

## SOUND SCIENTIFIC PRACTICES ACT

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SEPTEMBER 18, 1998.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. GOODLING, from the Committee on Education and the Workforce, submitted the following

### REPORT

together with

### MINORITY VIEWS

[To accompany H.R. 2661]

[Including cost estimate of the Congressional Budget Office]

The Committee on Education and the Workforce, to whom was referred the bill (H.R. 2661) to establish peer review for the review of standards promulgated under the Occupational Safety and Health Act of 1970, 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 out all after the enacting clause and insert in lieu thereof the following:

#### SECTION 1. SHORT TITLE.

This Act may be cited as the “Sound Scientific Practices Act”.

#### SEC. 2. PEER REVIEW.

(a) GENERAL RULE.—Whenever the Secretary of Labor determines that a standard should be promulgated under section 6(b) of the Occupational Safety and Health Act of 1970, the Secretary shall, in order to serve the objectives of such Act and in lieu of the authority of the Secretary to appoint an advisory committee described in section 6(b)(1) of such Act, appoint a panel of individuals to review—

(1) the scientific and economic data which forms the basis for such standard; and

(2) the relevance of the data to industries and workers which would be affected by such standard.

(b) PANEL.—A panel appointed under subsection (a) shall be balanced in terms of the points of view represented and shall consist of persons who are able to give independent judgment and who have expertise in scientific or economic analysis related to the matter which is the subject of the standard. Any individual with a fi-

nancial interest in the outcome of the standard shall be excluded as a member of the panel unless such individual fully discloses such interest to the Secretary.

(c) **REPORTS.**—Reports of the panel, including any individual or minority reports, shall be published together with any proposed or final rule promulgating a standard. The Secretary shall provide a written response to all significant comments of the panel and shall include such responses with the proposed or final rule to which the reports of the panel are attached.

(d) **NEGOTIATED RULEMAKING.**—The requirement of subsection (a) shall not apply when the rule is completed through negotiated rulemaking under subchapter III of chapter 5 of title 5, United States Code.

#### PURPOSE

The purpose of H.R. 2661, the Sound Scientific Practices Act, is to require the Occupational Safety and Health Administration (OSHA) to conduct peer review of the scientific and economic data which serves as the basis for an occupational safety and health standard.

#### LEGISLATIVE ACTION

The Subcommittee on Workforce Protections held a series of three hearings in 1997 on the subject of Occupational Safety and Health Administration's "reinvention" plans.

The first hearing was held on June 24, 1997, to learn the views and perspective of OSHA in its effort to "reinvent" the agency. The Acting Assistant Secretary for OSHA, Greg Watchman, testified at the hearing.

The second hearing was held on July 23, 1997, to examine OSHA's reinvention project, hearing testimony from a variety of individuals who have either studied or had recent experiences with OSHA. The witnesses included Mr. Ronald D. Schaible, Director, Global Safety, AMP Incorporated, Harrisburg, Pennsylvania, testifying on behalf of the National Association of Manufacturers; Ms. M. Kathleen Winters, Corporate Manager, Environmental Health and Safety, Mack Printing Company, Easton, Pennsylvania, testifying on behalf of Printing Industries of America, Inc.; Dr. Gary Rainwater, President, American Dental Association, Dallas, Texas; Mr. James J. Gonzalez, Attorney-at-Law, Holland & Hart LLP, Denver, Colorado; Mr. Richard S. Baldwin, Safety and Health Director, BE & K Engineering and Construction Company, Birmingham, Alabama, testifying on behalf of Associated Builders and Contractors; Professor John Mendeloff, Graduate School of Public and International Affairs, University of Pittsburgh, Pittsburgh, Pennsylvania; Ms. Lee Anne Elliott, Executive Director, Voluntary Protection Programs Participants' Association, Falls Church, Virginia; and Mr. Michael J. Wright, Director, Health, Safety and Environment, United Steelworkers of America, Pittsburgh, Pennsylvania.

The third hearing was held on September 11, 1997, to hear from individuals with a first-hand knowledge of OSHA's reinvention program and on changes that should occur as OSHA moves into the 21st century. The following witnesses testified: Mr. Gerald V. Anderson, President, Anderson Construction Company, Inc., Fort Gaines, Georgia, testifying on behalf of the Associated General Contractors of America; Mr. James L. Abrams, Attorney-at-Law, Denver Colorado; Mr. Frank A. White, Vice President, Organization Resources Counselors, Inc., Washington, DC; Mr. Michael C.

Nichols, Vice President, Management Development/Human Resources, SYSCO Corporation, Houston, Texas; Mr. Norbert Plassmeyer, Vice President and Director of Environmental Affairs, Associated Industries of Missouri, Jefferson City, Missouri; and Nicholas A. Ashford, Ph.D, J.D., Professor of Technology and Policy, Massachusetts Institute of Technology, Cambridge Massachusetts.

