Testimony of

Jackson B. Browning

Corporate Director
Health, Safety and Environmental Affairs

Union Carbide Corporation

on behalf of the

American Industrial Health Council

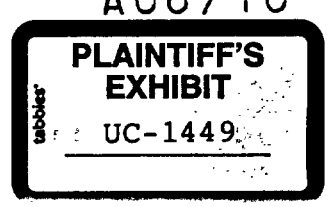
before the

Senate Governmental Affairs Committee

at hearings on S. 262 and other
bills providing for regulatory reform

May 18, 1979

A08710



Published by AsbestosClaims.Law
asbestosclaims.law/library/16577/1

Mr. Chairman and Members of the Governmental Affairs Committee:

I am Jackson B. Browning, Corporate Director of Health, Safety and Environmental Affairs for Union Carbide Corporation. On behalf of A-I-H-C, I wish to express appreciation for the opportunity to testify on the Chairman's bill, S. 262, and the other proposed regulatory reform measures before the Committee.

Our testimony addresses those sections dealing with the performance of a regulatory analysis. We have considerable first-hand experience with the issues raised by those provisions. The remaining provisions of S. 262 and the other bills before the Committee are significant and individual members of A-I-H-C have serious concerns about certain provisions in some bills (e.g., publ funding of intervenors in regulatory proceedings). However, A-I-H-C itself does not intend to comment on those provisions at this time.

The American Industrial Health Council

A-I-H-C is an organization of over 120 American companies and 60 trade associations which are coordinating their scientific and administrative resources to help the Federal government develop scientifically valid, reasonable policies for employee health in the industrial workplace. A-I-H-C's members include producers of chemicals, steel, aluminum, textiles, pharmaceutical products, oil and consumer goods.

When A-I-H-C was established in October 1977, OSHA was in the process of developing a generic regulation for the identificati classification, and regulation of carcinogens in the workplace. OS

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 2 of 24 asbestosclaims.law/library/16577/2

has not yet issued a final regulation but it has indicated that it will do so in the near future.

Summary of Comments and Recommendations

A-I-H-C understands that the Committee is seeking to develop a bill which will improve the regulatory decisionmaking process. We believe, along with the members of this Committee, that serious problems have arisen because Congress has not explicitly directed agencies to consider the economic impacts of their regulatory actions. The regulatory analysis requirements of S. 262 and the other bills before the Committee represent an important effort toward meeting these concerns.

The OSHA generic carcinogen rulemaking provides an excellent example, or case study, of how those regulatory analysis requirements could improve the federal regulatory decisionmaking process, enhance the delivery of benefits and reduce the cost of regulation. If this type of legislation had been in effect during that proceeding, we believe it would have been more focused and more likely to produce a reasonable, efficient approach to the regulation of workplace hazards.

The OSHA proceeding also demonstrates the need for certain modifications in the pending legislation in order to meet the objectives of the Committee. Based upon our experience in that proceeding, A-I-H-C's principal recommendations are that,

- The regulatory analysis provisions should be given substantive effect by requiring that the benefits of a rule be reasonably related to the compliance costs that must be borne.

- The regulatory analysis should be part

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 3 of 24 asbestosclaims.law/library/16577/3

of the record of a regulation subject to judicial review and be considered by a court at the time of its review of the regulation.

- All federal agencies should conduct a thorough analysis of the beneficial effects and economic and societal impacts of each alternative method of achieving the regulatory objectives.

- To ensure a full and balanced discussion of the desirability of the regulatory objective and alternative means of achieving it, there should be an opportunity for public comment prior to issuance of the proposed regulation.

- Regulations should set performance objectives rather than rigid design and operating standards where feasible.

- There should be external executive and legislative review of regulatory analyses to ensure their compliance with the legislative requirements.

Although passage of a regulatory reform measure would result in substantial improvements in regulatory decisionmaking, such legislation is not a panacea for all of the current regulatory problems faced by industry. As the President stated when submitting the Administration's regulatory reform bill,

> "All regulatory programs were created by legislation and many of their problems can be solved only be amending individual statutes. Much of the trouble with regulation built up because laws have gone unchanged in spite of changing needs."1/

For example, our experience with legislation concerned

1/ White House Press Release, at 5 (March 26, 1976).

