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SENATE

{ REPORT
105-188 }THE REGULATORY IMPROVEMENT
ACT OF 1998

R E P O R T

OF THE

COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

TOGETHER WITH

ADDITIONAL AND MINORITY VIEWS

TO ACCOMPANY

S. 981

TO PROVIDE FOR ANALYSIS OF MAJOR RULES



MAY 11, 1998.—Ordered to be printed

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THE REGULATORY IMPROVEMENT ACT OF 1998

MAY 11, 1998.—Ordered to be printed

Mr. THOMPSON, from the Committee on Governmental Affairs,
submitted the following

REPORT

together with

ADDITIONAL AND MINORITY VIEWS

[To accompany S. 981]

The Committee on Governmental Affairs, to which was referred the bill (S. 981) to provide for the analysis of major rules, to make the regulatory process more efficient and effective, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends by a vote of 8-4 that the bill as amended do pass.

I. PURPOSE AND SUMMARY

S. 981 is a bipartisan effort to achieve meaningful and lasting improvements to the federal regulatory process through important changes in the procedural requirements for issuing federal regulations. S. 981 would subject all “major rules” to rigorous economic and scientific analysis before being issued. By elevating the use of modern decisionmaking tools such as cost-benefit analysis and risk assessment, the legislation would promote more open, better-informed, and more accountable regulatory decisions. Upon introduction of S. 981, Senator Levin stated:

Those of us who believe in the benefits of regulation to [protect the environment and the public health and to increase worker safety] have a particular responsibility to make sure that regulations are sensible and cost effective.
* * * I believe this bill will improve the regulatory process, will build confidence in the regulatory programs that

are so important to this society's well-being, and will result in a better—and I believe—a less contentious regulatory process.¹

In the same vein, Chairman Thompson stated:

This legislation is an effort by some of us to devise a common solution to the problems of our regulatory system. We have some real political differences among us, but we all share the same goals: clean air and water, injury free workplaces, safe transportation systems, to name a few of the good things that can come from regulation. We also all share the goal of avoiding regulation which unnecessarily interferes in people's lives and businesses, which costs more than it benefits, or which—inadvertently—causes actual harm. * * * The Regulatory Improvement Act will promote the public's right to know how and why agencies regulate, improve the quality of government decision-making, and increase government accountability and responsiveness to the people it serves.²

A brief synopsis of the major provisions of the bill follows:

A. *Cost-benefit analysis*

Federal agencies would be required to perform a cost-benefit analysis for major rules (imposing costs over \$100 million or having other material adverse effects). The cost-benefit analysis would be done at the proposed and final rulemaking stages and would include:

An estimate of the anticipated benefits of the rule (quantifiable and nonquantifiable);

An estimate of the anticipated costs of the rule (quantifiable and nonquantifiable);

An analysis of a reasonable number of regulatory alternatives, including flexible regulatory options;

A reasonable determination: (1) whether the benefits of the rule are likely to justify the costs; (2) whether the rule is likely to achieve the rule making objectives in a more cost-effective manner, or with greater net benefits, than the other alternatives; and (3) whether the rule adopts a flexible regulatory option.

If the agency determines that the rule is not likely to satisfy these conditions, the agency shall explain the reasons for selecting the rule notwithstanding such determination, including identifying any statutory provision that required the agency to select such rule, and describe any reasonable alternative that would satisfy such conditions.

B. *Risk assessment*

Agencies would be required to follow risk assessment principles for: (1) major rules with the primary purpose of addressing risks to health, safety, or the environment; and (2) risk assessments not related to a rule making that the OMB Director determines would

¹ 143 Cong. Rec. S 6742, S 6744 (daily ed. June 27, 1997).

² Id. at 6749.

have a substantial impact on a significant public policy or on the economy.

To promote transparent and scientifically objective risk assessment, agencies would be required to: identify and explain significant assumptions made when estimating risks; notify the public about upcoming risk assessments and allow the public to submit relevant and reliable information; and disclose relevant information about the risk, including the range and distribution of the risk, including central and high-end estimates, and the corresponding exposure scenarios for the potentially exposed population and for any highly exposed or sensitive subpopulations. When appropriate scientific information is reasonably available, the agency would be required to compare the risk being analyzed with other reasonably comparable risks familiar to and routinely encountered by the public.

C. Peer review

Cost-benefit analyses and risk assessments required by the Act would be subject to independent peer review.

D. Judicial review

The legislation would provide for judicial review to ensure that agencies conduct required regulatory analyses. The regulatory analysis, including the cost-benefit analysis, cost-benefit determination, and risk assessment, would be included in the rulemaking record for purposes of judicial review, and would, to the extent relevant, be considered by the court in determining whether the final rule is arbitrary or capricious.

E. Guidelines, interagency coordination, and research

The Director of the Office of Management and Budget (“OMB”) would consult with the President’s Council of Economic Advisors, the Director of the Office of Science and Technology Policy (“OSTP”), and the relevant agencies to: develop guidelines for cost-benefit analysis, risk assessment, and peer review; improve agency analytical practices; and arrange for research to improve regulatory analysis.

F. Comparative risk analysis

OMB, in consultation with OSTP, would arrange for a study to compare and rank health, safety, and environmental risks; to improve methodologies for comparing various risks; and to make recommendations on using comparative risk analysis to set agency priorities for reducing such risks. Each relevant agency would use the results of the study to inform the agency in the preparation of its budget and strategic plans and performance plans under the Government Performance and Results Act.

G. Review of existing rules

Agencies would be required to conduct periodic reviews of existing regulations to modernize them and to reduce undue regulatory burdens. Agencies would issue 5-year schedules for the review of selected economically significant rules.

To ensure that agencies are more sensitive to the burdens of regulation on small businesses and small governments, the legislation would amend Section 610 of the Regulatory Flexibility Act (“RFA”). Every 5 years, agencies would be required to identify their RFA rules and develop review plans. Each year, agencies would list the selected rules to be reviewed that year. The Chief Counsel for Advocacy of the Small Business Administration and the Administrator of the OMB’s Office of Information and Regulatory Affairs (“OIRA”) would oversee the review process.

H. Executive oversight

OIRA would supervise and oversee implementation of the requirements of this legislation and would systematically review agencies’ regulatory proposals, subject to public disclosure requirements.

II. BACKGROUND

Since 1946, the federal regulatory process has been guided by the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 551–558. The APA was enacted following the dramatic delegation of discretionary authority to Executive Branch agencies stemming from the New Deal. It has served for over 50 years as the blueprint for how agencies issue regulations.

With the rapid growth of complex and wide-ranging regulatory programs since the late 1960s, the limited procedures of the APA have been faced with new challenges. This has moved the Committee over the years to review the adequacy of the regulatory process. Since 1981, three comprehensive bills have been reported by the Committee, though none of these has been enacted into law. S. 981, the “Regulatory Improvement Act of 1998,” is the product of the Committee’s work and experience in this area. –

A. Executive branch action on regulatory reform

The Committee’s concern about the adequacy and effectiveness of the federal regulatory process has paralleled a growing interest in centralized control and review by the president. The assertion of presidential authority over the rulemaking process began in 1971, when President Richard Nixon established “Quality of Life Reviews” for certain U.S. Environmental Protection Agency (“EPA”) regulations. Every President since Richard Nixon has implemented executive oversight of the regulatory process. President Gerald Ford required agencies to conduct an inflationary impact analysis for major rules. President Jimmy Carter established the Regulatory Analysis Review Group to review important regulations. He also required an economic impact analysis for major rules under Executive Order 12044.

President Ronald Reagan implemented the most dramatic reform over the rulemaking process when he issued Executive Order 12291 in 1981. This was a significant extension of an evolving centralized review process, and it required that all rules be reviewed by the Office of Information and Regulatory Affairs in the Office of Management and Budget before being issued in proposed or final form. It also required that each agency analyze the costs and benefits of each major rule and that, to the extent permitted by law,

agencies issue rules only if the potential benefits of the rule outweighed the potential costs. President Reagan also issued E.O. 12498 in March 1985, directing agencies to prepare a yearly agenda of all significant regulatory actions for the coming year. When he took office in 1989, President George Bush continued President Reagan's Executive Orders.

In 1993, President Bill Clinton replaced E.O. 12291 with E.O. 12866, which continues the requirement for centralized review of rules. E.O. 12866 applies only to "significant rules," not all rules, but it maintains the requirement for a cost-benefit analysis of significant rules—primarily those that have an annual effect on the economy of \$100 million or more—and it requires that, to the extent permitted by law, agencies issue rules "only upon a reasoned determination that the benefits of the intended regulation justify its costs." Centralized regulatory review by the President, using OMB, is critical to achieving the goals of this legislation: thorough analyses of regulatory proposals, balanced consideration of diverse viewpoints, effective coordination among agencies, and a cost-effective regulatory system.³

B. The Need for Regulatory Reform Legislation

OMB recently reported that there are over 130,000 pages of federal regulations, "with about 60 federal agencies issuing regulations at a rate of about 4,000 per year. * * * Federal regulations now affect virtually all individuals, businesses, State, local and tribal governments, and other organizations in virtually every aspect of their lives or operations."⁴

The Committee is well aware of the importance of sensible regulation in improving the quality of life for the American people. Regulation can help achieve important social and economic goals such as a clean environment, safe products, a safe workplace, and reliable economic markets. Over the past 25 years, the nation has made tremendous progress protecting public health, safety, and the environment and improving our quality of life. We no longer have rivers catching fire. Our air is cleaner.⁵ And American technology and expertise is in demand around the world. But more challenges lie ahead.

Achieving the benefits of regulatory programs does not come without cost. In a recent report to Congress, OMB estimated that the annual cost of regulation of the environment, health, safety and

³The Committee's oversight of the regulatory process has been continuous and longstanding. When Senator Glenn chaired the Committee, he held numerous hearings on President Reagan's Executive Order and the Competitiveness Council under President Bush. Senator Thompson held a hearing on President Clinton's Executive Order and other initiatives. As the Committee has viewed the regulatory process over a long period of time and from a variety of perspectives, there has been a consensus among a majority of the Committee on the need for a more transparent, effective, and accountable centralized review process.

⁴Office of Management and Budget, Office of Information and Regulatory Affairs, Report to Congress on the Costs and Benefits of Federal Regulations (Sept. 30, 1997). The OMB report was required by the Regulatory Accounting Amendment of Senator Ted Stevens, who was then the Chairman of the Governmental Affairs Committee. The Stevens Regulatory Accounting Amendment was modeled on the earlier and more detailed regulatory accounting provision in S. 291, the "Regulatory Reform Act of 1995." The Stevens Amendment was contained in Section 645 of the Treasury, Postal Services and General Government Appropriations Act, 1997 (Pub. L. 104-208), 1996 U.S.S.C.A.N. (110 Stat. 3009): 1088-89.

⁵See Testimony of Carol M. Browner, Administrator, U.S. Environmental Protection Agency, before the Senate Committee on Governmental Affairs, S. Hearing 104-419, March 8, 1995.

the economy is about \$300 billion.⁶ These costs are often passed on indirectly to the American consumer and taxpayer through higher prices, diminished wages, increased taxes, or reduced government services.⁷ Although deregulation in the 1970s and 1980s reduced the burden of economic regulation, the total cost of noneconomic or “social” regulation has been rising substantially. At the same time, there is strong public support for the benefits that well-designed regulations can produce.

