulations to implement the mammography statute to incorporate the requirements of H.R. 9 and elaborate on their application.

Under H.R. 9, the survey and record retention regulations would need to be justified by the agency as both the most cost-effective and the most flexible for the industry. It is unclear whether the agency could adopt the most cost-effective approach if it were not also the most flexible. It is also unclear what type of information, if any, would be available to the agency to make such determinations. Were it unable to develop either justification, it could not promulgate the regulation. Moreover, even if the agency were able to develop the necessary justification, that justification could be challenged in court. Thus, the effect of H.R. 9 is to create two opportunities, one for the agency and one for the courts, to overturn the clear statutory mandate of mammography facility quality standards.

2. *Inspection & Maintenance (CAA).* The enhanced motor vehicle inspection and maintenance program under the Clean Air Act of 1990 is required only in the most heavily polluted areas. According to recent testimony from the EPA Administration, this program is by far the most cost-effective air pollution control means, achieving reduction in emissions of volatile organic compounds at a cost of just over $500 per ton compared to $2,000 to $10,000 per ton for controls at stationary services. Applying the cost-effectiveness and flexibility decisionmaking mandates of section 3201 may well require the adoption by EPA of a nationwide enhanced inspection and maintenance program. This would transfer emission reduction burden from major industries to the average citizen—contrary to the Congressional determination in 1990.

3. *Hazardous Air Pollutants.* Title III would supersede the current technology-based approach for regulating hazardous air pollutants under section 112 of the Clean Air Act. Instead it would likely force the EPA to return to a process of analyzing risks and sources of individual pollutants similar to that employed by the agency from 1970 to 1990. Over those 20 years, EPA managed to set standards for only seven hazardous air pollutants. EPA was mired in endless debates over risk assessment and cost-benefit analyses for cancer risks and other risks (birth defects, reproductive effects, etc.) that are difficult or impossible to quantify. This process requires years of analysis for each pollutant and each source of pollution.

In 1990, Congress acknowledged the failure of the risk-based approach to protect public health and replaced it with a technology-based system. The emissions standards for hazardous air pollutants "shall require the maximum degree of reduction in emissions of hazardous air pollutants . . . that the Administrator, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements, determines is achievable for new or existing sources" in the subject category (Maximum Achievable Control Technology or MACT). A list of 189 pollutants was specified in the new law, and EPA was required to promulgate standards for major sources of these pollutants over a 10-year period.

Since 1990, EPA has been able to address 58 types of industrial toxic emitters, ranging from chemical plants to coke ovens. These actions will likely eliminate more than one billion pounds of toxic emissions annually.

Enactment of Title III, with its complex risk assessment and cost-benefit decisionmaking criteria, will confuse and undermine issuance of any further air toxics standards. It could reverse the gains already made by opening the door to petitions to revisit standards already in place.

4. *Hunting Season—Closed Before It Opens.* The sweeping approach of H.R. 9 will require the Fish and Wildlife Service to make various certifications, including that a cost-benefit assessment has been performed considering all risk assessments provided to the agency by any party, before it issues its annual regulations opening the waterfowl hunting season pursuant to the Migratory Bird Treaty. Tens of thousands of dollars will be wasted meeting irrelevant requirements. According to the Fish and Wildlife Service, under a best-case scenario, meeting the rulemaking certification requirements of H.R. 9 virtually will eliminate the 1995 hunting season in the United States.

INCREASED BUREAUCRACY AND BIGGER GOVERNMENT

The myriad complex requirements of H.R. 9, according to every responsible prediction and estimate, will create more paperwork and increase the number of bureaucrats who must be involved in decisionmaking and litigation. As Sally Katzen, Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OMB), testified:

> The effect of the requirements of Title III, whether taken alone or in conjunction with Title VII, is not to bring sound science to bear on regulation, but to load on the regulatory system so much that it cannot move forward, retarding substantially our ability to take sensible steps to protect human health and human safety and the environment while creating more bureaucracy, more paperwork, and less efficiency in government.

The extensive and prescriptive risk assessment requirements in subtitle A of Title III cover everything from major regulations, permits, and reports to Congress to the ambiguous category of "guidelines or protocols of general application." The drafters of the bill have insisted that it is not intended to provide a source of legal re-

lief for manufacturers who produce unsafe, contaminated, or filthy products. Yet, many factory inspections are based on guidelines or protocols of general application. This legislation thus aids companies who are determined to thwart the application of health or safety standards by creating a bureaucratic and legal maze for every guideline designed to ensure adherence to such standards—standards on which every American relies. Indeed, we were surprised by the Majority's refusal to expand the bill's narrow emergency exception even to accommodate "imminent" threats to human health, safety, or the environment, as Mr. Brown proposed in amendments at markup.