A08713

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 4 of 24 asbestosclaims.law/library/16577/4

with health hazards has demonstrated that the failure to separate scientific determinations from regulatory policy determinations is a fundamental deficiency which the pending legislation does not address.

I. THE BENEFICIAL EFFECTS OF A REGULATION SHOULD BE REASONABLY RELATED TO ITS ECONOMIC AND SOCIETAL COSTS

S. 262 and the other regulatory reform measures before th Committee represent a major step toward improving the regulatory decisionmaking process. However, there is a danger that the regulatory analysis mandated by this legislation could become a me academic exercise. To avoid that result, it is essential that the bill require such an analysis to be a significant part of the decisionmaking process.

A-I-H-C therefore recommends that S. 262 require that a regulatory analysis include an analysis of both the beneficial effects and the economic and societal impacts of each alternative approach considered by the agency, whether or not existing law requires such factors to be considered by the agency. To reduce the inflationary costs imposed by over-regulation and mis-regulati S. 262 also should require agencies to find that the benefits of a final rule are reasonably related to the economic and societal cos of compliance.

The Regulatory Analysis Review Group, chaired by the Council of Economic Advisors, recently stated in commenting upon EPA's proposed hazardous waste guidelines and regulations, "Efficient resource allocation requires that expenditure on

A08714

pollution control be directly related to the benefits which they are expected to produce." The Administrative Conference of the United States recently echoed this same view: "Wise decisionmaking presupposes that the potential benefits and costs of the actions under consideration will be identified, will be quantified if feasible, and will be appraised in relation to each other."[1/]

The Joint Economic Committee in a report published last April estimated that the annual cost of governmental regulation for fiscal year 1979 will exceed $102 billion, up 40% since 1976. (Cong Rec. March 5, 1979, at S 2024.) The rapid increase in the costs of regulation occurring as the social regulatory programs of the last decade begin fully to impact industry strongly suggests that Congre should ensure that these costs are reasonable in light of the benefits they produce.

For example, in issuing its standard for benzene OSHA made no attempt to analyze the health benefits that would result fr the required control measures or relate those benefits to the $500 million to $1 billion in costs. OSHA takes the position that the compliance costs of a standard are relevant only where the standard would "cause 'massive dislocation of industry' or 'imperil the existence' of the industry."[2/] The Fifth Circuit Court of Appeals struck down the benzene standard because the health

---

1/ 44 Fed. Reg. 12198 (March 6, 1979)(emphasis added).

2/ Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit, on behalf of the Secretary of Labor, at 13 n. 8 (filed December 1978).

A08715

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 6 of 24 asbestosclaims.law/library/16577/6

a "reasonable relationship" to the compliance costs imposed.

Congress should make clear that agencies must justify regulations having as significant an economic impact upon the economy as the benzene standard. Requiring agencies to analyze economic impacts and beneficial effects of proposed regulatons as S. 262 generally does, provides a framework for improved decision-making. Mandating that agencies find that the compliance and societal costs of a rule are reasonably related to its benefits should ensure that improvements actually occur.

The bill also should require agencies to allow the use of the most cost-effective approach in reaching regulatory objectives unless an agency finds there are good and sufficient reasons for taking a more costly approach. However, the most cost-effective means of achieving a particular regulatory objective may have an economic impact that is completely disproportionate to the value of the benefits obtained. It is for this reason that A-I-H-C recommends that the principal determination an agency should be required to make is whether the benefits of a regulation are reasonably related to its costs.

II. OSHA FAILED TO EVALUATE RISKS, BENEFITS OR COSTS ASSOCIATED WITH ITS PROPOSED GENERIC REGULATIONS

A. The OSHA Generic Regulation

A brief review of OSHA's generic carcinogen rulemaking illustrates both the need for regulatory reform legislation like S. 262 and certain areas in which it should be strengthened. OSHA's proposed regulation is referred to as a generic regulation because it will establish rules by which substances will be identified and

A08716

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 7 of 24 asbestosclaims.law/library/16577/7

controlled as carcinogens according to the nature of the evidence of their carcinogenicity. In turn, the classification of a toxic substance will determine automatically the controls which will be placed upon exposure to the substance, regardless of whether any benefits are demonstrated or not.