As the public demands better results while the costs of regulation rise, the need for a smarter, more cost-effective approach to regulation is more important than ever. The depth of this need is not widely appreciated because the costs of regulation are not as obvious as many other costs of government, such as taxes, and the benefits of regulation often are diffuse. But there is substantial evidence that the current regulatory system often misses opportunities for greater benefits and lower costs. As noted by the President’s chief spokesperson on regulatory policy, Sally Katzen:

Regrettably, the regulatory system that has been built up over the past five decades * * * is subject to serious criticism * * * [on the grounds] that there are too many regulations, that many are excessively burdensome, [and] that many do not ultimately provide the intended benefits.”⁸

The new challenges facing the regulatory system were not envisioned by the drafters of the Administrative Procedure Act some 50 years ago. While the APA has successfully adapted to many changes in the regulatory process, it was not designed to address the current regulatory landscape. Since the APA was passed, the goal of much federal regulation has changed from curbing monopoly power to addressing risks to the environment, health, and safety; the form of most federal regulation has changed from adjudication to informal rulemaking; and the scope of federal regulation has vastly expanded from single industries to economy-wide activity.

These dramatic changes have brought new problems that must be solved: agencies may fail to balance the benefits and costs of regulations, fail to find flexible and cost-effective solutions, or fail to consider unintended harms. Moreover, the rulemaking process is not sufficiently understandable to the public, nor is it as accountable as it should be.

To date, cost-benefit analysis, so important to the development of economically significant rules, has been generally required only through executive order and not through a statutory framework. There are no government-wide requirements for conducting risk assessments. Much of the analytical work of a rulemaking agency is

⁶Office of Management and Budget, Office of Information and Regulatory Affairs, Report to Congress on the Costs and Benefits of Federal Regulations (Sept. 30, 1997). Other studies, which include the full costs of paperwork and economic transfers, estimate that regulation costs about \$700 billion annually. See, e.g., U.S. Small Business Administration, *The Changing Burden of Regulation, Paperwork, and Tax Compliance on Small Business: A Report to Congress* (Oct. 1995).

⁷See, e.g., Resources for the Future, *Public Policies for Environmental Protection* (Paul R. Portney, ed. 1990); Thomas D. Hopkins, “Cost of Federal Regulation” 3, reprinted in *Regulatory Policy in Canada and the United States*, Rochester Inst. Tech., (1992).

⁸Testimony of Sally Katzen, Administrator of OIRA, before the Senate Committee on Governmental Affairs, S. Hearing 104–372, February 22, 1995.

done before the public has the opportunity to comment, and both the policy and scientific basis for the agency's choices are often unclear to the public, through obscure and hard-to-read rulemaking files or through the failure of the agency to make its thinking clear and readily available to the public.⁹

S. 981 seeks to address these problems. Central to that effort is the use of accurate and thoughtful cost-benefit analysis and risk assessment. We know that analyzing the costs and benefits of regulatory proposals is no longer an intellectual curiosity or academic exercise: it is a necessity. In its recent Report to Congress on the Costs and Benefits of Federal Regulations, OMB concluded:

[R]egulations (like other instruments of government policy) have enormous potential for both good and harm. Well-chosen and carefully crafted regulations can protect consumers from dangerous products and ensure they have information to make informed choices. Such regulations can limit pollution, increase worker safety, discourage unfair business practices, and contribute in many other ways to a safer, healthier, more productive, and more equitable society. Excessive or poorly designed regulations, by contrast, can cause confusion and delay, give rise to unreasonable compliance costs in the form of capital investments, labor and on-going paperwork, retard innovation, reduce productivity, and accidentally distort private incentives.

The only way we know how to distinguish between the regulations that do good and those that cause harm is through careful assessment and evaluation of their benefits and costs. Such analysis can also often be used to redesign harmful regulations so they produce more good than harm and redesign good regulations so they produce even more net benefits.¹⁰

Current practices in this regard need significant improvement. In 1996, Robert Hahn of the American Enterprise Institute published one of the most comprehensive analyses of the benefits and costs of recent environmental, health, and safety regulations.¹¹ Hahn concluded that about half the final rules analyzed in the study would not pass a cost-benefit test. Hahn's study also showed that the quality of federal agency cost-benefit analyses varies widely "from very poor to very good" and that we could "realize significant gains by more carefully targeting regulations." In 1997, Richard Morgenstern, an EPA official on leave with Resources for the Future, published a thorough analysis of 12 major rules from EPA

⁹See, e.g., Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, S. Hearing 105-335, September 12, 1997; Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, February 24, 1998; GAO, Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented, GAO/GGD-98-31 (Jan. 1998); GAO, Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations, GAO/RCED-84-62 (April 6, 1984).

¹⁰Office of Management and Budget, Office of Information and Regulatory Affairs, Report to Congress on the Costs and Benefits of Federal Regulations (Sept. 30, 1997), at 10.

¹¹Robert W. Hahn, "Regulatory Reform: What Do the Government's Numbers Tell Us?," in *Risks, Costs, and Lives Saved*, (Robert W. Hahn, ed. 1996). See also, Testimony of Robert W. Hahn before the Subcommittee on Financial Management and Accountability, Senate Committee on Governmental Affairs, S. Hearing 104-825, September 25, 1996.

subject to economic analysis.¹² Morgenstern concluded that the economic analyses helped reduce the costs of all 12 of the rules and, at the same time, helped increase the benefits of five of them. Studies by the U.S. General Accounting Office (“GAO”) have echoed such findings.¹³

There is broad support for reforming the regulatory process and the tools to accomplish that goal, including cost-benefit analysis, market-based mechanisms, risk-assessment, and comparative risk analysis. This support comes from diverse sources, such as the National Research Council,¹⁴ the Harvard Center for Risk Analysis,¹⁵ the American Enterprise Institute,¹⁶ the Brookings Institution,¹⁷ the Clinton Administration,¹⁸ Justice Stephen Breyer,¹⁹ the Carnegie Commission,²⁰ Resources for the Future,²¹ and other think tanks, commissions, and independent scholars throughout the country.²² The strong record on the need for regulatory reform and the tools to achieve it has contributed to this legislation.

¹² Resources for the Future, *Economic Analyses at EPA* (Richard D. Morgenstern, ed. 1997).

¹³ See, e.g., Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, February 24, 1998; Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, September 12, 1997; GAO, *Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations*, GAO/RCED-84-62 (April 6, 1984).

¹⁴ See, e.g., National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society* (1996); National Research Council, *Science and Judgement in Risk Assessment*, National Academy Press, Washington, D.C. (1994); National Research Council, *Issues in Risk Management*, National Academy Press, Washington, D.C. (1993); National Research Council, *Valuing Health Risks, Costs, and Benefits for Environmental Decision Making*, National Academy Press, Washington, D.C. (1990); National Research Council, *Improving Risk Communication*, National Academy Press, Washington, D.C. (1989); National Research Council, *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, D.C. (1983).

¹⁵ See, e.g., Harvard Center for Risk Analysis, *Reform of Risk Regulation: Achieving More Protection at Less Cost* (March 1995); John D. Graham, *Making Sense of Risk: An Agenda for Congress*, in *Risks, Costs, and Lives Saved* (Robert W. Hahn, ed. 1996); *The Greening of Industry: A Risk Management Approach*, Harvard University Press (John D. Graham & Jennifer Kassalow Hartwell, eds. 1997).

¹⁶ See, e.g., American Enterprise Institute & Brookings Institution, *An Agenda for Regulatory Reform* (Robert W. Hahn & Robert E. Litan, eds. 1997); American Enterprise Institute & Brookings Institution, *Improving Regulatory Accountability* (Robert W. Hahn & Robert E. Litan, eds. 1997); American Enterprise Institute, The Annapolis Center & Resources for the Future, *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation* (1996); American Enterprise Institute, *Benefit-Cost Analysis of Social Regulation: Case Studies from the Council on Wage and Price Stability*, Washington, D.C., (James C. Miller & Bruce Yandle, eds. 1979); M.J. Bailey, *Reducing Risks to Life: Measurement of Benefits*, American Enterprise Institute, Washington, D.C. (1980); Robert W. Hahn & J.A. Hird, *The Costs and Benefits of Regulation*, 8 *Yale J. on Reg.* 233 (Winter 1991).

¹⁷ See, e.g., Lester Lave, *The Strategy of Social Regulation*, Brookings Institution, Washington, D.C. (1981); Lester Lave, *Quantitative Risk Assessment in Regulation*, Brookings Institution, Washington, D.C. (1982); Robert W. Crandall, *Controlling Industrial Pollution: The Economics and Politics of the Clean Air Act*, Brookings Institution, Washington, D.C. (1983).

¹⁸ Office of Management and Budget, Office of Information and Regulatory Affairs, Report to Congress on the Costs and Benefits of Federal Regulations (Sept. 30, 1997), at 2 (cost-benefit analysis significantly enhances the consideration of alternative approaches to achieving regulatory goals, ultimately producing more benefits and fewer costs); National Performance Review, *Creating a Government that Works Better and Costs Less*, Washington, D.C. (1993); National Performance Review, *Improving Regulatory Systems*, Washington, D.C. (Sept. 1993).

¹⁹ Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, Harv. Univ. Press, Cambridge, MA (1993); Stephen Breyer, *Regulation and its Reform* (1982).

²⁰ Carnegie Commission on Science, Technology, and Government, *Risk and the Environment: Improving Regulatory Decisionmaking*, Washington, D.C. (June 1993).

²¹ J. Clarence Davies & Jan Mazurek, *Pollution Control in the United States, Resources for the Future* (1998); Paul R. Portney, *Public Policies for Environmental Protection, Resources for the Future* (1990); Paul R. Portney, *Economics and the Clean Air Act*, 4 *J. Econ. Perspectives* 173 (Fall 1990); Resources for the Future, *Worst Things First?: The Debate Over Risk-Based National Environmental Priorities*, Washington, D.C. (Adam N. Finkel and Dominic Golding, eds. 1994).

²² See, e.g., Cass R. Sunstein, *Congress, Constitutional Moments, and the Cost-Benefit State*, 2 *Stan. L. Rev.* 247 (1996); Cass R. Sunstein, *Health-Health Tradeoffs*, 63 *U. Chi. L. Rev.* 1533

C. Governmental Affairs Committee action on regulatory reform

The Committee has been involved in overseeing the regulatory decisionmaking process for over two decades. Through a variety of studies, hearings, legislative proposals, and oversight of the regulatory process, the Committee has developed a broad expertise on the strengths and weaknesses of the regulatory process and proposals for reform. This expertise has contributed to the development of S. 981.

In 1975, the Senate passed a resolution, S. Res. 71, directing the Governmental Affairs Committee to conduct a comprehensive study of Federal regulations, to assess the impact of regulatory programs, and to analyze the need for change. The Committee spent almost two years carrying out that mandate and concluded with a six-volume report on various aspects of the regulatory system, from public participation in the regulatory process, to the role of congressional oversight.²³ These volumes constitute the most thorough review of the regulatory process ever conducted by the Congress. The problems identified and solutions proposed have substantially informed subsequent debates on regulatory reform, both within and outside of the Committee, and have influenced the drafting of this legislation. The study emphasizes, for example, that poor, costly, and burdensome agency regulations often are a product of defective preliminary analysis which fails adequately to account for costs, the possibility of alternative regulatory solutions, or no regulation at all.²⁴

(1996); Cass R. Sunstein, "After the Rights Revolution," Harv. Univ. Press, Cambridge, MA (1990); National Academy of Public Administration, *Resolving the Paradox of Environmental Protection: An Agenda for Congress, EPA & the States*, (Sept. 1997); Enterprise for the Environment, *The Environmental Protection System in Transition: Toward a More Desirable Future* (Jan. 1998); Marian R. Chertow & Daniel C. Esty, *Thinking Ecologically: The Next Generation of Environmental Policy* (1997); Murray L. Weidenbaum, "Business and Government in the Global Marketplace," Prentice Hall, Englewood Cliffs, NJ (5th ed. 1995); W. Kip Viscusi, "Fatal Tradeoffs: Public and Private Responsibilities for Risk," Oxford Univ. Press, NY (1990). See also, Administrative Conference of the United States, ACUS Recommendation 85-2, "Agency Procedures for Performing Regulatory Analysis of Rules" (1985); ACUS Recommendation 88-9, "Presidential Review of Agency Rulemaking" (1988); ACUS Recommendation 93-4, "Improving the Environment for Agency Rulemaking" (1993).