The Subcommittee on Workforce Protections held two legislative hearings in 1998 on several bills amending the OSH Act, including two bills to require OSHA to conduct peer review of scientific and economic data used in rulemakings (H.R. 2871 and H.R. 2661). The first hearing was held on March 27, 1998, and the following witnesses testified: Ms. Claudia Brumm, Director, Risk Management, Borg Warner Automotive, Inc., Chicago, Illinois, testifying on behalf of the Labor Policy Association; Mr. Linwood O. Smith, Vice President, Risk and Safety Management, T. A. Loving Company, Goldsboro, North Carolina, testifying on behalf of the Associated General Contractors of America; Mr. James “Mike” McMichael, The McMichael Company, Central, South Carolina, testifying on behalf of the National Association of Home Builders; Mr. Ronald W. Taylor, Attorney-at-Law, Venable, Baetjer & Howard, Baltimore, Maryland, testifying on behalf of the United States Chamber of Commerce; Mr. Jerry Hartman, President, Reese Press, Inc., Baltimore, Maryland, testifying on behalf of the Printing Industries of America, Inc.; and Ms. Margaret M. Seminario, Director, Occupational Safety and Health Department, American Federation of Labor-Congress of Industrial Organizations (AFL-CIO), Washington, DC.

The Subcommittee on Workforce Protections held a second hearing on April 29, 1998, on pending legislation to amend the OSH Act, including H.R. 2871 and H.R. 2661. The following witnesses testified at the hearing: Mr. Charles N. Jeffress, Assistant Secretary for Occupational Safety and Health, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, DC; Mr. George R. Salem, Attorney-at-Law/Partner, Akin, Gump, Strauss, Hauer & Feld, LLP, Washington, DC, testifying on behalf of the National Association of Manufacturers; Mr. Richard E. Schwartz, Attorney-at-Law/Partner, Crowell & Moring LLP, Washington, DC, testifying on behalf of the American Iron & Steel Institute; Mr. John W. Bishop, President, Gurnee Heating & Air Conditioning Corporation, Closter, New Jersey, testifying on behalf of Associated Builders and Contractors; Mr. David G. Sarvadi, Attorney-at-Law, Keller and Heckman, Washington, DC; and Mr. Thomas J. Meighen, Safety & Risk Manager and Vice President, Stromberg Sheet Metal Works, Inc., Beltsville, Maryland, testifying on behalf of the Mechanical Electrical Sheet Metal Alliance.

The Subcommittee on Workforce Protections approved H.R. 2661, as amended, by a roll call vote of 6–4 on May 14, 1998, and ordered the bill favorably reported to the Full Committee. The Committee on Education and the Workforce approved H.R. 2661, as amended, by a roll call vote of 24–15 on June 10, 1998, and ordered the bill favorably reported to the House of Representatives.

## COMMITTEE VIEWS

*Background*

Peer review is the critical evaluation of scientific and technical work products by independent experts.<sup>1</sup> Expert review of government regulations is not a new topic, but is one that has been of considerable interest to many Members of Congress and their constituents given the increased presence of the federal government in the nation's economic affairs.

Peer review has been recommended as a helpful regulatory reform by a wide variety of groups that have studied the federal government's environmental, health and safety rulemaking processes, including the Presidential/Congressional Commission on Risk Assessment and Risk Management.<sup>2</sup> The Commission had this to say about peer review in its final 1997 report:<sup>3</sup>

Peer review is an important and effective mechanism for evaluating the accuracy or appropriateness of technical data, observations, interpretations, and the scientific and economic aspects of regulatory decisions. . . . Peer review should play a critical role in evaluation of the quality of technical information used in regulatory decision-making. Peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information. The primary criterion for membership on peer review panels should be expertise in the area of concern; however, financial conflicts must be avoided.

Not only is peer review important to credible regulatory action, but it is also a common and widely accepted aspect of credible science generally. As the General Accounting Office stated:<sup>4</sup>

Peer review is well established as a mechanism for assuring the quality, credibility, and acceptability of individual and institutional work products. This assurance is accomplished by having the products undergo an objective, critical review by independent reviewers. Peer review has long been used by academia, professional organizations, industry, and government.

Many government agencies regularly use peer review in making scientific and regulatory decisions. Congressionally mandated peer review of both grants and research occurs at the National Insti-

<sup>1</sup>U.S., General Accounting Office, *Peer Review: EPA's Implementation Remains Uneven* (GAO/RCED-96-236, September 24, 1996), p. 1.

<sup>2</sup>The Presidential/Congressional Commission on Risk Assessment and Risk Management was mandated by Congress in 1990 "to make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances . . . The Commission held hearings across the country and made recommendations about the uses and limitations of risk assessment, economic analysis, risk management, and regulatory decision-making." Final Report, vol. 2 (1997), pp. 103-105.

<sup>3</sup>U.S., The Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Assessment and Risk Management in Regulatory Decision-Making*, vol. 2 (1997), p. 103.

<sup>4</sup>U.S., General Accounting Office, *Peer Review: EPA's Implementation Remains Uneven* (GAO/RCED-96-236, September 24, 1996), p. 2.

tutes of Health.<sup>5</sup> At the Consumer Product Safety Commission (CPSC), a formal peer review process is required before issuance of certain rules related to cancer, birth defects, or gene mutations, and the agency employees peer review voluntarily in certain cases with scientific controversy.<sup>6</sup> The Environmental Protection Agency and the Department of Energy use peer review in their regulatory processes.<sup>7</sup> Several states—including Alaska, Arizona, California, Connecticut, Florida, Georgia, Kansas, Louisiana, Maine, Michigan, New York, North Dakota, Ohio, Tennessee, and Texas—specifically incorporate peer review in various portions of their state code.<sup>8</sup> The General Accounting Office has recently recommended that the Office of Management and Budget encourage all federal agencies to conduct peer review of economic analyses used as the basis for regulatory actions.<sup>9</sup>

In its report on the use of peer review by the Environmental Protection Agency (EPA), the General Accounting Office described the benefits of peer review not only to the quality of regulations but also to the agency:<sup>10</sup>

. . . [EPA's] senior leadership has stated that peer review is an important mechanism for enhancing the quality, credibility, and acceptability of products that may ultimately form the basis of regulations and other key decisions by the agency. Properly implemented, peer review can also conserve resources by steering product development along the most efficient, effective course, thereby avoiding costly and time-consuming delays. EPA's current policy, issued in June 1994, expands on the agency's prior policy and practices. The new policy continues to emphasize that major scientific and technical work products should normally be peer reviewed.