In future rulemaking hearings aimed at issuing occupational safety and health standards for specific substances, OSHA proposes not to allow the introduction of any new scientific evidence bearing on the invalidity of the identification criteria or the inappropriateness of the mandatory control measures. Thus, evidence challenging those determinations, no matter how compelling or persuasive, would not be admissable in future hearings on specific substances. The generic regulation itself would have to be challenged to change any of these determinations; a slow, cumbersome and expensive procedure.

B. The Impact of the Regulation

The proposed generic regulation would determine to a large extent the control mechanisms to be mandated for specific substances. For example, a substance which produces benign tumors in a single animal test and a positivie response in a short term test for mutagenicity would be classified in the "confirmed carcinogen" category, or Category I. Substances in Category I would be subject to the following generic control requirements without a determination of the benefits of control and whether the benefits are reasonably related to the cost:

- Control of exposure to the lowest feasible level without consideration of potency of the substance;

A08717

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 8 of 24 asbestosclaims.law/library/16577/8

- Control of exposure to the mandated level by means of engineering controls, rather than personal protective equipment or other protective measures;

- Prohibition of all exposure if "suitable substitutes," an undefined term, are available;

- Prohibition of all eye or skin exposure; and,

- Extensive recordkeeping, monitoring and medical examination requirements.

OSHA proposed this control system for all substances meeting the criteria for Category I classification despite the fact that OSHA acknowledges that there is more than a millionfold difference in the potency of animal carcinogens which could fall within this category. Because the regulation does not provide for any differentiation between substances according to their carcinogenic potency, a low potency substance such as saccharin possibly could be subject to the same control measures as a very potent carcinogen like bischloromethylether.

C. OSHA's Analysis of the Regulation

When it proposed its generic carcinogen regulation, OSHA stated that the economic impact statements required by Executive Orders 11821 and 11949 would be performed in future rulemakings conducted on individual substances. The generic regulation was claimed by OSHA not to have any direct cost impact. Therefore, OSHA did not:

- Estimate the risk to workers from exposure to the substances to be regulated;

A08718

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Test... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 9 of 24 asbestosclaims.law/library/16577/9

- Estimate the benefits to workers from such control of exposure;

- Estimate the projected costs to industry of implementing the control measures; or

- Analyze alternative approaches for reducing exposure to carcinogens in the workplace to acceptable levels.

Although determinations which would control the costs of regulating potential workplace carcinogens would be made in the generic proceeding, OSHA proposed to defer consideration of costs to future rulemakings on specific substances where these determinations could not be altered.

The Foster D. Snell Division of Booz, Allen & Hamilton, Inc. prepared for A-I-H-C under very severe time constraints a preliminary cost study of the proposed regulations. The costs of compliance for three regulatory scenarios at two levels of control were examined. The estimated, direct compliance costs were as follows:

A08719

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 10 of 24 asbestosclaims.law/library/16577/10

Direct Compliance Costs ($ Billion, 1977)

Scenario 1/	Capital Cost 10 ppm	Capital Cost 1 ppm*	Annual Cost 10 ppm	Annual Cost 1 ppm
Low scenario (38 high volume substances)	9	23	6	11
Medium scenario (1,870 substances)	17	47	10	20
High scenario (2,415 substances)	30	88	18	36

(Source: Snell Report at 29.)

*Reduction of airborne concentrations to the 10 or 1 part per million level.

1/ The low scenario assumes that regulations will be issued coverir the 38 substances on the 1976 NIOSH suspected carcinogen list that are produced at levels above 25 million pounds per year and that have been assigned to Category I or II (based on the proposal's classification criteria) by the staff of NIOSH's National Occupational Hazard Survey (NOHS).