²³The Governmental Affairs Committee published the following six volumes of the Study on Federal Regulation between January 1977 and December 1978:

1. Senate Committee on Government Operations, 95th Cong., 1st Sess., 1 Study on Federal Regulation, "The Regulatory Appointments Process" (Comm. Print 1977).
2. Senate Committee on Government Operations, 95th Cong., 1st Sess., 2 Study on Federal Regulation, "Congressional Oversight of Regulatory Agencies" (Comm. Print 1977).
3. Senate Committee on Governmental Affairs, S. Doc. 95-71, 95th Cong., 1st Sess., 3 Study on Federal Regulation, "Public Participation in Regulatory Agency Proceedings" (Comm. Print 1977).
4. Senate Committee on Governmental Affairs, S. Doc. 95-72, 95th Cong., 1st Sess., 4 Study on Federal Regulation, "Delay in the Regulatory Process" (Comm. Print 1977).
5. Senate Committee on Governmental Affairs, S. Doc. 95-91, 95th Cong., 2d Sess., 5 Study on Federal Regulation, "Regulatory Organization" (Comm. Print 1977).
6. Senate Committee on Governmental Affairs, S. Doc. 96-13, 96th Cong., 1st Sess., 6 Study on Federal Regulation, "Framework for Regulation" (Comm. Print 1978).

²⁴The following conclusion from the 1978 Study rings true today:

The report finds that decisions when and how to regulate all too often are based on insufficient analysis and consideration of alternatives. Simply because a problem exists and, in theory is remediable, does not mean that regulation or other government intervention is desirable. Controls should only be undertaken where there is a clearly identified problem that cannot otherwise be solved, and where the anticipated achievements are significant and vitiated by projected adverse consequences.

We believe that before Congress or the agency adopts any proposed regulatory scheme, the possible economic justifications for regulation should be scrutinized. The discipline inherent in that procedure is a key element in helping to insure good regulatory decisions. (6 Study on Federal Regulation, pp. xi-xii.)

The Committee's Study provided the foundation for extensive hearings in the 96th²⁵ and 97th²⁶ Congresses. These led to the introduction of S. 1080, the "Regulatory Reform Act of 1981," which was jointly referred to the Governmental Affairs Committee and the Judiciary Committee. After receiving unanimous support in Committee, S. 1080 passed the full Senate in 1982 by a vote of 94-0. S. 1080 reflected the increasing concern that the costs of federal regulation in too many cases do not justify the benefits and that the scientific and policy assumptions underlying regulatory decisions often are questionable. Although S. 1080 was overwhelmingly endorsed by the Senate, it was not acted on in the House of Representatives and died there.

Early in the 104th Congress, Chairman Bill Roth introduced legislation to improve the regulatory process, S. 291, the "Regulatory Reform Act of 1995." S. 291 contained some of the basic elements of S. 1080, such as cost-benefit analysis, centralized regulatory review, and periodic review of existing rules. S. 291 added other requirements, such as risk assessment of major environmental, health and safety rules, regulatory accounting, and comparative risk analysis for setting more rational regulatory priorities. S. 291 was reported unanimously by the Committee.

Another regulatory reform bill, S. 343, the "Comprehensive Regulatory Reform Act of 1995," was introduced early in the 104th Congress. S. 343 covered many of the same issues as S. 1080 and S. 291, but differed in some major respects. For example, the cost-benefit requirements were "decisional criteria" that would have amended the substantive standards of the statutes authorizing the regulations. The decisional criteria would have required agencies to select, as a matter of law, the regulatory alternative with the greatest net benefits. S. 343 also contained a process to allow parties to petition agencies to review existing rules. S. 343 was jointly referred to the Governmental Affairs Committee and the Judiciary Committee.

After the Governmental Affairs Committee unanimously passed S. 291, the Judiciary Committee reported out S. 343. S. 343 became the subject of extensive negotiations before it was brought to the floor for consideration during the summer of 1995. The long floor debate ended after three unsuccessful cloture votes on S. 343 and a close vote defeating the Glenn-Chafee substitute amendment, which was based on S. 291.

Following the contentious regulatory reform debate of the 104th Congress, Senators Levin and Thompson agreed to work together to develop bipartisan reform legislation. S. 981 is rooted in past Committee initiatives but has been significantly streamlined and modified to reflect advances in administrative law, policy, and science. This legislation is grounded in a philosophy of greater transparency, better informed decision making, and increased ac-

²⁵Hearings on Regulatory Legislation, Senate Committee on Governmental Affairs, 96th Cong., 1st Sess. (1979) (2 parts). These hearings, encompassing 11 days of testimony from 80 witnesses, are summarized in S. Rep. No. 96-1018, part 1, 52-55, 96th Cong., 2d Sess. (1980).

²⁶Hearings on Regulatory Reform Legislation of 1981, Senate Committee on Governmental Affairs, 97th Cong. 1st Sess. (1981). See also, S. Rep. No. 97-305, 97th Cong., 1st Sess. 1981. The development of the reform legislation was in close cooperation with the Senate Judiciary Committee. See S. Rep. No. 96-1018, Part 2, 96th Cong., 2d Sess. (1980) (joint report of the Senate Governmental Affairs and Judiciary Committees).

countability. This philosophy was supported by the growing Committee record on the shortcomings of the regulatory process.

In 1996, Senator Thompson, then Chairman of the Subcommittee on Financial Management and Accountability, initiated oversight on the implementation of the Administration's Executive Order 12866 and other initiatives to reinvent regulation. The Committee heard testimony from many witnesses and reviewed investigations of the GAO indicating that E.O. 12866 and the Administration's "Cutting Red Tape" initiative were not performing as well as intended.

When Senator Thompson became Chairman of the Committee in 1997, he initiated a series of GAO investigations of the regulatory process with Ranking Member John Glenn. These investigations reviewed implementation of Title II of the Unfunded Mandates Reform Act of 1995; agency efforts to eliminate and revise existing regulations; agency documentation of changes made to regulatory proposals during the OMB review process; and agency use of cost-benefit analysis. All of these investigations indicated that the current regulatory process is inadequate.²⁷

On September 12, 1997 and February 24, 1998, the Committee held hearings on S. 981. During these hearings and the Committee's drafting process, many individuals representing diverse sectors of our society strongly supported the legislation, including many State and local government organizations; the National Academy of Sciences; the American Farm Bureau Federation; many educational organizations; the GAO; John Graham, Director of the Harvard Center for Risk Analysis; Bob Hahn of the American Enterprise Institute; Bob Litan of the Brookings Institution; Warren Belmar, Chair of the Administrative Law Section of the American Bar Association; the National Federation of Independent Businesses; Paul Portney, President of Resources for the Future; former Federal regulators; the Alliance for Understandable, Sensible and Accountable Regulation; and many other scholars, officials, and experts on the regulatory process. Their comments included the following:

Governor George V. Voinovich of Ohio, Chairman of the National Governors' Association ("NGA"), and Governor E. Benjamin Nelson of Nebraska, Chairman of the NGA Committee on Natural Resources, said in their testimony:

We believe that risk assessment and cost benefit analysis are important tools that can better inform regulatory decisions while improving the protection of public health, safety, and the environment. We believe that the regulatory improvements required by [S. 981] will enable federal officials to do a better job of protecting public health, safety, and the environment in a number of ways.²⁸

²⁷ See GAO, Unfunded Mandates: Reform Act Has Little Effect on Agencies' Rulemaking Actions, GAO/CGD-98-30 (Feb. 1998); GAO/GGD-98-30 (Feb. 1998); GAO, Regulatory Reform: Changes Made to Agencies' Rule Are not Always Clearly Documented, GAO/GGD-98-31 (Jan. 1998) (); GAO, Regulatory Reform: Agencies' Efforts to Eliminate and Revise Rules Yield Mixed Results, GAO/GGD-98-3 (Oct. 1997).

²⁸ Testimony of the Honorable George V. Voinovich, Governor of Ohio and Chairman of the National Governors' Association (NGA), and the Honorable E. Benjamin Nelson, Governor of Nebraska and Chair of the NGA Committee on Natural Resources, before the Senate Committee on Governmental Affairs, February 24, 1998.

Dr. Milton Russell, former Assistant Administrator of EPA, told the Committee:

In contrast to previous proposals, which I did not support, I believe that S. 981 casts the correct balance in encouraging appropriate analysis to assure effective and efficient regulation, in avoiding counterproductive, excessive review by the courts, and in ensuring that regulation moves swiftly to implementation to protect the health and safety of the American people and of the environment.²⁹

Nye Stevens, Director of Federal Management and Workforce Issues in GAO's General Government Division, said:

The bill [S. 981] thoughtfully addresses many issues in regulatory management that have long been the subject of controversy. * * * S. 981 contains a number of provisions to improve regulatory management. * * * Passage of S. 981 would provide a statutory foundation for such principles as openness, accountability, and sound science in rulemaking.³⁰

Dr. Bruce Alberts, President of the National Academy of Sciences, told the Committee:

[M]any scientists and engineers who have devoted their careers to working on environmental problems are puzzled as to why anyone might oppose S. 981.³¹

These parties and others expressed strong support for the need for better use of cost-benefit analysis and risk assessment, more serious consideration of flexible regulatory approaches, more rational priority-setting, stronger regulatory review by OMB, and more serious review of existing regulations.

Others, including representatives of environmental, public safety, and labor groups, opposed the bill. They argued that the requirement that agencies state whether the proposed rule the agency selected is likely to have benefits that justify the costs or is likely to be more cost-effective or have greater net benefits than the other regulatory alternatives considered by the agency would "restrict current authority"³² of agencies to issue protective regulations and that "lengthy delays in issuing rules due to analytical demands and review procedures * * * would sharply increase the time, difficulty, and costs of developing new safeguards."³³ They also ar-

²⁹Testimony of Dr. Milton Russell, Senior Fellow, Joint Institute for Energy and Environment, Professor Emeritus of Economics at University of Tennessee, before the Senate Committee on Governmental Affairs, February 24, 1998.

³⁰Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, General Accounting Office, before the Senate Committee on Governmental Affairs, September 12, 1997.

³¹Testimony of Dr. Bruce Alberts, President, National Academy of Sciences, before the Senate Committee on Governmental Affairs, February 24, 1998.

³²Testimony of David Hawkins, Senior Attorney, Natural Resources Defense Council, before the Senate Governmental Affairs Committee, September 12, 1997.

³³Testimony of David Hawkins, Senior Attorney, Natural Resources Defense Council, before the Senate Governmental Affairs Committee, September 12, 1997.

gued against the peer review requirements of the bill³⁴ and the provisions requiring the review of rules.³⁵

The Committee considered at length the concerns raised by the witnesses opposed to S. 981. Many of the issues raised by the bill's opponents were addressed in the substitute amendment offered by Senators Levin and Thompson on February 4, 1998, and adopted at the markup. Others were adopted by the Committee as amendments during markup. (See Section III.) In the end, the Committee disagrees with the analysis of the organizations opposing the bill for the reasons identified and explained throughout this report.