Peer review is so widely accepted that the U.S. Supreme Court has observed that "submission to the scrutiny of the scientific community is a component of 'good science.'" <sup>11</sup> An article in the *New England Journal of Medicine* indicated that "when properly used it is a powerful means of protecting and improving the quality of what is published. Peer review has its limitations, but it is hard to imagine how we could get along without it." <sup>12</sup>

<sup>5</sup> U.S., Congress, House, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Review of the Occupational Safety and Health Act, 105th Cong., 2nd sess. (April 29, 1998). Testimony of Mr. Richard E. Schwartz, Attorney-at-Law/Partner, Crowell & Moring LLP, Washington, DC, testifying on behalf of the American Iron & Steel Institute.

<sup>6</sup> U.S., The Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making, vol. 2 (1997), p. 104.

<sup>7</sup> U.S., Congress, House, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Review of the Occupational Safety and Health Act, 105th Cong., 2nd sess. (March 27, 1998). Testimony of Mr. Ronald W. Taylor, Attorney-at-Law, Venable, Baetjer & Howard, Baltimore, Maryland, testifying on behalf of the United States Chamber of Commerce.

<sup>8</sup> Ibid.

<sup>9</sup> U.S., General Accounting Office, Regulatory Reform: Agencies Could Improve Development Documentation, and Clarity of Regulatory Economic Analyses (GAO/RCED-98-142, May 1998), p. 33.

<sup>10</sup> U.S., General Accounting Office, Peer Review: EPA's Implementation Remains Uneven (GAO/RCED-96-236, September 24, 1996), p. 1.

<sup>11</sup> *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593 (1993).

<sup>12</sup> Relman and Angell, "How Good is Peer Review," *New England Journal of Medicine*, vol. 321, pp. 827-829 (September 21, 1989), cited in testimony of Mr. Richard E. Schwartz, Attorney-at-Law/Partner, Crowell & Moring LLP, Washington, DC, testifying on behalf of the American

Despite the overwhelming body of opinion that peer review is essential to credible science and regulatory action, OSHA still has failed to incorporate peer review into its regulatory process, and only infrequently has submitted data used as the basis for a standard to an independent peer review process.<sup>13</sup> The Committee believes that independent peer review is essential to “sound science” in OSHA rulemaking, just as it is for other regulatory agencies and throughout the scientific community.

*Peer review in OSHA’s standard-setting process*

OSHA’s standard-setting process is set forth in section 6(b) of the OSH Act.<sup>14</sup> Information supporting a proposed standard is developed by OSHA and/or submitted by interested persons.<sup>15</sup> OSHA must publish a proposed rule in the Federal Register and allow not less than 30 days for interested persons to submit comments and/or request a public hearing on the proposed rule.<sup>16</sup> Subsequent to the comment period and whatever time for public hearing is provided, OSHA may issue a final rule.<sup>17</sup> In order to satisfy the purposes of notice and comment under the OSH Act and the Administrative Procedures Act, the final rule must generally follow the “logical outgrowth” of the agency’s proposed rule.<sup>18</sup> Thus, the analysis and technical decisions of the agency prior to the publication of the proposed rule dictate to a large extent the agency’s final regulatory decisions.

H.R. 2661 requires that independent peer review of the scientific and economic data take place “whenever the Secretary of Labor determines that a standard should be promulgated.” The bill thus requires peer review of the economic and scientific data before a proposed standard is published. Requiring independent peer review of technical data early in the rulemaking process, before the proposed rule is published, will help ensure that the standard is based on sound science and help OSHA avoid misinterpretations and mistakes that might otherwise set the agency’s standard in an “unsound” direction.

*The need for expert review of OSHA standards*

For years, the Committee has heard testimony that OSHA’s safety and health standards are burdensome and excessively costly and ineffective in improving safety and health.<sup>19</sup> Despite promises by the Clinton Administration to “reinvent” OSHA and deliver “com-

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Iron & Steel Institute, at a hearing before the House Subcommittee on Workforce Protections, April 29, 1998.

<sup>13</sup> The Department of Labor drafted a peer review policy for OSHA in 1991; however it was not formally adopted, and the effort to do so was dropped by the Clinton Administration.

<sup>14</sup> 29 U.S.C. Section 655(b). In addition, a number of other statutes and executive orders may apply to the process of writing an occupational safety and health standard, including the Administrative Procedures Act, the Paperwork Reduction Act of 1965, the Small Business Regulatory Fairness Enforcement Act, the Negotiated Rulemaking Act, and Executive Order No. 12866.

<sup>15</sup> 29 U.S.C. Section 655(b)(1).