The medium scenario assumes that 1,870 substances from the 1976 NIOSH suspected carcinogen list will be regulated as assigned to Category I or II by the staff of NOHS.

The high scenario assumes that all 2,415 substances on the NIOSH suspected carcinogens list will be regulated whether or not they have been categorized by the NOHS staff.

A0872C

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 11 of 24 asbestosclaims.law/library/16577/11

However, the significance of the Snell Report lies not in the preliminary cost estimates, but rather in the inescapable fact that the economic impact of this rulemaking is likely to be substantial by any standard. A methodology for a complete economic analysis was set out in an appendix to the preliminary cost study prepared by Snell. (A copy of this methodology is in the Snell Report which has been submitted to the Committee.)

In March of 1978, the President issued Executive Order 12044. After the close of the rulemaking hearing in July, OMB prevailed upon OSHA to conduct a regulatory analysis pursuant to Executive Order 12044. OMB recognized that the economic impact of a generic regulation which preempts later regulatory decisions would never be evaluated unless it was evaluated prior to adoption of the generic regulation.

OSHA's regulatory analysis was made available after the close of the public comment period on the proposed regulation. The administrative law judge who had conducted the proceeding re-opened the record to receive comments on the regulatory analysis. Comment were submitted by A-I-H-C, the Regulatory Analysis Review Group (RARG) and others.

The comments of A-I-H-C and others noted that OSHA had made no attempt in its regulatory analysis to estimate benefits, risks, or costs associated with the proposed generic regulation. These comments also disputed OSHA's contentions that risk assessments evaluating the danger of exposure to carcinogens could not be made and that the costs of such a regulation could not be estimated.

A08721

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 12 of 24 asbestosclaims.law/library/16577/12

The recent publication by the Interagency Regulatory Liaison Group, of which OSHA is a member, of a document on risk assessment for suspected carcinogens establishes that scientific risk assessments for human cancer risks can be made. The Foster D. Snell Study also set forth an appropriate methodology for estimating the economic impacts of the proposed regulation.

OSHA did not give serious consideration to the alternative proposals presented during the hearings. For example, OSHA failed to examine a significant alternative proposed in September 1978 by the RARG. The RARG alternative called for separation of the scientific function of identifying and evaluating the potential risk from carcinogens and the regulatory function of setting standards based on a weighing of risks and benefits and costs. The RARG alternative also suggested that OSHA make greater use of personal protective equipment for reducing exposure instead of expensive engineering controls. OSHA also did not consider an alternative similar to RARG's proposed by A-I-H-C in February 1978. We believe the A-I-H-C proposal would provide workers with protection as great as OSHA's proposal but in a less burdensome manner.

These deficiencies in OSHA's regulatory analysis were recognized by the RARG, which concluded:

> "Because both the potential costs and benefits are likely to be very large, and because of the proposals' inflexibility and lack of sensitivity to cost-effectiveness considerations, we recommend that OSHA complete a more comprehensive and analytical regulatory analysis and consider modifying its proposal along the lines outlined [in the RARG Report."1/

1/ Regulatory Analysis Review Group Report on OSHA's Proposed Generic Regulation, submitted in OSHA Docket H-090 by the President's Council on Wage and Price Stability, at 8 (October 24, 1978).

We do not know whether OSHA will in fact issue a more comprehensive regulatory analysis upon promulgation of the final regulations.

The OSHA regulatory analysis and the comments on it submitted by A-I-H-C and others are part of the hearing record. However, Executive Order 12044 explicitly states that it does not provide new grounds for judicial review nor supersede existing statutory obligations governing rulemaking, and OSHA maintains that it is not required by statute to show that the economic and societae costs of proposed health and safety standards bear a reasonable relationship to their benefits.