III. LEGISLATIVE HISTORY AND COMMITTEE CONSIDERATION

A. *Committee Hearings*

On September 12, 1997, the Governmental Affairs Committee held its first hearing on S. 981. This hearing built on the Committee's extensive hearing record and legislative history on regulatory reform from the 104th Congress. Testifying at this hearing were Sally Katzen, the Administrator of OMB's Office of Information and Regulatory Affairs; L. Nye Stevens, the Director of Federal Management and Workforce Issues, General Government Division, General Accounting Office; Thomas F. Walton, Director of Economic Policy, General Motors Corporation, on behalf of the Alliance for Understandable, Sensible and Accountable Regulation; Sal Risalvato, a small business owner, on behalf of the National Federation of Independent Business; James L. Martin, Director, Office of State-Federal Affairs, National Governors' Association; Ernest Gellhorn, Professor of Law, George Mason University School of Law; John D. Graham, Director of the Harvard Center for Risk Analysis; C. Boyden Gray, Partner, Wilmer, Cutler and Pickering and former White House Counsel to the Presidential Task Force on Regulatory Relief; David G. Hawkins, Senior Attorney, Natural Resources Defense Council; Paul R. Portney, President, Resources for the Future; and David Vladek, Director, Public Citizen Litigation Group.

The Committee held its second regulatory reform hearing on February 24, 1998. The first two witnesses were the Honorable George Voinovich, Governor of Ohio and President of the National Governors' Association, and the Honorable Ben Nelson, Governor of Nebraska and Chairman of the Committee on Natural Resources, National Governors' Association. Also testifying were Dr. Milton Russell, Senior Fellow of the Joint Institute for Energy and the Environment and Professor Emeritus at the University of Tennessee; Nancy Donley, President, Safe Tables Our Priority; Sue Doneth, Member, Safe Tables Our Priority; Dr. Lester Crawford, Georgetown Center for Food and Nutrition Policy; Michael Resnick, National School Boards Association; Dr. Bruce Alberts, President, National Academy of Sciences; Warren Belmar, Chair, ABA Administrative Law Committee; Frank Mirer, Director of Health and Safe-

³⁴Testimony of David Vladek, Director, Public Citizen Litigation Group, before the Senate Governmental Affairs Committee, September 12, 1997; Testimony of Dr. Franklin E. Mirer, Director of Health and Safety Department, United Auto Workers, before the Senate Governmental Affairs Committee, February 24, 1998.

³⁵Testimony of Karen Florini, Senior Attorney, Environmental Defense Fund, before the Senate Governmental Affairs Committee, February 24, 1998.

ty, United Auto Workers; Karen Florini, Senior Attorney, Environmental Defense Fund; Robert Litan, Director of Economic Studies and Cabot Family Chairholder of Economics, Brookings Institution; and Robert Hahn, Resident Scholar, American Enterprise Institute.

B. Amendments and Committee Action

On March 10, 1998, the Committee on Governmental Affairs marked up and favorably reported S. 981 in the nature of a substitute by a vote of 8 to 4. Voting in the affirmative were Senators Thompson, Levin, Nickles, Glenn, Stevens, Cochran, Collins, and Brownback. Voting in the negative were Senators Lieberman, Akaka, Durbin, and Cleland. In addition, Senators Roth and Domenici voted in the affirmative by proxy, and Senator Torricelli voted in the negative by proxy.

Moreover, a number of amendments were offered, debated and voted upon. The following were adopted:

(1) Senator Cleland offered an amendment to clarify the savings clause (adopted by voice vote), as amended by Chairman Thompson's second degree amendment (adopted 9-5). Voting in the affirmative on Chairman Thompson's second degree amendment were Senators Roth (by proxy), Collins, Brownback, Domenici, Cochran, Nickles, Glenn, Levin, and Thompson. Voting in the negative were Senators Lieberman, Akaka, Durbin (by proxy), Torricelli, and Cleland.

(2) Senator Nickles offered an amendment to broaden the scope of information considered by agencies when conducting risk assessments (adopted by voice vote), as amended by Chairman Thompson's second degree amendment (adopted by voice vote).

(3) Senator Nickles offered an amendment to amend the definition of "risk assessment" to ensure that agency risk assessments are scientifically objective and based on the weight of the evidence (adopted by voice vote), as amended by Senator Levin's second degree amendment (adopted by voice vote).

(4) Senator Nickles offered an amendment to ensure that agencies consider and determine whether to adopt flexible regulatory options (adopted by voice vote).

(5) Senator Nickles offered an amendment to ensure that agencies describe flexible regulatory options considered and provide an explanation if they are not adopted (adopted by voice vote).

(6) Senator Lieberman offered an amendment to encourage agencies to consider regulatory options that protect sensitive subpopulations, or populations exposed to multiple and cumulative risks (adopted by voice vote).

IV. ADMINISTRATION VIEWS

OMB Director Franklin Raines delivered a letter to the Committee the day before the mark-up, expressing the Administration's views on S. 981.³⁶ Mr. Raines stated that the Administration "believes strongly in responsible regulatory reform." He said that the bill presented to the Committee for mark-up contained "significant improvements over" the bill as introduced. However, Mr. Raines wrote that "[w]hile the substitute is responsive to many of our con-

³⁶Letter of OMB Director Franklin D. Raines to Chairman Fred Thompson, March 6, 1998.

cerns,” the Administration “concluded that the bill does not yet meet the test we have articulated, and therefore the Administration would oppose the bill if it were to be adopted in its current form.” Mr. Raines then proceeded to identify seven concerns the Administration has with the bill and 20 possible amendments that would address those concerns.

V. SECTION-BY-SECTION ANALYSIS

Section 1. Short title

The name of this legislation is the “Regulatory Improvement Act of 1998”.

Section 2. Findings

Section 2 lays out eight basic findings by the Committee. These findings underscore both the strengths and limitations of regulatory analysis and review. The findings also reflect the experience and expertise of the Committee, as informed by scores of experts, government officials, and stakeholders in the regulatory process.³⁷ These findings are as follows:

First, effective regulatory programs provide important benefits to the public, including improving the environment, worker safety, and public health. Regulatory programs also impose significant costs on the public, including individuals, businesses, and State, local, and tribal governments.

Second, improving the ability of Federal agencies to use scientific and economic analysis in developing regulations should yield increased benefits and more effective protections while minimizing costs.³⁸

Third, cost-benefit analysis and risk assessment are useful tools to better inform agencies in developing regulations, although they do not replace the need for good judgment and consideration of values.

Fourth, the evaluation of costs and benefits must involve the consideration of the relevant information, whether expressed in quantitative or qualitative terms, including factors such as social values, distributional effects, and equity.

Fifth, cost-benefit analysis and risk assessment should be presented with a clear statement of the analytical assumptions and uncertainties, including an explanation of what is known and not known and what the implications of alternative assumptions might be.

³⁷See, e.g., Letter of Baruch Fishoff, Professor of Social and Decision Sciences and Professor of Engineering and Public Policy, Carnegie Mellon University, to Chairman Fred Thompson, July 15, 1997, S. Hearing 105–535, at 294 (“The Findings are a remarkably succinct summary of what we have learned over the past 20 years regarding the role of analysis in regulation. We would be much better off as a society were the wisdom in them more widely understood and accepted.”)

³⁸See, e.g., Testimony of Paul R. Portney, President, Resources for the Future, before the Senate Committee on Governmental Affairs, September 12, 1997 (Under this legislation, “we might be able to shave off a chunk of the nearly \$300 billion OIRA estimates we spend each year on environmental, health and safety regulation * * * without compromising the benefits we get from regulations. * * * Even a cynical public ought to warm to a \$30 billion ‘free lunch’ each year that does not compromise the quality of their environment or safety of their food and other products they consume each year.”); Testimony of John D. Graham, Director, Harvard Center for Risk Analysis, before the Senate Committee on Governmental Affairs, September 12, 1997.

Sixth, the public has a right to know about the costs and benefits of regulations, the risks addressed, the risks reduced, and the quality of scientific and economic analysis used to support decisions. Such knowledge will promote the quality, integrity and responsiveness of agency actions.

Seventh, the Administrator of the Office of Information and Regulatory Affairs should oversee regulatory activities to raise the quality and consistency of cost-benefit analysis and risk assessment among all agencies.

Eighth, the Federal Government should develop a better understanding of the strengths, weaknesses, and uncertainties of cost-benefit analysis and risk assessment and conduct the research needed to improve these analytical tools.

This legislation is designed to elevate the use of modern decision-making tools, such as risk assessment and cost-benefit analysis, to make the regulatory process more transparent, more efficient and effective, and more accountable to the public.

Section 3. Analysis of agency rules

Section 3(a) substantially amends chapter 6 of title 5, United States Code. Section 3(a) creates three new subchapters. Subchapter II requires analysis of agency rules, including cost-benefit analysis, risk assessment, peer review, and guidelines, as well as a comparative risk analysis study. Subchapter III requires the review of rules. Subchapter IV requires executive oversight of the rule making process. Section 3(b) amends Section 610 of the Regulatory Flexibility Act, heretofore chapter 6 of title 5 (hereafter subchapter I), to promote agency review of rules significantly affecting small businesses and small governments. Section 3(c) is a savings clause, stating that the current legislation does not limit any of the President's constitutional duties and authorities, including the authority to review regulatory actions not covered by this legislation. Finally, section 3(d) provides the technical and conforming amendments necessary to reorganize chapter 6 into subchapters, including, for example, moving the Regulatory Flexibility Act to subchapter I of chapter 6.

In amending title 5, United States Code, the Committee-passed bill applies the definition of "agency" under section 551 to subchapters II, III and IV of the bill—the regulatory analysis, review of rules, and executive oversight requirements. This definition includes the independent regulatory agencies within the scope of this legislation. Thus, the requirements to identify major rules, to perform cost-benefit analyses and risk assessments, and to review existing rules would apply not only to departments and other executive agencies, but also to the independent regulatory agencies, such as the Federal Energy Regulatory Commission, the Nuclear Regulatory Commission, and the Consumer Product Safety Commission.

This legislation also would require independent regulatory agencies, like all other Executive Branch agencies, to be subject to Presidential oversight for compliance with the requirements of this legislation. Such Presidential oversight includes the review of proposed and final major rules by OMB's Office of Information and Regulatory Affairs. Since 1981, OIRA's regulatory review authority under Presidential executive order (E.O. 12291, 12498, and 12866)

has explicitly exempted independent regulatory agencies and made their participation in the regulatory review process voluntary. The Committee believes that the provisions of this legislation should apply to all Executive Branch agencies, including the independent regulatory agencies. The growing need for more efficient and effective government regulation, as well as for more coherent management of the Executive Branch, supports lowering some walls that have separated the independent agencies from other Executive Branch agencies.³⁹ Specific exemptions are provided within the definition of “rule” where this Committee or other authorizing Committees determined that there would not be significant benefits from regulatory analysis or OIRA review.

SECTION 3(a)

Section 3(a) creates new subchapters II, III, and IV in chapter 6, title 5, United States Code.

Subchapter II. Regulatory Analysis

Subchapter II establishes provisions for new definitions (sec. 621); applicability and effect (sec. 622); regulatory analysis (sec. 623); principles for risk assessments (sec. 624); peer review (sec. 625); deadlines for rule making (sec. 626); judicial review (sec. 627); guidelines, interagency coordination, and research (sec. 628); and risk-based priorities study (sec. 629).