<sup>16</sup> 29 U.S.C. Section 655(b)(2),(3).

<sup>17</sup> 29 U.S.C. Section 655 (b)(4).

<sup>18</sup> See, e.g., *Fertilizer Institute v. EPA*, 935 F.2d 1303 (D.C. Cir. 1991); *Rybachek v. EPA*, 904 F.2d 1276 (9th Cir. 1990).

<sup>19</sup> U.S., Congress, House, Committee on Economic and Educational Opportunities, Subcommittee on Oversight and Investigations, Hearing on the Need for Regulatory Reform: The Case of OSHA and NIOSH, 104th Cong., 1st sess., ser. 104-11 (February 16, 1995).

mon sense” regulations, concerns about OSHA rulemakings remain strong.

These concerns were expressed during Subcommittee on Workforce Protection hearings. Mr. Ronald D. Schaible, Director of Global Safety for AMP, Inc. in Harrisburg, Pennsylvania testified that “OSHA continues to pursue promulgation of standards that would amount to super-regulation of the workplace, resisting calls for peer review and independent studies . . . AMP [remains] concerned . . . [about] OSHA’s over-regulation of the workplace.”<sup>20</sup>

Mr. Jerry Anderson, President of Anderson Construction Company in Ft. Gaines, Georgia testified—<sup>21</sup>

While the “Reinvent OSHA” was a recognition by OSHA that its traditional approach to enforcement was no longer relevant, it falls short in one crucial respect. None of the changes proposed in “Reinvent OSHA” are permanent. There are no guarantees that the next OSHA administrator will maintain the policies set forth in the “Reinvent OSHA” initiative. The question facing Congress is how to make both the changes within OSHA and the positive safety and health achievements occurring in the private sector permanent.

Mr. Anderson then went on to testify in support of OSHA safety and health standards based on sound science. He stated that most OSHA safety and health standards are broadly written standards that end up imposing huge compliance costs on contractors.<sup>22</sup> “Moreover, OSHA’s safety and health standards do not have to be based on peer-reviewed sound science. . . . By requiring OSHA safety and health standards to be based on sound science, the agency will be forced to focus its regulatory efforts on those hazards that harm the most workers. It will also keep OSHA from enforcing safety and health standards that do little to enhance workplace safety.”<sup>23</sup>

Mr. Michael C. Nichols, Vice President for Management Development and Human Resources for SYSCO Corporation also testified about problems with OSHA’s standard-setting process:<sup>24</sup>

. . . we are skeptical of such initiatives [like OSHA’s safety and health program standard, its indoor air pollution rule, and its desire for an ergonomics program] because they are supported by inadequate science, are likely to be vague in critical respects (raising daunting compliance challenges), and seek to superimpose Federal government ‘solutions’ to problems and safety challenges that many employers successfully handle on their own.

As these and other witnesses have testified, the history of OSHA’s standards demonstrates a need to improve OSHA’s regu-

<sup>20</sup> U.S., Congress, House, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Hearing to Examine the Occupational Safety and Health Administration’s Reinvention Project, 105th Cong., 1st sess. (September 11, 1997). Testimony of Mr. Ronald D. Schaible, AMP, Inc., Harrisburg, Pennsylvania.

<sup>21</sup> Ibid. Testimony of Mr. Jerry Anderson, Anderson Construction Company, Fort Gaines, Georgia.

<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

<sup>24</sup> Ibid. Testimony of Mr. Michael C. Nichols, SYSCO Corporation, Houston, Texas.

latory process. But even if OSHA's regulatory record were better, peer review should be a part of the agency's rulemaking process. Promulgating sound safety and health standards is a difficult challenge. As one expert on the process stated before the Subcommittee on Workforce Protections:<sup>25</sup>

Regarding peer review, the scientific decisions being made by agencies today are complex and difficult, often at the cutting edge of scientific knowledge. Given the changing nature of this knowledge, it seems unquestionable that it would be advantageous to have outside review of agency scientists' work. Indeed, in all other endeavors, an individual's efforts are subject to the kind of critical review that we think of when we use the words, peer review.

A second reason for supporting peer review is that the agency staff cannot possibly have expertise in all of the areas that a regulation needs to address. It must of necessity consult outside experts. In this sense, the peer review bill simply requires OSHA to formalize what should already be a part of its process. And it offers the benefit of giving greater stature and prestige to the decisions which are now made solely by those on the inside.

*Peer review will improve the standard-setting process*

Even though the Department of Labor claims that peer review is unnecessary,<sup>26</sup> other witnesses before the Subcommittee on Workforce Protections have described how peer review would improve OSHA's standard-setting process. For example, Mr. Richard Schwartz described past mistakes that could have been avoided:<sup>27</sup>

OSHA has made some major mistakes that could have been prevented by peer review. For example, AISI objected to OSHA's 1989 air contaminants rulemaking-which involved 428 substances simultaneously-because AISI believed that OSHA was not using good science. Unions also challenged the standards on the grounds that OSHA had not properly used the scientific data. Eventually, the U.S. Court of Appeals agreed with us and vacated the standards-but only after OSHA had wasted an immense amount of time on them, and AISI had expended considerable resources on litigation. The court pointed out that 'in most cases, OSHA cited a few studies and then established a [Permissible Exposure Limits] PEL without explaining why the studies mandated the particular PEL chosen.' The court also faulted OSHA for relying on assumptions that had no basis in reputable scientific evidence. These sorts of errors are likely to be spotted by a peer review panel.