III. THE REQUIREMENTS FOR A REGULATORY ANALYSIS SET FORTH IN THE PROPOSED SENATE LEGISLATION NEED MODIFICATION

OSHA's generic carcinogen rulemaking sheds considerable light on several of the important issues raised by S. 262 and the other regulatory reform bills before the Committee. It is noteworthy that throughout that proceeding A-I-H-C urged OSHA to perform the types of analyses required for a careful regulatory analysis and to adopt less costly alternatives for reaching its regulatory objectives -- the principal objectives of the bills before this Committee

Adherence to the objectives of S. 262 and the other pending measures clearly would have improved the OSHA rulemaking proceeding. However, the experience of that rulemaking demonstrates that the pending bills need to be modified in some respects if real reform of the regulatory process is to be achieved.

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 14 of 24 asbestosclaims.law/library/16577/14

A. A Regulatory Analysis Should Contain a Finding that the Benefits of a Regulation Are Reasonably Related to Its Costs

Current law may vary regarding the need for some agencies to conduct an evaluation of the beneficial effects and economic and societal impacts of a proposed regulation. However, as discussed earlier, such an evaluation should be performed by every agency for each significant rulemaking. The initial regulatory analysis should include a thorough analysis of the costs and benefits which would be produced by each alternative means of achieving the regulatory objective. In assessing costs, the length of time to be provided for compliance should be explicitly considered by the agency in its analysis because it is an important factor in determining both the compliance costs and the societal benefits of a regulation.

The final regulatory analysis should include a finding by the agency that the benefits of the alternative chosen bear a reasonable relationship to its costs. As Alfred Kahn recently testified before Congress,

> "By exactly the same reasoning -- that it is irrational to try to assess these regulations in terms of their costs alone without looking also at their benefits -- it is irrational to decree that society must bear those costs without having made one's own best judgment that the benefits do indeed justify doing so."

We do not suggest that agencies be required to compute the dollar benefits conferred by a regulation and make a finding that they exceed the costs imposed. We do suggest that an agency should

A08724

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 15 of 24 asbestosclaims.law/library/16577/15

be required to find that the benefits of a particular rule bear a reasonable relationship to the economic and societal costs of compliance.

An evaluation of the beneficial effects and economic and societal impacts of a rule will allow members of the public, industry, the executive and Congress to understand the nature of the regulatory decisions being made. It is therefore important tha all Federal agencies be subject to this requirement. Limiting an agency to analyzing only those economic impacts which the agency is permitted by existing law to take into account would sharply diminish the significance of regulatory reform for agencies, such as OSHA, which take a narrow view of their enabling legislatio

Such a limitation is also a potentially ambiguous constraint. It could produce confusion and delay where agencies are uncertain as to which impacts they are required to take into account and thus must describe in the regulatory analysis.

B. A Regulatory Analysis Should Be Performed Where Proposed Rules Or Closely Related Rules Have Significant Economic Impacts

A-I-H-C believes the requirement in S. 262 for performanc of a regulatory analysis where regulations would have an impact of at least $100 million upon the national economy is reasonable. We also support the provision in the bill allowing for consideration of a series of closely related rules as one rule for determining whether the $100 million threshold is met. However, we believe that such consideration of a series of closely related rules shoul

A08725

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 16 of 24 asbestosclaims.law/library/16577/16

be made mandatory. The legislative history also should make clear that generic rules and their progeny are a series of closely related rules for purposes of the regulatory requirements.

The need for the bill to cover generic rules is demonstrated by our experience in the OSHA carcinogen rulemaking proceeding. OSHA maintained that the generic regulation would impose no costs and thus required no economic impact analysis despite the fact that the regulation seeks to resolve virtually all the issues which will affect the costs of future regulations on specific substances. By requiring consideration of a series of closely related rules as one rule the argument OSHA used for avoiding the preparation of a regulatory analysis would be eliminated.

A-I-H-C also believes there is considerable wisdom in having the economic impact criteria encompass substantial economic impacts upon individual industries, geographic regions or local governments, in addition to covering broad national impacts.

C. Regulations Should Set Performance Rather Than Design Objectives

One of the principal reasons why the cost of regulation is greater than it has to be is that many agencies have a strong preference for issuing design and operating rules which contain detailed, inflexible standards rather than performance standards. Performance standards require agencies to determine what the real objectives of a regulation are and should be required to be used whenever possible.