§ 621. Definitions

This section defines certain terms used in regulatory analysis. Many of these definitions are used not only in the new subchapter II, but also are referred to and incorporated into subchapters III and IV.

(1) The term “Administrator” means the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget.

(2) The term “benefit” means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule.

The term “benefit” has broad meaning. Benefits are the favorable effects that are causally related to the rule. In other words, benefits are the improvements upon the status quo as a result of the rule. Federal agencies issue regulations to implement laws passed by Congress. As such, the value of a regulation is the extent to which it provides the public benefits envisioned by the underlying law. Regulations addressing health, safety, or environmental risks, for example, provide benefits from reducing risk, and the evaluation of those risk-reduction benefits would be based on the risk assessment performed under section 624 of this Act.

³⁹ See, e.g., ACUS Recommendation 95-3: “Review of Existing Agency Regulations” (1995); Administrative Law Conference of the United States: Recommendation 88-9: “Presidential Review of Agency Rulemaking” (1988); American Bar Association, Commission on Law and the Economy, *Federal Regulation: Roads to Reform* (1979), at 108; American Bar Association, *Administrative Law Report No. 110* (1986); Peter L. Strauss & Cass R. Sunstein, “The Role of the President and OMB in Informal Rulemaking,” 38 *Admin. L. Rev.* 181, 205 (1986).

Benefits can be readily apparent, as in economic benefits obtained from standardized hazardous material transportation rules or in the regained safety of a locality's drinking water supply. Benefits also can be very broad, as in the growth of an economic sector or improved nation-wide employment rates. Finally, regulatory benefits can be significant but difficult to quantify, such as the value of increased visibility over the Grand Canyon.

This wide variety of possible benefits must be recognized in the rulemaking process. However, merely because benefits may be varied or difficult to quantify should not relieve agencies from identifying the specific benefits of a rule. The identification and evaluation of regulatory benefits should enable agencies to improve the effectiveness and efficiency of the regulatory process and to best serve the goals of the enabling statute.

As a part of this broad meaning of "benefit," the Committee intends agencies to consider direct as well as the indirect benefits. Many benefits can be clearly attributed to a regulatory action. Many, however, flow in more tangential ways. The Committee expects agencies to make a reasonably thorough effort at identifying and analyzing all significant benefits that flow from a regulatory action. At the same time, the Committee cautions agencies against speculative attribution of distant outcomes to a regulatory action.

The definition of benefits is not limited to favorable effects that can be quantified. They may include, for example, identifiable and significant but potentially nonquantifiable benefits, such as increased freedom of choice for consumers or enhanced opportunities for public enjoyment of the environment. In other words, benefits that cannot be monetarily quantified, or even numerically measured, also should be considered and explained by the agency.

At the same time, the definition of benefits is limited to those that are "significant." Benefits should be more than trivial or de minimis. The Committee does not anticipate that agencies will spend valuable resources trying to assess every small, remote benefit of a rule; during the cost-benefit analysis, only significant benefits need be addressed.

(3) The term "cost" means the reasonably identifiable significant adverse effects, quantifiable or nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule. The definition of "cost" parallels that of "benefit," and the concerns expressed above regarding "benefit" apply equally here.

As in the case of "benefits," the Committee intends to give broad meaning to the term "cost." Agencies must be sensitive to all of the significant costs regulation can impose. While compliance costs often comprise a substantial portion of total costs, there are other costs of regulation. To name a few, these costs include adverse effects on health, safety or the environment; such adverse effects increase the net cost of a regulatory alternative. Costs also include adverse impacts on consumer choice, technological innovation, wages, productivity, economic growth, and lower employment. Again, agencies should eschew unreliable speculation about costs, as with benefits, but they should try to responsibly identify all "significant" costs imposed by a regulatory action. The concept of "cost"

for cost-benefit analysis includes opportunity costs.⁴⁰ Accordingly, agencies should be more sophisticated in cost estimation than only summing up compliance costs.

Finally, agencies must identify and evaluate direct and indirect costs, as well as quantitative and nonquantitative costs. If a rule sets in motion a series of legally required actions that result in costs, even if those actions will be taken by entities other than the regulatory agency, the agency should consider such adverse effects as “costs” under this Act.⁴¹

(4) The term “cost-benefit analysis” means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practical for reasoned decisionmaking on the matter involved, taking into consideration uncertainties, the significance and complexity of the decision, and the need to adequately inform the public. This definition includes the minimum essential features of cost-benefit analysis.

The Committee intends that the agencies use the best available techniques for these analyses and tailor the specificity and rigor of the analysis to the consequences of the decision to be made and the need to inform stakeholders and the public. This provides the agency with reasonable flexibility in the level of detail and rigor that should be employed. However, the Committee expects that the analysis will follow the basic requirements of this legislation.

(5) The term “Director” means the Director of the Office of Management and Budget, acting through the Administrator of the Office of Information and Regulatory Affairs. The reason for this definition is two-fold. First, the Committee expects the Director of OMB, not just the Administrator of OIRA, to be directly accountable for the prompt and effective implementation of this legislation. Second, the Committee at the same time intends to recognize the important role and responsibility of OIRA in the regulatory process. Since 1980, when the Committee passed the Paperwork Reduction Act, the Committee has viewed the Administrator of OIRA as a important partner in ensuring that the regulatory process is efficient, effective, and accountable. This legislation will further this critical role of OIRA.

(6) The term “flexible regulatory options” means regulatory options that permit flexibility to regulated persons in achieving the

⁴⁰ As Paul Portney told the Committee:

[T]he sum total of out-of-pocket expenditures is not identical to “costs” as economists think of them for a benefit-cost analysis. [Costs] include the value of time that people must spend waiting in line for permits, car inspections, etc. It includes the adverse health effects they incur because of the time involved to bring a potentially effective new therapeutic drug to market. It includes the inconvenience they suffer when a product becomes less effective on account of a regulation, or disappears from the market altogether. None of these “costs” involves any out-of-pocket expenditure, but they must all be counted in any serious benefit-cost analysis.

Testimony of Paul R. Portney, Resources for the Future, before the Senate Committee on Environmental Affairs, February 8, 1995.

⁴¹ For example, EPA recently issued a major rule under the Clean Air Act to reduce particulate matter and ozone and performed a cost-benefit analysis for the rule under Executive Order 12866. This rule will require states to change their State Implementation Plans (“SIPs”) to satisfy the tighter standards. These SIP revisions will impose costs that are attributable to the EPA rule and such costs would be included in a cost-benefit analysis under this legislation, just as EPA was required to include such costs in its cost-benefit analysis performed under E.O. 12866.

objective of the statute as addressed by the rule making, including market-based mechanisms, outcome-oriented performance-based standards, or other options that promote flexibility. The Committee believes that flexible regulatory options have the potential to be more efficient and effective than command-and-control regulation.

“Market-based mechanisms” include regulatory programs or requirements that impose legal accountability for achieving the regulatory objective on each regulated entity, afford maximum flexibility to each regulated entity in meeting mandatory regulatory objectives, and allow those regulated entities to respond freely to changes in pertinent economic conditions and circumstances without undermining the achievement of the program’s regulatory mandate or requiring a new rulemaking.

The Committee has heard testimony that some of our greatest regulatory successes have been achieved through market-based mechanisms.⁴² One such example is the program for reducing nationwide sulfur dioxide emissions, established under Title IV of the Clean Air Act. There, Congress imposed directly on sources of emissions explicit pollution reduction requirements. The sources were allowed to meet those requirements through any means they chose, including purchasing credits representing the performance of needed reductions by other sources. This program is achieving greater emissions reductions at a small fraction of the anticipated costs of command-and-control regulation and is far ahead of the statutory schedule.⁴³

“Performance-based standards” include requirements, expressed in terms of outcomes or goals instead of prescriptive command-and-control measures, that permit discretion and the use of market-based mechanisms in determining how best to meet specific requirements in particular circumstances. In contrast to command-and-control regulation, performance-based standards simply establish the ultimate regulatory goal and free regulated parties to meet or exceed that goal as they choose. Like market-based mechanisms, the Committee requires agencies to seriously consider performance-based standards because they have similar elements of flexibility, cost-effectiveness, and accountability.

⁴² See, e.g., Statement of Paul R. Portney, President, Resources for the Future, before the Senate Committee on Governmental Affairs, September 12, 1997; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, September 12, 1997; Testimony of Thomas F. Walton, Director of Economic Policy, General Motors Corporation, before the Senate Committee on Governmental Affairs, September 12, 1997; Testimony of Joseph Goffman, Senior Attorney, Environmental Defense Fund, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Alan J. Krupnik, Senior Fellow, Resources for the Future, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Jonathan B. Wiener, Associate Professor, Duke University School of Law and Duke University School of Environment, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Carol M. Browner, Administrator, U.S. Environmental Protection Agency, before the Senate Committee on Governmental Affairs, March 8, 1995.

⁴³ See Testimony of Joseph Goffman, Senior Attorney, Environmental Defense Fund, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Alan J. Krupnik, Senior Fellow, Resources for the Future, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of Jonathan B. Wiener, Associate Professor, School of Law, Duke University, before the Senate Committee on Governmental Affairs, March 8, 1995; Testimony of C. Boyden Gray, Partner, Wilmer, Cutler & Pickering and Chairman, Citizens for a Sound Economy, before the Senate Committee on Governmental Affairs, September 12, 1997.

(7) The term “major rule” is defined to include two categories of significant rules: economically significant and other significant rules designated by the Director of OMB.

The first category of “major rule” is defined in subsection 621(7)(A) as a rule that the relevant agency or the Director of OMB reasonably determines is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs.” To be classified as “major,” such a rule should be reasonably likely to have such an effect in any one year following its adoption.

The Committee’s decision to set the threshold for major rules at \$100 million follows the long-standing tradition under centralized executive review of rules. Since President Ford, every President has required by executive order the review of regulations which impose annual costs on the economy of \$100 million or more. The bill maintains the traditional \$100 million threshold because the Committee believes that it will not unduly increase the analytical burden of the agencies and that rules of such significance can benefit greatly from thorough analysis. All significant costs of a rule should be considered in determining whether a rule is “major” under subsection 621(7)(A).

Subsection 621(7)(B) provides a second prong to the major rule definition. This allows the President, through the OMB Director, to subject to cost-benefit analysis those rules which, while not imposing costs of \$100 million on the economy, still have a substantial impact. This category includes rules likely to adversely affect, in a material way, the economy, a sector of the economy (including small business), productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities.

Regulatory agencies and the OMB Director should be mindful of the disproportionate impact their actions can have on certain groups or sectors of the economy, even if the impact on the country as a whole is not substantial. This is particularly true of small business.⁴⁴ The Committee encourages the Director and the agencies to be sensitive to these concerns.

(8) The term “reasonable alternative” means a reasonable regulatory option that would achieve the objective of the statute as addressed by the rule making and that the agency has authority to adopt under the statute granting rule making authority, including flexible regulatory options.

Reasonable alternatives embrace the range of options that the agency has discretion to consider under the statute authorizing the rulemaking. The Committee included flexible regulatory options in the definition of “reasonable alternative” to encourage agencies to seek out such alternatives. The agency should consider the range of options authorized by the underlying statute to best achieve the objective being addressed by the rulemaking. “Reasonable alternatives” do not include alternatives prohibited by the statute authorizing the rule.