<sup>25</sup> U.S., Congress, House, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Review of the Occupational Safety And Health Act, 105th Cong., 2nd sess. (April 29, 1998). Testimony of Mr. David Sarvadi, Washington, DC.

<sup>26</sup> Ibid. Testimony of Mr. Charles N. Jeffress, Assistant Secretary for Occupational Safety and Health, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, DC.

<sup>27</sup> Ibid. Testimony of Mr. Richard E. Schwartz, Attorney-at-Law/Partner, Crowell & Moring LLP, Washington, DC, testifying on behalf of the American Iron & Steel Institute.



Errors such as the one described in the preceding paragraph result in years of wasted effort and costs by both the Department of Labor and by the parties who would be affected by the standard. Indeed, the GAO's study of EPA's implementation of peer review made precisely the same point: not conducting peer review can be more costly to the agency in time and resources than conducting peer review because it can help avoid mistakes that later take years to correct.<sup>28</sup>

*Explanation of the Sound Scientific Practices Act (H.R. 2661)*

The Sound Scientific Practices Act was introduced by Representative Scott McInnis with bipartisan cosponsorship. It is similar to legislation (H.R. 2871) introduced by Representative Cass Ballenger. H.R. 2661 requires independent peer review of standards promulgated under the Occupational Safety and Health Act of 1970. During markup by the Subcommittee on Workforce Protections, Representative Cass Ballenger offered an amendment in the nature of a substitute which was accepted by voice vote. The amendment to H.R. 2661 makes three changes to the bill as it was introduced by Representative McInnis.

The first change is similar to a provision in a "peer review" bill (H.R. 2871) introduced by Representative Ballenger. This provision requires that if OSHA adopts a rule as a result of negotiated rulemaking, then a separate peer review of the scientific and economic basis for the standard is not required (though OSHA is not prohibited from conducting peer review). Mr. Ronald Taylor, a witness before the Subcommittee, clearly stated the rationale for this change:<sup>29</sup>

Peer review expands on and will complement the success of negotiated rulemaking. It shares the same benefits that negotiated rulemaking affords the standards-setting process—critical review by diverse parties, yielding sounder, more widely accepted standards and the prospect of decreased litigation.

The second change made by the Ballenger amendment is to strengthen the requirement that the peer review panel be independent of the agency. The amendment specifically added that the "panel appointed under subsection (a) shall be balanced in terms of the points of view represented and shall consist of persons who are able to give independent judgement and who have expertise in scientific or economic analysis related to the matter which is the subject of the standard." Peer review is successful only if the members are viewed as not being influenced by the agency. The Presidential/Congressional Commission on Risk Assessment and Risk Management stated that:<sup>30</sup>

<sup>28</sup> U.S., General Accounting Office, Peer Review: EPA's Implementation Remains Uneven (GAO/RCED-96-236, September 24, 1996), p. 4.

<sup>29</sup> U.S., Congress, House, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Review of the Occupational Safety And Health Act, 105th Cong., 2nd sess. (March 27, 1998). Testimony of Mr. Ronald W. Taylor, Attorney-at-Law, Venable, Baetjer & Howard, Baltimore, Maryland, testifying on behalf of the United States Chamber of Commerce.

<sup>30</sup> U.S., The Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making, vol. 2 (1997), p. 104.

Peer review should provide balanced, independent views. When used well, peer review can serve as a system of checks and balances for the technical aspects of the regulatory process.

Appointing peer review panels which are balanced, expert, and independent is the most important aspect of effective peer review. The obligation to do so under H.R. 2661 is on the Secretary of Labor.

The third provision of the Ballenger amendment provides that the peer review panels required by H.R. 2661 are in lieu of “standards advisory committees” currently authorized by section 6(b)(1) of the OSH Act. The amendment replaces OSHA’s current standards advisory committees, which do not have a clear purpose in the statute, with peer review panels, which do have a clear purpose and are a well-established aspect of credible regulatory proceedings.

Section (2)(b) of H.R. 2661 requires that any individual appointed to the peer review panel must fully disclose any financial interests in the outcome of a standard to the Secretary of Labor or the individual will be excluded from the panel. This provision ensures those individuals with the knowledge and expertise needed to provide peer review of complex and difficult OSHA standards are able to do so while also bringing any potential conflicts of interest out into the open.<sup>31</sup>

Section (2) (c) of the bill requires that reports of the panel will be published with any proposed or final rule promulgating a standard and that the Secretary of Labor shall provide a written response to all significant comments of the panel and includes copies of these responses with the proposed or final rule. This provision ensures that the public remains informed of the decisions reached by the peer review panel and the necessary action taken by the Department of Labor in response to these views.

In testimony before the Subcommittee on Workforce Protections, the Assistant Secretary of Labor for Occupational Safety and Health gave four reasons for the Department of Labor’s opposition to H.R. 2661: (1) peer review is unnecessary because the OSH Act requires notice, comment, and opportunity for public hearing; (2) peer review will delay the time required to issue standards; (3) peer review will “provide [peer review panel members] an additional closed-door opportunity to influence rulemaking after the public process is complete”; and (4) H.R. 2661 would create an additional statutory committee.