A08726

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 17 of 24 asbestosclaims.law/library/16577/17

D. A-I-H-C Supports the Proposal in S. 262 That Agencies Be Required to Evaluate Alternative Approaches

A-I-H-C strongly supports the provision in S. 262 requiring an agency to consider alternatives and appraise their effectiveness in meeting the regulatory goals. We believe that the bill could be strengthened if it also required that agencies,

(1) explain why the proposed rule attains the objectives with less adverse economic effects than other alternatives, or explain why an approach entailing greater economic effects was selected; and

(2) if the proposed rule is a design or operating standard, explain why a performance standard could not be used to achieve the regulatory objective.

These suggested amendments would further agency and public analysis of the proposed regulation, while providing a standard for judging the effectiveness of the regulation.

E. An Advance Notice of Proposed Rulemaking or Similar Procedure Should Be Utilized to Facilitate Public Participation

The early publication of an advance notice of proposed rulemaking (ANPR) or similar procedure would allow the public an opportunity to propose methods of achieving regulatory objectives which could be analyzed in the initial regulatory analysis. A-I-H-C therefore recommends that S. 262 provide for an ANPR or similar procedure to help prevent an agency from examining only its proposal and straw man alternatives.

A08727

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 18 of 24 asbestosclaims.law/library/16577/18

In addition, ANPR's could aid in expediting rulemaking proceedings by providing sufficient notice to allow interested persons time to commence preparation of a well thought out response to the proposed regulations.

F. A Regulatory Analysis Should Be Subject To Public Comment at the Earliest Possible Point in the Proceedings

We strongly support the requirement in S. 262 for publication of an initial or preliminary analysis concurrent with the proposal of a rule. An agency obviously should perform a regulatory analysis prior to proposing specific action and the public should have an opportunity to comment upon it at the earliest possible point in the proceeding. In fact, the initial regulatory analysis should greatly assist the public in making meaningful comments on a proposed rule.

The requirement in each of the bills before the Committee for a final regulatory analysis with the same elements as an initial analysis is sound. Requiring additionally that the final analysis assess public comments would be valuable because it would compel the agency to reevaluate its chosen alternative in light of the comments received. In the OSHA proceeding, well thought out, less burdensome alternatives have been outlined by A-I-H-C and others, but there is no indication that OSHA will give these alternatives serious consideration. Specifically requiring the agency to review its initial analysis in light of comments received could improve the decision-making process.

A08728

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 19 of 24 asbestosclaims.law/library/16577/19

G. There Should Be External Review of Agency Compliance with Requirements for a Regulatory Analysis

S. 262 recognizes the need for some external review of agency compliance with the regulatory analysis requirements and places the responsibility for such review in the Congressional Budget Office. A-I-H-C strongly urges the Committee also to consider requiring executive branch review. We suggest that the executive, perhaps OMB or the RARG, be given explicit responsibility for reviewing regulatory analyses and ensuring their compliance with the legislative requirements. There are existing examples of this type of external review arrangement, such as CEQ's responsibility for reviewing NEPA statements. Agency review of their own compliance as proposed in the Administration bill, is unlikely to be effective.

H. Reviewing Courts Should Be Able to Consider the Regulatory Analysis

The objectives of S. 262 will not be fully achieved in our opinion if courts are barred from considering the regulatory analysis. The regulatory analysis should be part of the administrative record which can be considered by the courts in the context of review of the final regulations. The possibility of such review will encourage the agencies to do a thorough job and not just give lip service to the regulatory analysis requirements, as some agencies have done in the past.

A08729

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 20 of 24 asbestosclaims.law/library/16577/20

A-I-H-C is not proposing that S. 262 allow for judicial review of the regulatory analysis separate or apart from the review of a final regulation. We are recommending that the regulatory analysis be included explicitly in the administrative record of a regulation which is subject to review. This is certainly appropriate since the analysis likely will provide the most thorough description and analysis of the regulation by the agency. The reviewing court thus will be allowed to determine on the basis of the entire record, including the regulatory analysis, if the regulations are arbitrary or capricious or are not supported by substantial evidence, depending upon the applicable standard of review.