⁴⁴ See Statement of Karen Kerrigan, President, Small Business Survival Committee, before the Senate Committee on Governmental Affairs, September 12, 1997 (citing Small Business Administration study showing that the annual regulatory cost per worker for companies with less than 20 employees is \$5,532).

(9) The term “risk assessment” means the systematic, objective process of organizing hazard and exposure information and, based on a careful analysis of the weight of the scientific evidence, estimating the potential for specific harm to an exposed population, subpopulation, or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions.

Like the definition of “cost-benefit analysis,” the definition of “risk assessment” includes specific qualitative factors which the Committee views as minimum essential features of a risk assessment. Specifically, the risk assessment should be scientifically “objective”⁴⁵ and “based on a careful analysis of the weight of the scientific evidence.”⁴⁶ Full consideration of the weight of the evidence often involves balancing positive and negative findings. The definition further requires that the risk estimate, to the extent feasible, must contain a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions. The Committee believes that this type of information is necessary to get a complete and meaningful estimate of the risk.

The Committee recognizes that risk assessment is a flexible process by which complex technical data are combined and analyzed to provide decision makers with useful information to make policy decisions. In some decision contexts, such as evaluating food additives, it is useful to distinguish four steps in the risk assessment: hazard identification, dose-response analysis (which together comprise “hazard assessment”), exposure assessment, and risk characterization. In other contexts, such as transportation safety, one or another of the first three steps may not be relevant. The Committee believes that the definition adopted by this legislation is sufficiently generic to apply to the wide variety of risks covered by this legislation. The Committee encourages advances in state-of-the-art risk assessment practices.

(10) The term “rule” has the same meaning as such term is defined in section 551(4) of title 5, United States Code, with a number of exclusions.

First, subparagraph (A) exempts from the definition of “rule” any rule that is exempt from notice and public comment procedures under section 553 of title 5 of the United States Code. These include: rules relating to a military or foreign affairs functions; interpretative rules; rules relating to grants, benefits, or loans; rules relating to agency management or personnel; and rules relating to the acquisition, management or disposal of federal property. In some cases, these rules could have a significant impact on the economy. Yet, the Committee decided to minimize the burdens on the

⁴⁵ Agency risk assessments should be scientifically objective to the extent possible, neither minimizing nor exaggerating the nature and magnitude of the risks. Such risk assessments should be more transparent and credible, leading to less contentious risk management decisions. Such assessments should lead to a more risk-based regulatory system, offering the opportunity for greater overall protection with the available resources. See Testimony of John D. Graham before the Senate Committee on Governmental Affairs, September 12, 1997; Safe Drinking Water Act of 1996, Section 103, 42 U.S.C. § 300g-1(b)(3).

⁴⁶ See Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Assessment and Risk Management in Regulatory Decision-Making (“Risk Commission Report”), Vol. 1, at 4, 23, 38.

agencies; where notice and comment pursuant to section 553 is not required, a cost-benefit analysis will not be required either.

However, the Committee cautions the agencies that any statement of general applicability that actually alters or creates rights or obligations of persons outside the agency is included in this definition. While informal agency guidance is encouraged, agencies should not attempt to evade the requirements of this legislation through mischaracterizations of such materials.

Subparagraph (B) excludes rules involving the internal revenue laws. The Committee was concerned that the enormous economic impact of such rules might make an overwhelming number of tax regulations major rules. While many IRS rules have a major economic impact or are otherwise significant, they have this impact because their goal is to raise revenue, pursuant to the explicit mandates of the underlying statute with little or no agency discretion.

Subparagraph (C) excludes rules of particular applicability that approves or prescribes for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing.

This exemption applies to rules “of particular applicability” as that phrase is understood in section 551(4) of title 5. These are rules which, while technically within the definition of “rule,” are more properly considered as licenses or orders because they apply only to a small group or a single individual. The Committee believes that such rules would not greatly benefit from the cost-benefit analysis and periodic review requirements of this legislation because they are generally developed through complex and lengthy proceedings, which often involve sophisticated economic analysis.

Subparagraphs (D) and (E) exclude from the legislation’s scope certain rules relating to monetary policy or to the safety or soundness of federally insured depository institutions.

Subparagraph (F) excludes certain rules relating to the integrity of the securities or commodities futures markets or to the protection of investors in those markets.

Subparagraph (G) excludes certain rules issued by the Federal Election Commission and the Federal Communications Commission.

Subparagraph (H) excludes certain rules required to be promulgated at least annually pursuant to statute. This exemption would include certain rules that establish, modify, open, close, or conduct a regulatory program for a commercial, recreational, or subsistence activity related to hunting, fishing, or camping.

Subparagraph (I) excludes certain rules or agency actions relating to the public debt or fiscal policy of the United States.

In all of these instances, the Committee believes that the analytic requirements of the legislation would not enhance the efficiency or effectiveness of these rules.

Subparagraph (J) exempts from “rule” any rule that authorizes the introduction into commerce, or recognizes the marketable status of, a product. The Committee has been advised that adequate procedures and safeguards exist to screen out potentially dangerous or undesirable new products. For example, the Federal Food, Drug and Cosmetic Act contains detailed requirements for

obtaining approval to market pharmaceuticals, medical devices, and food additives. Similarly, the Toxic Substances Control Act contains requirements for authorizing the use of new chemicals and new uses of existing chemicals. The Committee did not want to disturb those procedures.

(11) The term “substitution risk” means a significant increased risk to health, safety, or the environment reasonably likely to result from a regulatory option. A regulatory option designed to decrease certain risks may sometimes actually increase other risks. A substitution risk is an unintended adverse consequence. The provisions of S. 981 are intended to focus greater attention on the possibility of such adverse consequences, including addressing the likelihood of their occurrence, estimating the nature and magnitude of their impacts, and systematically considering substitution risks as a part of sound regulatory policy-making. The agency should identify, describe, and evaluate any substitution risks in the regulatory analysis. The agency should integrate such risks in its analyses and in making the determinations required under Section 623(d).

By “significant,” the Committee means that the effect of the substitution risk should be important. “Significant” does not refer to the magnitude of the increase in risk as the term “significant risk” is used or interpreted under various environmental, health, and safety statutes;⁴⁷ it refers to the relative relationship a risk may have to the effect of a rule. A risk need not have a likelihood of a particular level, such as one in ten thousand, to be significant. For a “significant increased risk” to qualify as a substitution risk, it need not be greater than the original risk reduction otherwise being achieved by the rule. By “reasonably likely to result,” the Committee means that the substitution risk should not be hypothetical or implausible. For example, the Committee does not intend that attenuated arguments, such as the assertion that changes in lifestyle or health care that could result from changes in income of individuals potentially attributable to a regulatory option, should be considered a substitution risk under this legislation.⁴⁸

§ 622. Applicability and effect

Section 622 clarifies the scope and effect of this legislation. Subsection 622(a) provides that this legislation applies to all “major rules” through the proposed and final rulemaking stages, except as provided in Subsection 623(f).

Subsection 622(b) clarifies that nothing in Subchapter II shall be construed to alter or modify: (1) the substantive standards otherwise applicable to a rulemaking under other statutes; or (2) an opportunity for judicial review made applicable under other statutes. This so-called “savings clause” clarifies two important points: First, this legislation is not intended to override existing statutory standards. Second, this legislation does not alter or diminish any opportunities for judicial review made applicable under other statutes.

⁴⁷ See Occupational Safety and Health Act, 29 U.S.C. § 651.

⁴⁸ See Hearing before the Senate Committee on Governmental Affairs, “Risk-Risk Analysis,” S. Hearing 102-1144 (March 19, 1992); GAO, Risk-Risk Analysis: OMB’s Review of a Proposed OSHA Rule, GAO/PEMD-92-33 (May 1992).

The first part of the savings clause means that the cost-benefit analysis, risk assessment, and cost-benefit determination required by this legislation do not supersede or override the substantive standards in the statute under which a rule is being issued. In other words, S. 981 does not contain a so-called “supermandate.”

Subsection 622(b) also clarifies that this legislation does not curtail opportunities for judicial review available under other statutes. To the extent that another Federal statute provides an opportunity for judicial review of agency action, that opportunity for judicial review continues to apply.

Section 622(b) preserves existing opportunities to secure judicial review and preserves the nature and scope of judicial review provided by another Federal statute.

§ 623. Regulatory analysis

A. Background

This section lays out the requirements for agencies to conduct regulatory analysis, including cost-benefit analysis, risk assessment, and substitution risk analysis when issuing proposed and final major rules. The Committee believes that better use of these important decisionmaking tools will lead to a significantly more efficient and effective regulatory process.

The Committee also recognizes that many of the problems with the regulatory process can be traced to the failure of agencies to consider all of the potential effects of their rules before promulgation. The cost-benefit analysis is intended to provide a framework for the agency to assess the impact of its rule on the economy and society as a whole. The concept of cost-benefit analysis has developed over the past several administrations to the point where some very sophisticated analyses have been prepared. The Committee intends that the analysis be used by agencies to consider alternative regulatory approaches, to compare the benefits and costs of such approaches, and to produce better decisions.⁴⁹

A satisfactory cost-benefit analysis would enable the agency to make an informed judgment whether the benefits of the rule justify its costs, and whether the rule substantially achieves the statutory objectives in the most cost-effective manner, or with the greatest net benefits. This determination is based on the whole rulemaking record.

To fulfill its potential for improving the regulatory process, the preliminary cost-benefit analysis must be made public by the agency to allow comment and criticism by interested parties. As more information is submitted to support or rebut the analysis, it and the final rule will be improved. The preliminary cost-benefit analysis must be summarized in the notice of proposed rulemaking.

The bill requires the cost-benefit analysis to be developed by the agency during the development of the rule. The cost-benefit analysis must guide the agency decision-making process, not provide a

⁴⁹ When well used, cost-benefit analysis is a highly effective tool to increase the efficiency and effectiveness of regulation. See, e.g., *Resources for the Future, Economic Analysis at EPA*, (Richard D. Morgenstern, ed. 1997). One EPA study found that “the return to society from improved environmental regulations is more than one thousand times EPA’s investment in cost-benefit analysis.” See, U.S. Environmental Protection Agency, “EPA’s Use of Cost-Benefit Analysis: 1981–1986” (Aug. 1987), at p. 5–2.

post-hoc rationalization for a decision made before the analysis was prepared. Once completed, the final cost-benefit analysis must be made public with the statement of basis and purpose accompanying the rule. An executive summary of the analysis must be published with the rule in the Federal Register. If the analysis is properly performed, it will provide an excellent brief in support of the agency's factual conclusions and policy choices. The cost-benefit analysis required by this legislation will help to identify questions clearly, to describe assumptions made, and then to clarify the rationale justifying the proposed action so it is open for public debate. An agency must have this information before it, along with other relevant information, in order to make an informed choice.⁵⁰

B. Framework for conducting cost-benefit analysis

The first step, outlined in subsection 623(a), is for agencies, before publishing a notice of proposed rulemaking, to determine whether the rule is or is not a major rule under subsection 621(7)(A)—that is, whether the rule is likely to have a gross annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs. If the rule does not fall within subsection 621(7)(A), then the agency must determine whether the rule is a major rule under subsection 621(7)(B).

If the agency does not determine a rule to be major, subsection 623(a)(2) allows the Director of OMB to exercise the same authority not later than 30 days after the close of the comment period for the rule. This provision is designed to ensure effective Executive Branch oversight of the cost-benefit requirements. A notice of any major rule determination shall be published in the Federal Register, as a part of the notice of proposed rulemaking where possible, and such notice shall include a succinct explanation of the agency's or the Director's action.