The Assistant Secretary’s arguments do not reflect the bill as passed by the Committee. First, as described above, peer review of the economic and scientific data would be required in the “pre-proposed rule” stage, before the major decisions about the direction and parameters of the standard are set. Under the OSH Act, notice and comment on standards are at a later point in the rulemaking process, and serve a different purpose than does peer review.<sup>32</sup>

Second, there is simply no evidence to support the Assistant Secretary’s claim that peer review delays rules. In fact, the Chairman

<sup>31</sup> General “conflict of interest” provisions in other laws, such as 18 U.S.C. Section 208, would also apply to peer review panels.

<sup>32</sup> U.S., General Accounting Office, Peer Review: EPA’s Implementation Remains Uneven (GAO/RCED-96-236, September 24, 1996), p. 3.

of the Subcommittee on Workforce Protections has repeatedly asked witnesses, including the Assistant Secretary, for evidence to back up that claim, and none was submitted. As mentioned earlier, the only evidence on this point is to the contrary: EPA has found that not doing peer review can delay standards.

Third, peer review is not a “closed door process” that would give unfair advantage to panelists. The bill requires that the full report, including minority views, of the panel be published with the proposed rule. In addition, the Federal Advisory Committee Act<sup>33</sup> applies to the appointment and conduct of the peer review panels. That law requires that all panel member meetings shall be open to the public and records of meetings be available to the public.<sup>34</sup>

Fourth, H.R. 2661 does not add any new “statutory committee.” While requiring OSHA to use peer review panels, it repeals the current authority for advisory committees whose function and purpose is less defined.

Finally, peer review would not impose a substantial financial burden on OSHA. In responding to questions from the House Committee on Appropriations, the Assistant Secretary for OSHA indicated that the anticipated cost for a peer review panel would range from \$36,000 to \$54,000 for each panel convened. Over its 28-year history, OSHA has averaged between 2 and 3 completed rulemakings per year. Thus, the cost of peer review is not a substantial amount, but will help ensure that the standards which OSHA does complete are based on sound and acceptable use of technical data and information.

### *Conclusion*

The Sound Scientific Practices Act is one of several steps needed to bring about reform in OSHA. It is reasonable legislation that helps bring increased accountability to the federal regulatory process. As the sponsor of H.R. 2661, Representative Scott McInnis said:<sup>35</sup>

This legislation would put common sense back into the regulatory process. I believe that it is important to consult with individuals who are experts in the affected field, and the government will have greater access to this expertise if a peer review system is implemented. This is logical and rational legislation; rather than creating regulations in a vacuum, OSHA will be forced to consider testimony from sources outside the federal government.

### SUMMARY

The Sound Scientific Practices Act establishes peer review of standards promulgated under the OSH Act. It requires OSHA to appoint an independent panel of scientific experts to provide peer review of the scientific and economic data on which a proposed OSHA standard is based.

<sup>33</sup> U.S.C. Appendix 2, Sections 1–15.

<sup>34</sup> U.S.C. Appendix 2, Section 9.

<sup>35</sup> U.S., Congress, House, Committee on Education and the Workforce, Subcommittee on Workforce Protections, Review of the Occupational Safety And Health Act, 105th Cong., 2nd sess. (March 27, 1998). Statement of the Honorable Scott McInnis, Member of Congress, March 27, 1998.

## SECTION-BY-SECTION ANALYSIS

*Section 1. Short title*

The title of the bill is the “Sound Scientific Practices Act.”

*Section 2. Peer review*

This section of the bill subjects standards promulgated under section 6(b) of the Occupational Safety and Health Act of 1970 to independent scientific peer review by a panel of experts who will review the scientific and economic data underlying OSHA standards and the relevance to industries and workers affected by a standard. OSHA’s current advisory committees are repealed and replaced by the peer review panels. This section also states that if a rule is adopted as a result of negotiated rulemaking, a separate peer review of the scientific and economic basis for the standard is not required.

## STATEMENT OF CONSTITUTIONAL AUTHORITY

H.R. 2661 requires that standards promulgated under the OSH Act be subject to independent peer review and thus falls within the scope of Congressional powers under Article I, Section 8, Clause 3 of the Constitution of the United States to the same extent as does the OSH Act.

## EXPLANATION OF AMENDMENTS

The Amendment in the Nature of a Substitute is explained in the body of this report.

## APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch. This bill, the Sound Scientific Practices Act, requires the Occupational Safety and Health Administration (OSHA) to conduct peer review of the scientific and economic data which serves as the basis for an occupational safety and health standard. The bill does not prevent legislative branch employees from receiving the benefits of this legislation.

## UNFUNDED MANDATE STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act requires a statement of whether the provisions of the reported bill include unfunded mandates. This bill, the Sound Scientific Practices Act, requires the Occupational Safety and Health Administration (OSHA) to conduct peer review of the scientific and economic data which serves as the basis for an occupational safety and health standard. As such, the bill does not contain any unfunded mandates.

## STATEMENT OF OVERSIGHT FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE

In compliance with clause 2(l)(3)(A) of rule XI and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Commit-

tee's oversight findings and recommendations are reflected in the body of this report.

STATEMENT OF OVERSIGHT FINDINGS OF THE COMMITTEE ON  
GOVERNMENT REFORM AND OVERSIGHT

With respect to the requirement of clause 2(1)(3)(D) of rule XI of the Rules of the House of Representatives, the Committee has received no report of oversight findings and recommendations from the Committee on Government Reform and Oversight on the subject of H.R. 2661.