Although OMB reports that 96% of the total costs of government regulation occur as a result of regulations with an economic impact of $100 million or more, the risk assessment, cost-benefit analysis, and peer review requirements of Title III extend to additional regulations with a national economic impact of $25 million. In a $7 trillion economy, this means that hundreds of government employees would be hired to scrutinize regulations that could have a financial impact of as little, on average, as $500,000 per state. We note that President Reagan (Executive Order 12291) selected $100,000,000 as the appropriate rulemaking threshold for requiring cost-benefit analyses and every subsequent President has followed suit.

H.R. 9 creates a complicated labyrinth of decisionmaking, requiring agencies to: engage in analyses and re-analyses; perform specific types of comparisons (whether relevant or not); provide detailed explanations, calculations, estimations, representations, and recapitulations; and "certify" to a series of complex decisionmaking criteria. It requires at least one level of peer review, and more in cases where the decision may have a "significant" policy impact. It requires peer review not only of scientific matters but of economic analyses as well. While couching these requirements in the murky fuzz of "if feasible or appropriate," the bill actually limits the agency's ability to determine what is or is not appropriate, and will lead to endless debates over whether a particular action is feasible.

The petition process added by amendment during Committee markup requires agencies to establish a mechanism whereby any citizen may ask the agency retroactively to review—and potentially revise—any risk assessment associated with a major rule and "any health or environmental effects value . . . in . . . any compilation . . . used . . . as a scientific basis for regulatory action" at the local, state, or federal level. The agency is required to respond to each petition within 90 days and, within one year, either to deny the petition and provide reasons for doing so or to initiate the "action requested in the petition."

Thousands of such petitions may be envisioned under this process, challenging virtually every environmental, health, or safety rule on the books today. The agency's denial of any such petition, or its failure to act in accord with these requirements (including failure to meet preposterously short time frames), is specifically subject to legal challenge. Today, without this incredibly burdensome petition requirement, citizens have the right to—and do—petition regulatory agencies in a logical time frame through a well-defined process. Such agencies will be required to increase their

staffing manyfold to deal with the flood of petitions that may well result from enacting this provision.

DRAGGING SCIENCE THROUGH THE COURTS

The petition process will not be the only source of litigation generated by H.R. 9. The bill as reported is nothing short of a lawyer's relief act. It invites litigation concerning virtually every significant agency decision assessing risks and determining cost-benefit relationships. These legal challenges will not necessarily be limited to the agency's substantive decisions, or even to the procedural lapses that are the traditional province of the courts under the Administrative Procedure Act. Instead, they will render every hypertechnical step in the entire process vulnerable to judicial second-guessing.

Wholly apart from the vague, duplicative, and inconsistent provisions that set Title III of H.R. 9 at war with other titles, Title III itself will spawn ceaseless, circular battles over matters that lawyers and unelected federal judges are peculiarly unsuited to resolve. Such cases will revolve around issues of science on which more often than not the scientists themselves disagree and around data which are highly susceptible to subtle manipulation and subjective interpretation. We know from experience that the evidentiary tools and equitable remedies available to a federal judge are rather blunt and unsatisfactory instruments for the resolution of complex scientific disputes.

Both the introduced version of the bill and the Republican substitute offered in the Committee left somewhat unsettled the question of whether and to what extent judicial review of agency risk assessments and risk-characterization analyses would be available. Those doubts, however, were settled upon the adoption of the Barton amendment, which makes clear that a reviewing court "shall consider the agency action unlawful" if a significant risk assessment or characterization document "does not comply with the requirements of section 3104 or 3105."

These two sections purport to set forth "principles" for risk assessment, characterization, and communication. Their evolution—and their interaction with the Barton amendment—are a telling example of how the bill's proponents, when criticized for trying to cripple outright the federal government's ability to respond to health, safety, and environmental threats, have sought to accomplish the same end by clever indirection. The Administration's testimony criticized the bill in general, and sections 3104 and 3105 in particular, for imposing a highly prescriptive, one-size-fits-all regime on every statute, program, agency, and major regulation dealing with health, safety, and the environment. The Administration sought the introduction into those sections of a greater rule of reason to guide agency decisionmaking.