Both the preliminary and final cost-benefit analysis should address in detail the issues presented by the regulation, including the need for the rule, the various alternative approaches (including the potential advantages and disadvantages of each), the legal basis for agency action, and an assessment of the benefits and costs of the proposed action. The analysis should provide an objective, critical, and impartial discussion of the regulatory problem and of the potential solutions.

Although basically parallel, the preliminary and final cost-benefit analyses differ in several important respects. In most instances, the quality of analysis and data relevant to the analysis will improve between the time a rule is first proposed and when it is finally issued. Later estimates typically apply better data sources more sophisticated analyses. This tends to improve the accuracy and reliability of estimates, often substantially. To a large degree, such additional information will be provided by peer review, public comments, or other material developed by the agency. Thus, the later analysis should generally be more complete. In addition, the final analysis should address significant comments submitted on the preliminary analysis. The preliminary cost-benefit and cost-effectiveness evaluations required by subsection 623(b)(2) will be fol-

⁵⁰ See, e.g. Risk Commission Report, Vol. 1, pp. 29–36; Vol. 2, p. 93.

lowed by the formal determinations required by the final cost-benefit analysis. The final determinations, of course, should consider any additional data received by the agency since the publication of the preliminary cost-benefit analysis.

C. Content of the cost-benefit analysis

Subsection 623(b) requires the agency to place an initial regulatory analysis⁵¹ in the file of a major rule and publish in the Federal Register a summary of such analysis. The agency then must provide an opportunity for interested persons to comment pursuant to section 553 of title 5, United States Code. This Subsection reflects the Committee's firm conviction that sound analysis of the benefits and costs of various alternative regulatory options before the rule is proposed is essential to reasoned decision making. An agency needs this information, along with other relevant information, to make the best regulatory choice.⁵²

According to subsection 623(b)(2), each initial regulatory analysis must contain three major items: (1) a cost-benefit analysis; (2) a risk assessment, if required; and (3) information on any substitution risks.

Under subsection 623(b)(2)(A), each initial cost-benefit analysis shall contain 5 major components:

(i) An analysis of the benefits of the proposed rule.

(ii) An analysis of the costs.

(iii) An evaluation of the relationship of the benefits of the proposed rule to its costs, taking into account the results of any risk assessment, including the determinations whether the identified benefits of the proposed rule justify its identified costs; whether the proposed rule is likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than other reasonable alternatives considered by the agency; and whether the rule adopts a flexible regulatory option.

(iv) An evaluation of the benefits and costs of a reasonable number of reasonable alternatives reflecting the range options that would achieve the objectives of the statute as addressed by the rulemaking, including alternatives that require no government action; provide flexibility for small entities under the Regulatory Flexibility Act; provide flexibility for State, local or tribal agencies delegated to administer a Federal program; employ flexible regulatory options; and assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks.

(v) A description of the scientific or economic evaluations or information on which the agency substantially relied in the cost-benefit analysis and risk assessment, and an explanation of how the agency reached the determinations under subsection (d).

In addition to the cost-benefit analysis, if the rule requires a risk assessment under section 624, that assessment must be incorporated into the regulatory analysis under subsection 623(b)(2)(B).

⁵¹A regulatory analysis under this legislation encompasses a cost-benefit analysis, any risk assessment, and, if applicable a substitution risk analysis.

⁵²The Risk Commission Report emphasizes the importance of evaluating the costs and benefits of regulatory options before making a decision; this is an essential feature of the Commission's framework for environmental health risk management. See Vol 1, at 29–36; Vol. 2, at 93–101.

Finally, Subsection 623(b)(2)(C) requires the agency to identify and evaluate substitution risks. The analysis of substitution risks is an important part of the rational decisionmaking framework established by this legislation. The Committee believes that if an agency properly identifies and evaluates the potentially adverse health, safety, or environmental effects of a regulatory option, the agency will be best prepared to make a regulatory decision that accounts for such substitution risks. The Committee is concerned that government has not always been sensitive to substitution risks caused or exacerbated by certain regulatory actions.⁵³ The agency must explicitly identify a substitution risk, provided there is reasonably available scientific information on the risk, such as in the scientific literature or as provided during the public comment period. The phrase “reasonably available to the agency” connotes that the agency is expected to engage in an affirmative and reasonably thorough search for information on potential substitution risks, but the search does not have to be exhaustive.

1. Identification of the problem

Every cost-benefit analysis, whether preliminary or final, should begin with a discussion of the nature of the problem. The agency should identify those persons that the underlying statute and the regulation is intended to benefit and discuss the nature of the harm that likely will occur if no action is taken. The analysis should identify the cause or causes of the problem and possible solutions.

The agencies should identify the statutory authority relied upon to promulgate the regulation. The agency should briefly explain why its proposals are within its statutory jurisdiction and is consistent with congressional intent. A similar analysis should be done for each significant alternative.

2. Benefits

The heart of a cost-benefit analysis is a review and discussion of the benefits and costs of the proposed rule and the reasonable alternatives considered by the agency, including an attempt to balance and compare those costs and benefits. Subsections 623(b)(2)(A)(i), (A)(iii), (A)(iv), and (c)(2) require the agency to analyze and describe the benefits of a rule and its alternatives. Economists have noted that the valuation and calculation of benefits generally pose the greatest problem in preparing a cost-benefit analysis, although cost estimates also can be difficult. The benefits of regulation—particularly environmental, safety, and health standards—often are substantial, yet difficult to calculate. The Commit-

⁵³ Cass R. Sunstein, “Health-Health Tradeoffs,” 63 U. Chi. L. Rev. 1533 (1996). See also, John D. Graham & Jonathan Weiner, *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment*, Harv. Univ. Press (1995). One example of the substitution risk problem is the asbestos scare in the early 1980s. Government scientists argued that asbestos exposure could cause thousands of deaths. Public alarm led Congress to pass a sweeping law that led cities and states to spend between \$15 and \$20 billion to remove asbestos from public buildings. But about three years later, EPA officials confirmed that asbestos removal had been a very costly mistake. Ripping out asbestos raised the risk to the public because asbestos fibers became airborne during removal. Removing the asbestos also delayed the opening of many schools and other buildings. See Gregg Easterbrook, *A Moment on the Earth: The Coming Age of Environmental Optimism*, 250–53 (1995); Stephen Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation*, 12–13 (1993).

tee does not expect all cost-benefit analyses will assign numerical values to all projected benefits. The agencies should use a rule of reason. When some aspect of a benefit cannot be quantified, the agency should describe the benefit in detail, state what significance it attributes to the nonquantifiable aspects of the benefit, and explain the basis for its conclusion of this point. Those benefits that cannot be quantified should be described precisely and succinctly. If the agency provides a monetary or other quantitative estimate, the analysis should include the methodological justification. The ranges of predictions and margins of error also should be specified. The cost, benefit, or risk assessment information relied on by the agency, whether quantifiable or nonquantifiable, should be supported by material that would allow the public to assess the accuracy, reliability, and validity of such information.

The agency should bear in mind that, just as markets may not function perfectly, neither do regulatory programs. When considering the benefits of regulating, agencies should not compare imperfect markets or externalities with idealized, perfectly functioning regulatory programs. Recognizing these limitations, the agency should make a reasonable attempt to predict the real-world results of the rule in the cost-benefit analysis.

3. Costs

Subsections 623(b)(2)(A)(ii), (A)(iii), and (A)(iv) make clear that the cost-benefit analysis should address several critical issues in assessing the costs of a regulation. The cost-benefit analysis should look beyond the immediate compliance costs of regulation and attempt to quantify, or at least identify, the significant direct and indirect costs and adverse effects which may result from the rule.

Agencies should estimate the total costs of compliance and opportunity costs. Agencies also should estimate costs to government units, including costs of compliance, administration, enforcement, or lost tax revenue.

It is conceivable that some agency actions could impose costs in the form of new risks to public health, safety, or the environment. These risks should be viewed as increasing the net cost of the regulatory alternative. Alternatively, reducing the compliance burden imposed on one group or sector of the economy may increase the burden on another; those costs also should be considered.

Agencies should consider lost benefits as a cost. Opportunity costs can be difficult to project but also can be among the most significant costs of regulation. The inefficient use of resources, and investment disincentives, can have a significant impact on the economy.

4. Alternatives

Subsection 623(b)(2)(A)(iv) requires the preliminary cost-benefit analysis to contain a brief description of alternatives that reflect the range of the agency's discretion for achieving the objective of the statute as addressed by the rulemaking. Agencies must consider alternatives proposed by the public, but they also should take the initiative to develop alternatives that could achieve the statutory objective as addressed by the rulemaking in a less costly or more effective manner. In the past, agencies have sometimes adopt-

ed rules without seriously considering alternatives that could more effectively achieve the statutory goals or achieve those goals in a less costly manner. This provision is intended to compel agencies to seek out and consider a “reasonable number” of such alternative approaches, particularly flexible options. The legislation focuses the agency’s discussion on a “reasonable number” of alternatives so that agencies are not forced to engage in limitless or wasteful discussions of theoretical regulatory alternatives. At the same time, the Committee cautions the agencies against using this provision to justify ignoring compelling alternatives or using the cost-benefit analysis as a post-hoc rationalization for a pre-determined political decision.

Under this subsection, the agency should evaluate the benefits and costs of a reasonable number of reasonable alternatives reflecting the range of the agency’s discretion, including, where feasible,⁵⁴ alternatives that—(I) require no government action; (II) provide flexibility for small entities under the Regulatory Flexibility Act; (III) provide flexibility for State, local or tribal agencies delegated to administer a Federal program; and (IV) employ flexible regulatory options; and (V) assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks.

Alternatives that achieve substantially all of the benefits of a proposal should be identified and considered, to determine if such alternatives could reduce the net costs of the regulation. Alternative levels and methods of compliance may be appropriate. The alternative of having no regulation should be a starting point in the analysis. There may be existing voluntary,⁵⁵ market, judicial, state, or local regulatory mechanisms that could adequately resolve the problem identified by the agency for action.

In recent years, agencies have developed a number of innovative regulatory techniques to make regulatory programs less costly and more effective. For example, performance-based standards can be used instead of design standards to reduce compliance cost while still meeting regulatory goals. Market-based mechanisms, such as the sale of marketable permits, have been used to reduce the costs of pollution control while meeting or exceeding regulatory goals.

While far from complete, a fundamental shift is taking place in the way federal regulators go about their business, a shift that this legislation is intended to encourage. In the past, agencies too often reached for a single tool, command-and-control regulation, relying on administrative sanctions imposed through formal enforcement procedures, to solve any regulatory problem that arose. Traditional regulation, while necessary and appropriate in some cases, can be time-consuming and costly to both stakeholders and governments, and can create disincentives to innovation. Command-and-control regulation is frequently less effective and more costly than more flexible approaches.

⁵⁴The qualifier “where feasible” in Subsection 623(b)(2)(A)(iv) reflects the Committee’s intent that the alternatives must be both legally feasible, as well as technically feasible.

⁵⁵Some agencies have successfully used voluntary programs, such as EPA’s 33/50 Program, to achieve substantial reductions in pollution in a cost-effective, flexible manner. See Testimony of Carol M. Browner, Administrator, U.S. EPA, before the Senate Committee on Governmental Affairs, March 8, 1995.