COMMITTEE ESTIMATE

Clause 7 of rule XIII of the Rules of the House of Representatives requires an estimate and a comparison by the Committee of the costs that would be incurred in carrying out H.R. 2661. However, clause 7(d) of that rule provides that this requirement does not apply when the Committee has included in its report a timely submitted cost estimate of the bill prepared by the Director of the Congressional Budget Office under section 403 of the Congressional Budget Act.

BUDGET AUTHORITY AND CONGRESSIONAL BUDGET OFFICE COST  
ESTIMATE

With respect to the requirements of clause 2(1)(3)(B) of rule XI of the House of Representatives and section 308(a) of the Congressional Budget Act of 1974 and with respect to requirements of 2(1)(3)(C) of rule XI of the House of Representatives and section 403 of the Congressional Budget Act of 1974, the Committee has received the following cost estimate for H.R. 2661 from the Director of the Congressional Budget Act:

U.S. CONGRESS,  
CONGRESSIONAL BUDGET OFFICE,  
*Washington, DC, July 14, 1998.*

Hon. WILLIAM F. GOODLING,  
*Chairman, Committee on Education and the Workforce, U.S. House  
of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2661, the Sound Scientific Practices Act.

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

Sincerely,

JUNE E. O'NEILL, *Director.*

Enclosure.

*H.R. 2661—Sound Scientific Practices Act*

Summary: H.R. 2661 would require the Secretary of Labor to appoint an advisory panel when promulgating an occupational safety and health standard. Under current law the Secretary may, at her discretion, appoint an advisory committee in such situations. Since such an advisory body is not now convened every time the Secretary promulgates a rule, passage of the bill would increase the

time and resources spent on the rulemaking process. The Occupational Health and Safety Administration (OSHA), which enforces occupational safety and health regulations has an authorization of such sums as necessary. If appropriations are made in the full amount of the additional resources required to fulfill the requirements of this legislation, CBO estimates that enacting H.R. 2661 would result in additional discretionary spending of \$3 million over the 1999–2003 period.

H.R. 2661 would not affect direct spending or receipts; therefore pay-as-you-go procedures would not apply. The legislation also does not contain any intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

**Estimated cost to the Federal Government:** The estimated budgetary impact of H.R. 2661 is shown in the following table. The costs of this legislation fall within budget function 550 (health). For the purposes of this estimate, CBO assumes that appropriations would be made to pay for the additional resources that would be used by OSHA to fulfill the requirements of this legislation. CBO also assumed that such appropriations would be made by the start of each fiscal year and that outlays would follow the historical spending patterns for OSHA.

[By fiscal year, in millions of dollars]

	1998	1999	2000	2001	2002	2003
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law:						
Budget Authority <sup>1</sup> .....	336	348	360	372	384	396
Estimated Outlays .....	335	347	358	370	382	394
Proposed Changes:						
Authorization Level .....	0	1	1	1	1	1
Estimated Outlays .....	0	( <sup>2</sup> )	1	1	1	1
Spending Under H.R. 2661:						
Authorization Level .....	336	349	361	373	385	397
Estimated Outlays .....	335	347	359	371	383	395

<sup>1</sup> The 1998 level is the amount appropriated for that year.

<sup>2</sup> Less than \$0.5 million.

**Basis of estimate:** Under current law OSHA has the authority to convene an advisory committee when promulgating a rule. However, OSHA rarely exercises this option. Therefore, by requiring OSHA to convene an advisory panel and conduct a peer review every time a rule is promulgated, H.R. 2661 would increase the resources and time put into the rulemaking process. Based on information from OSHA, CBO estimates that it would cost approximately \$45,000 to pay for the expenses of a peer review panel and \$35,000 in contract funds and about one additional full-time employee to respond to the peer review comments. OSHA promulgates about 5 regulations per year. As a result, CBO estimates that implementing the proposal under H.R. 2661 would increase OSHA's costs by \$0.7 million in fiscal year 1999. If appropriations are made in the full amount of these costs, federal discretionary spending would increase by \$0.1 million in fiscal year 1999 and \$3 million over the 1999–2003 period.

**Pay-as-you-go considerations:** None.

**Intergovernmental and private-sector impact:** H.R. 2661 contains no intergovernmental or private sector mandates as defined in the

Unfunded Mandates Reform Act and would not affect the budgets of state, local, or tribal governments.

Estimate prepared by: Federal Costs: Cyndi Dudzinski, impact on State, Local, and Tribal Governments: Marc Nicole, impact on the Private Sector: Kathryn Rarick.