The Republican substitute responded to those concerns by adding phrases like "to the maximum extent feasible," "to the extent relevant," "to the extent feasible," "to the extent feasible and scientifically appropriate," "to the extent practical and appropriate," and so forth. In the absence of judicial review, these phrases would have been a helpful guide to the agencies and—together with an element of "reasonableness" still missing from the legislation—

would have provided some commonsense flexibility in the prescriptive nature of these two sections. With the adoption of the Barton amendment, however, every of these phrases becomes fodder for a lawsuit, each word susceptible to the subjective and elastic interpretations for which thousands of lawyer-hours will be billed. If H.R. 9 is exacted with these provisions intact, we would not be surprised to see risk assessment and cost-benefit lawsuits become the biggest growth market for the American bar, as law firms all over the country tap into this litigation gold mine. Sadly, their clients and ultimately all taxpayers will foot the bill for this folly.

Many in American business who support this legislation in its current form genuinely believe it will be advantageous to them, but creating new causes of action can be a two-edged sword. We cannot (and should not try to) create these rights only for industry. When we allow our government's decisions to be challenged, our courts must be open to any and all aggrieved parties. Yet the Barton amendment and this bill as reported will put a powerful new tool in the hands of environmental groups, public interest organizations, consumer advocates, local community associations, and others who will be able to sue agencies by arguing that the risks and costs of any new agency decision in favor of business (such s decisions in favor of siting or permitting facilities, or even renewing existing permits) were not appropriately considered.

All of these groups, like business and industry, have available to them under current law a whole panoply of remedies that allow agency decisions to be challenged. If an agency violates a substantive statute, or makes a decision that is not supported by the record, or takes an action that is arbitrary and capricious, aggrieved parties may take their case to court. Under an amendment offered by Mr. Rush and unfortunately rejected by the Committee, whatever rights any person may now have to sue—whether under the APA or under the actual substantive statutes themselves—would have been preserved. But the Rush amendment also would have ensured that this legislation itself would spawn no new litigation.

In cases where parties aggrieved by agency action must resort to the courts for relief, the disagreements at issue generally revolve around disputed questions of law, which the courts are uniquely well-suited to decide, or around disputed but relatively narrow issues of fact, rooted in a carefully constructed administrative record, which can be remanded if necessary to an expert agency for further resolution. The courts, however, are most certainly not the best place in which to resolve complex disputes over risk, cost-benefit ratios, and other highly technical scientific and statistical questions—as to which there is often no consensus even within the relevant scientific community. In reporting this legislation, the majority has elected to encourage frivolous litigation and to anoint lawyers and judges as the arbiters of scientific disputes.

### WHY THE RUSH TO JUDGMENT?

This sweeping legislation was introduced on January 4, 1995, and in spite of its massive implications for the whole fabric of American health, safety, environmental, and administrative law, only two days of hearings were held on it in our Committee on Feb-

ruary 1 and 2. The three subcommittees to which the bill was referred were not permitted time to mark up the bill, and following one morning of opening statements on February 7, the legislation was pushed through a full Committee markup in a single ensuing day. The Oxley-Bilirakis Substitute, which essentially served as the markup vehicle, was not provided to the Members of the Committee until they arrived at the markup to deliver their opening statements, and it was not provided to the Minority staff for analysis until after 10 p.m. the night before.

Haste in the processing of legislation can be a useful but dangerous tool. It can be employed to hide controversial or obscure special interest provisions; it can be used to deny the Minority time to discover and publicize a bill's faults; and it can be to utilized to prevent an organization of effort in opposition to the legislation. But such a rush to judgment can have embarrassing and unintended consequences as well, since it denies even the bill's supporters an opportunity to learn of and correct its faults and weaknesses.

A single example will suffice to make the point. The Republican substitute offered at the markup purported to narrow the scope of Title III to a list of eight specific agencies. One of them is "The Department of Transportation (including the National Transportation Safety Administration)." We have searched diligently through the United States Government Manual and have been unable to find the National Transportation Safety Administration, either within DOT or elsewhere. Do the authors of the legislation mean the National Highway Traffic Safety Administration, which is one of DOT's modal agencies? Or do they mean the National Transportation Safety Board, which is not within DOT at all but rather an independent agency with no rulemaking authority but only the power to analyze the causes of accidents and make safety recommendations? [We wonder whether our Republican colleagues are even aware of this error. If so, they made no effort to correct it at the markup.] Like the mammography example in footnote 1 above, perhaps more time would have permitted more careful and deliberate consideration.