We do not believe that S. 262 intends to prevent the regulatory analysis from being included in the administrative record. However, there should be no ambiguity on this point. The bill should make clear that the analysis is a part of the record and thus a matter for consideration by the courts on review of the regulation. We do not believe that such a limited review provision would engender any additional litigation or otherwise delay the regulatory process. However, it would help turn what could otherwise be a paper exercise into something of consequence for the regulatory process.

IV. THERE IS A NEED FOR OBJECTIVE AND SCIENTIFICALLY VALID HEALTH RISK DETERMINATIONS

The failure to separate the scientific and regulatory functions involved in the regulation of chronic health hazards is

A0873C

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 21 of 24 asbestosclaims.law/library/16577/21

very evident in the OSHA rulemaking proceeding and the proposed generic regulation itself. The determination that a substance poses a potential risk of carcinogenicity is a very complex scientific question. Yet under OSHA's proposed generic regulation inflexible criteria are substituted for the judgment of scientists.

The significance of the failure to separate the scientific and regulatory decisions has been made clear by the President's Office of Science and Technology Policy (OSTP) in a report issued February 1, 1979, and entitled "Identification, Characterization, and Control of Potential Human Carcinogens: A Framework for Federal Decisionmaking." This thoughtful report proposes that the regulatory procedure be divided into two stages. In Stage I there would be a scientific evaluation of the data and an evaluation of the human carcinogenic risk posed by a particular substance. Stage II would be concerned with the regulatory decisions made on the basis of that risk evaluation and other information such as costs and benefits. (A copy of the OSTP report has been provided to the Committee.)

The RARG alternative to OSHA's proposed generic regulation also called for separation of the Stage I scientific function of identifying and evaluating the potential risk from carcinogens from the Stage II regulatory function of setting standards based on an evaluation of risks, benefits and costs.

A-I-H-C has proposed to OSHA, EPA and CPSC that an independent Data Evaluation and Classification Panel be established

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 22 of 24 asbestosclaims.law/library/16577/22

for the purpose of determining the potential carcinogenic risk of particular substances. The Panel would be part of the Federal government but would be composed of outside experts in the various scientific disciplines relevant to making such determinations. Reaching determinations concerning carcinogenic risk through the Panel would promote efficiency, consistency and accuracy in the regulatory process, without infringing upon the regulatory functions for which the individual agencies are responsible.

At the Present time OSHA, EPA, CPSC and FDA are independently performing important scientific function of identifying carcinogenic substances and assessing the risk from exposure to such substances. This results in inefficiency, inconsistency and inaccuracy in the determination of carcinogenic risks. Adoption of the Panel proposed by AIHC would produce major improvements in the regulation of chronic health hazards generally.

Ideally, new legislation would be the best method to create such a Panel. However, A-I-H-C has requested OSHA not to await legislation. We have urged OSHA to recommend to the President that he establish such a Panel by Executive Order pursuant to the powers granted the President under the Reorganization Act of 1977, 5 U.S.C. § 901 et seq. OSHA has chosen not to do so.

There are many instances where the efficiency, consistency and accuracy of the regulatory process might be improved through the use of independent, expert panels to resolve scientific issues.

A08732

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 23 of 24 asbestosclaims.law/library/16577/23

The regulation of chronic health effects is only the one with which we are most familiar. This Committee should consider requirin agencies to use such procedures where appropriate and feasible.

Conclusion

S. 262 and the other regulatory reform measures before the Committee could significantly improve the regulatory decisionmaking process. A-I-H-C has presented recommendations for strengthening S. 262 to ensure that this legislative objective is achieved.

We will be happy to assist the Committee's staff in preparing specific statutory language to implement the recommendations we have made.

A08733

Union Carbide trial exhibit UC-1449: Jackson B. Browning, on behalf of the American Industrial Health Council, Te... Published by AsbestosClaims.Law
ACL Doc 16577 · Page 24 of 24 asbestosclaims.law/library/16577/24