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

## ROLL CALL VOTE

## COMMITTEE ON EDUCATION AND THE WORKFORCE

ROLL CALL 1

Bill H.R. 2661

DATE June 18, 1998

PASSED 24 - 15

**SPONSOR/AMENDMENT** Mr. Ballenger/ motion to report the bill to the House with an amendment  
and with the recommendation that the amendment be agreed to and that the bill as amended do pass

MEMBER	AYE	NO	PRESENT	NOT VOTING
Mr. GOODLING, Chairman	X			
Mr. PETRI, Vice Chairman	X			
Mrs. ROUKEMA	X			
Mr. FAWELL	X			
Mr. BALLENGER	X			
Mr. BARRETT				X
Mr. HOEKSTRA	X			
Mr. McKEON	X			
Mr. CASTLE	X			
Mr. JOHNSON	X			
Mr. TALENT	X			
Mr. GREENWOOD	X			
Mr. KNOLLENBERG	X			
Mr. RIGGS	X			
Mr. GRAHAM	X			
Mr. SOUDER	X			
Mr. McINTOSH	X			
Mr. NORWOOD	X			
Mr. PAUL	X			
Mr. SCHAFFER	X			
Mr. PETERSON	X			
Mr. UPTON	X			
Mr. DEAL	X			
Mr. HILLEARY	X			
Mr. PARKER	X			
Mr. CLAY		X		
Mr. MILLER				X
Mr. KILDEE		X		
Mr. MARTINEZ		X		
Mr. OWENS		X		
Mr. PAYNE		X		
Mrs. MINK		X		
Mr. ANDREWS		X		
Mr. ROEMER		X		
Mr. SCOTT		X		
Ms. WOOLSEY		X		
Mr. ROMERO-BARCELO				X
Mr. FATTAH		X		
Mr. HINOJOSA		X		
Mrs. McCARTHY		X		
Mr. TIERNEY		X		
Mr. KIND				X
Ms. SANCHEZ		X		
Mr. FORD				X
Mr. KUCINICH				X
<b>TOTALS</b>	24	15		6



#### MINORITY VIEWS—H.R. 2661 SEPTEMBER 18, 1998

We strongly oppose H.R. 2661 as reported by Committee. If enacted, this legislation will place significant and unreasonable burdens on the ability of the Occupational Safety and Health Administration (OSHA) to ensure the safety and health of workers. This legislation does not enhance or improve the process by which health and safety standards are developed. Rather, H.R. 2661 appears to be intended to afford special business interests a further opportunity to influence the rulemaking process; to delay by months, and perhaps years, the time it takes for OSHA to issue standards; and to invite unnecessary and time-consuming litigation challenging such standards as are issued. H.R. 2661 will not improve the way standards are developed, nor will it lessen litigation.

Under OSHA's current procedures, proposed standards and the underlying scientific and economic data and analyses are subject to extensive public review. Written comments are solicited and public hearings are conducted where OSHA presents its analyses and is subject to cross examination by all interested parties. OSHA's current procedures ensure full public review of the standard and the underlying data supporting the standard.

Creating a closed process involving panels that include representatives with a direct interest in the outcome of the rulemaking will not improve the scientific basis for the standard. Normal practice for scientific peer review panels is to exclude anyone with a direct economic interest in the outcome. H.R. 2661, as introduced, permitted people who represented entitled that had a potential conflict of interest to serve on panels so long as that information was disclosed. The bill, as introduced, also provided that where a standard affected a single entity, no peer reviewer representing that entity may be included on the review panel.

As reported by Committee, the bill is significantly worse. Only those with a direct financial interest in the outcome of the standard have an obligation to publicly disclose what is clearly a conflict of interest. Where a panel member works for an entity that has an interest in the outcome of standard, but does not have a personal financial interest in the standard, no public disclosure is required under the chairman's amendment. In addition, the language prohibiting reviewers who represent an entity from serving on panels considering a standard that solely affects that entity was dropped in Committee. In effect, the legislation now not only invites those who have a direct conflict of interest to judge the scientific basis for a proposed OSHA standard, but it allows those individuals to hide that conflict of interest from the public.

Proponents of the bill contend that it will promote consensus and serve to limit litigation challenging OSHA standards. In fact, the legislation appears to be drafted to produce exactly the opposite effect. H.R. 2661 requires the so called "peer review" panels to issue

reports that must be published with any proposed or final rule promulgating a standard. Such reports are to include individual and minority reports and the Secretary of Labor is required to respond in writing to "all significant comments of the panel." Far from promoting consensus, the requirement that panel reports include minority and individual views not only guarantees divergence, but those views will inevitably serve to inspire litigation challenging implementation of new standards.

H.R. 2661 will further prolong a standard setting process that, in the view of many, is already seriously flawed. Recent OSHA standards on respiratory protection, methylene chloride, and 1,3-butadiene each took 12 to 16 years to develop. During the years those standards wound their way through the promulgation process, thousands of workers were unnecessarily exposed to dangerous levels of toxic substances. H.R. 2661 ensures that the ability of OSHA to generate new standards will be further delayed in the future by imposing a review process that is at best redundant and more likely counter-productive. As a consequence, it ensures that more workers will be exposed for a greater period of time to significant risks to their health and safety. H.R. 2661 does not simply embody flawed policy, it promotes a dangerous policy that invites further needless injury and death for American workers.

WILLIAM L. CLAY.  
DALE E. KILDEE.  
MAJOR R. OWENS.  
PATSY T. MINK.  
LYNN WOOLSEY.  
CHAKA FATTAH.  
CAROLYN MCCARTHY.  
RON KIND.  
HAROLD E. FORD, JR.  
GEORGE MILLER.  
MATTHEW G. MARTINEZ.  
DONALD M. PAYNE.  
ROBERT E. ANDREWS.  
ROBERT C. SCOTT.  
CARLOS ROMERO-BARCELÓ.  
RU'EN HINOJOSA.  
JOHN F. TIERNEY.  
LORETTA SANCHEZ.  
DENNIS J. KUCINICH.