In this case, the rush to judgment seems to have been driven not by a desire to do what is right or even what is popular, but by a schedule for floor consideration fixed arbitrarily by the Republican leadership without any regard for the need to address the defects in this bill. We regret that in the service of this arbitrary deadline, the Majority has elected to depart from the tradition of careful and precise legislating for which this Committee has been traditionally and justly proud. We can only wonder what other errors, perhaps even more serious, lie embedded in the text we have had so little time to review and consider.

## CONCLUSION

As this legislation advances toward the floor of the House, we will continue to support the imposition on our federal bureaucracy of a strong and credible program of risk assessment, cost-benefit analysis, and peer review to guide regulatory action. However, in order to earn our votes, such legislation must be rational, reasonable, carefully drafted, and well-tailored to the ills it seeks to ad-

dress. The version of H.R. 9 reported by the Committee fails every one of these tests. We hope that our Republican colleagues will abandon their taste for the straitjacket and the blunderbuss. Perhaps they might consider instead working cooperatively with us to craft a precise, finely tuned, and responsible piece of legislation that will accomplish the goals we all share—and to do so without undermining the fundamental protections of public health, safety, and the environment that have so dramatically improved American life in the last several decades.

JOHN D. DINGELL.
HENRY A. WAXMAN.
EDWARD J. MARKEY.
RON WYDEN.
JOHN BRYANT.
RICK BOUCHER.
THOMAS J. MANTON.
ELDOLPHUS TOWNS.
GERRY E. STUDDS.
FRANK PALLONE, Jr.
SHERROD BROWN.
BLANCHE LAMBERT LINCOLN.
BART GORDON.
ELIZABETH FURSE.
PETER DEUTSCH.
BOBBY L. RUSH.
ANNA G. ESHOO.
RON KLINK.
BART STUPAK.

## ADDITIONAL DISSENTING VIEWS OF MR. MARKEY

H.R. 9, as introduced, allows corporate insiders and lobbyists to serve on the peer review panels considering regulations that might have a direct economic impact on a particular corporation or industry. The bill provides that such peer review panels "shall not exclude peer reviewers merely because they represent entities that may have a potential interest in the outcome, provided that interest is fully disclosed to the agency."

The Republican majority's substitute took some partial steps towards alleviating the deficiencies of this provision. For example, the substitute provides that peer reviewers should be required to sign confidentiality agreements so that they would be barred from disclosing confidential trade secrets. I am pleased that our Republican colleagues moved to respond to this important problem, which I raised during the hearing process.

However, the Republican substitute fails to address the underlying problem in H.R. 9 of peer reviewers with potential financial conflicts-of-interest. The Republican substitute merely provides that "in the case of a regulatory decision affecting a *single entity* no peer reviewer representing such entity may be included on the panel" (italic added). Apparently my Republican colleagues were willing to concede that there are some circumstances under which a peer reviewer should be excluded because of a financial conflict-of-interest. However, since their exclusion is limited to rules that affect only one company, it would not be available in the vast majority of instances where a peer review panel would be convened—inasmuch as a proposed rule under consideration by the peer review panel might affect two, three, a dozen, or even a hundred companies. Under the Republican substitute, peer reviewers from each of the affected companies would be free to serve on the panel, despite the fact that they were employed by entities with a direct financial stake in the outcome of the agency rulemaking. This is exactly the opposite of what we should be trying to do with the scientific peer review process. It degrades the credibility of peer reviews and it calls into question the fundamental scientific and technical credibility of the entire peer review process.

Under an amendment I offered—which was unfortunately rejected by the Committee—peer reviewers would have been excluded when they are associated with entities that may have a financial interest in the outcome, unless such interest is disclosed to the agency and the agency has determined that such interest will not reasonably be expected to create a bias in favor of obtaining an outcome that is consistent with such interest. This amendment would have given the agencies the ability they need to receive both full disclosure regarding any potential conflicts-of-interest that could potentially lead a peer reviewer to have bias, and the authority for such agencies to exclude reviewers whose associations may give

rise to such a conflict. The opposition of the Republican Majority to this common sense provision is inexplicable, and raises serious concerns about whether the peer review process established under H.R. 9 will operate effectively to assure that agency rules have a strong scientific or economic basis, or whether it will merely be exploited by parties with an interest in the outcome of agency rules to generate additional litigation.

EDWARD J. MARKEY.

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