5. Analysis of flexible regulatory options

The specific reference in section 623(d)(1)(C) to consider flexible regulatory options, such as market-based mechanisms and performance-based standards, reflects not only the Committee's belief in the importance of considering these options to design regulatory programs, but also the specific steps agencies must follow so that these options will be consistently considered when formulating major rules. When the agency is developing a major rule, subsection 623(d)(1)(C) requires the agency to determine whether the rule adopts a flexible regulatory option. Subsection 623(d)(2)(C) requires the agency to describe any flexible regulatory option considered by the agency and to explain why that option was not adopted. If agencies fulfill the requirement of setting forth the extent to which the designs of proposed regulatory programs incorporate flexible regulatory options, then each rulemaking process, as well as the record created therein, necessarily should reflect discussion and analysis of flexible regulatory options. Since the Committee believes that such alternatives have the potential to produce better performing and more cost-effective regulatory programs, then flexible regulatory options will be an important standard against which agency design efforts can be judged.

6. Scientific or economic evaluations or information

Subsection 623(b)(2)(A)(v) has 2 major purposes. First, it promotes the public's right to know the key information underlying important regulatory decisions. Second, it helps protect against the use of invalid scientific or economic assumptions by requiring an agency to describe what information the agency relied on in making its cost-benefit determinations under section 623(d), and to explain how that information supported the agency's conclusions. This requirement is intended to help ensure the accuracy and scientific validity of the data and studies upon which the agency relies.

7. Cost-benefit determinations

Subsections 623(b)(2)(A)(iii) & (iv) and 623(d) are the heart of the cost-benefit requirements of this legislation. They take the agencies one step beyond the descriptive exercises of other subsections. They serve the critical goals of promoting the public's right to know how and why agencies make important regulatory decisions; enhancing the quality of information underlying agency decisions; and increasing the accountability of government to the public it is there to serve.

Subsection 623(d) requires that, in the final cost-benefit analysis for a major rule, the agency must make a three-fold determination based on the whole rulemaking record: (1) whether the benefits of the rule justify its costs; (2) whether the rule will achieve the rulemaking objective in a more cost-effective manner, or with greater net benefits, than the other alternatives before the agency; and (3) whether the rule adopts a flexible regulatory option. This requirement mirrors that in subsection 623(b)(2)(A)(iii) for the preliminary cost-benefit analysis issued in connection with the notice of proposed rulemaking for a major rule.

In the first requirement, the choice of the word “justify” is an important one. It conveys two concepts: first, that precise quantification of costs and benefits is not mandated; second, that agencies may bring to bear certain judgmental factors to supplement their numerical analysis in making the required determination.

The second requirement, that the rule “achieve the rulemaking objectives in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency” also is not a purely “objective” quantitative exercise. The agency is not required to adopt the alternative with the lowest compliance costs where another alternative provides substantially greater benefits. The term “cost-effective” implies a balancing and weighing of not only the cost of each alternative considered, but also the differing degrees of effectiveness of each such alternative.⁵⁶

The third requirement, discussed above, reflects the Committee’s intent to promote flexible regulatory options. Such options hold great promise to be more efficient and effective than traditional command-and-control approaches.

The Committee is aware that there are limits to quantifying certain benefits, as well as costs. However, this does not mean that agencies are free to act arbitrarily or in the absence of appropriate record support in making their determinations under subsections 623(b)(2)(A)(iii) and 623(d). An agency’s cost-benefit determinations must be “reasonable.” By imposing this requirement of reasonableness, the Committee intends that the agency will engage in “reasoned decision making.” To satisfy this standard, an agency must explore a reasonable range of alternatives, apply clearly articulate and understandable criteria, and explain the reasons why it has reached the determinations required under subsections 623(b)(2)(A)(iii) and 623(d).

The Committee realizes that in some cases it will not be possible or desirable to attempt to quantify all of the costs or benefits of a regulatory proposal or of the reasonable alternatives to it. Although nonquantifiable, such costs and benefits are not to be ignored; they must be described in the cost-benefit analysis, identified in as precise a manner as possible, and considered in making the determinations required by section 623(d). The determinations need not be made primarily on a numerical or mathematical basis.

The Committee recognizes that regulations sometimes implement Congressional policy choices that are not consistent with efficiency criteria. For example, Congress may provide an economic incentive to create networks and infrastructure facilities available to Americans in both rural and urban areas. This policy choice may impose minor quantifiable costs on the entire population in order to provide significant nonquantifiable benefits to discrete populations and to ensure that the country benefits from truly national networks, infrastructure, services, and opportunities therefrom. The Committee does not intend that the provisions of this legislation, particu-

⁵⁶The concept of “cost-effectiveness” is fully consistent with providing protective and responsible regulatory standards. Cost-effectiveness does not require the smallest incremental ratio of cost to effectiveness when mutually exclusive alternatives are compared. See Hearing before the Senate Committee on Governmental Affairs, September 12, 1997, at 300-01 (Letter of John D. Graham, Harvard Center for Risk Analysis).

larly the cost-benefit analysis requirements, override Congress' policy choice.

Where quantifiable costs and benefits are provided, they should be made in the most appropriate units of measurement and specify the ranges of predictions and explain the margin of error involved in the quantification methods and in the estimates used. For example, a hypothetical cost-benefit analysis might describe one of the quantifiable benefits of a regulation as "cases of serious injury reduced." The most precise estimate may be the prediction that actual benefits will be within a range of "ten to fifty cases annually" (this is the "range of prediction"). The probability that the number of cases reduced will actually be within this range may be eighty percent.

However, the Committee reiterates that benefits and costs need not always be expressed in monetary terms. Nonetheless, reducing costs and benefits to common units of measurement can make the analytical and evaluative exercise more useful and understandable. Hence, efforts should be made to translate costs and benefits into monetary or other concrete terms where appropriate. For example, benefits that consist of reducing or controlling adverse effects on health or the environment could be described in the first instance by estimating, using the risk assessment procedures of this legislation, the degree to which the rule would reduce the risk that such effects would occur.

These requirements recognize that quantification of costs and benefits is far from an exact science. As stated elsewhere in this Report, the Committee intends a reasonable analysis and comparison employing the degree of precision appropriate to each situation. The requirements also recognize that past regulatory analyses have not always adequately disclosed the imprecisions inherent in numerical estimates or the assumptions built into the methodologies used to arrive at them. The significant assumptions and uncertainties in the analysis should be prominently displayed, a requirement paralleling the directive in subsection 627(d) that the agency's evaluation of cost-benefit relationships be "reasonable."

Subsection 623(e) provides a practical mechanism to provide the public with better information about regulatory decisions. That information needs to be provided in a way that is understandable and accessible to the public. In the past, the critical information underlying rulemakings often has been buried in long, technical documents in large agency rulemaking files.⁵⁷ This does not serve

⁵⁷ See Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, September 12, 1997; Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, GAO, before the Senate Committee on Governmental Affairs, February 24, 1998; GAO, Cost-Benefit Analysis Can Be Useful in Assessing Environmental Regulations, Despite Limitations, GAO/RCED-84-62 (April 6, 1984) (recommending that regulatory analyses contain executive summaries that recognize all benefits and costs, including nonquantifiable; identify a range of values for benefits and costs subject to uncertainty, as well as sources of uncertainty; and compare all feasible alternatives); GAO, Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer, GAO/RCED-97-38 (April 1997) (finding deficiencies in EPA regulatory analyses and reiterating 1984 GAO recommendations). See also, GAO, Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented, GAO/GGD-98-31 (Jan. 1998) (finding that selected federal agencies usually did not comply with requirements of E.O. 12866 to identify for the public "in a complete, clear, and simple manner" the substantive changes made to regulatory actions while

the public's interest, nor does it serve the interests of Congress, stakeholders, or the President. In fact, it could inhibit communication among relevant decision makers inside and outside the agency, whether they be technical experts, legal counsel or policy makers. Subsection 623(e) addresses this problem by requiring a succinct executive summary of the regulatory analysis. The Committee intends that the executive summary be a useful tool to communicate the important information about the rulemaking to the public, stakeholders, Congress, the President, and the relevant decision makers. The minimal information to be provided includes: (1) the benefits and costs of the rule, and any determinations required under subsection 623(d); (2) the results of any risk assessment; (3) the benefits and costs of reasonable alternatives; and (4) the key assumptions and scientific information upon which the agency relied. In addressing the key scientific information and assumptions, the agency should discuss significant uncertainties and the quality of the science or economics that is the basis of the regulatory analysis, including whether experts are divided over competing paradigms.

Subsection 623(f)(1) provides a limited exemption from compliance with the requirements of this legislation prior to issuance of the rule where: (1) the agency finds that conducting the analysis under this legislation before the rule becomes effective is impracticable or contrary to an important public interest; and (2) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons for the finding. The Committee intends to provide sufficient flexibility for agencies to respond to a true emergency when a rule must be promulgated without awaiting completion of the analysis. This exemption closely tracks the category of rules exempted from the notice and comment procedures of the Administrative Procedure Act, and the Committee does not expect this exemption to be used often.

Subsection 623(f)(2) requires that, if a major rule is adopted under subsection 623(f)(1) without prior compliance with the legislation, then the agency shall comply with this legislation as promptly as possible unless compliance would be unreasonable because the rule is, or soon will be, no longer in effect.

Subsection 623(g) incorporates and extends the consultation requirements of Section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. § 1534). Agencies must develop, maintain and use effective processes and solicit meaningful and timely input of State, local and tribal governments (or their designated employees with authority to act on their behalf) into the development of any regulatory proposals that contain significant Federal intergovernmental mandates. Such processes and consultations shall be consistent with Section 204 of the Unfunded Mandates Reform Act and shall be exempt from the Federal Advisory Committee Act. The Committee believes that federal agency consultation with State, local, and tribal governments before a decision is made will improve the quality, fairness, and responsiveness of federal regulations. In many respects, State, local, and tribal officials are closer to the public; they

under review at OMB's OIRA, and to identify the changes made at the suggestion or recommendation of OIRA).

also are often burdened with unfunded mandates imposed by regulations or with implementing and enforcing them. The term “significant regulatory proposal” is substantially broader than the term “major rule,” which triggers the cost-benefit requirements of this legislation. Accordingly, the consultation requirements of this legislation apply to agency actions exempted from the cost-benefit requirements of this legislation.

Section 624. Risk assessment

Risk assessment is a widely recognized tool to structure information for regulatory decision making related to the environment, health and safety. The acceptance of risk assessment as a standard tool can be traced back to the seminal report issued by the National Academy of Sciences in 1983: *Risk Assessment in the Federal Government: Managing the Process*. The report presented a conceptually sound and logical approach that has been widely adopted by federal and state agencies to assess environmental, health, and safety risks.

Fifteen years after publication of the NAS risk report, there is general agreement that the risk assessment process needs to be refined. The process should be better understood and more accountable. Risk assessment can be most useful when those who rely on it to inform the risk management process understand the strengths and limitations of risk assessment, and use it accordingly. Decision makers should at least understand that the process must rely on assumptions and cannot completely be divorced from assessors’ values. Decision makers must understand what assumptions were used in the assessment in question, and what values they reflect; that the risk estimate is expressed as a range and distribution; and that variability is expressed to the degree that it is known, i.e., how many and what kind of persons (e.g., children) will likely be at significantly higher or lower risk than the hypothetical average individual. Risk managers must take all of those factors into account in making a decision, along with political, economic, and social factors extrinsic to the risk assessment.

In recent years, many studies have supported the use of risk assessment and recommended improvements to the process. In 1993, the Carnegie Commission on Science, Technology, and Government issued “*Risk and the Environment: Improving Regulatory Decision Making*.” In 1994, the NAS issued “*Science and Judgment in Risk Assessment*” to review and evaluate the risk assessment methods of EPA. In March, 1995, the Harvard Center for Risk Analysis issued “*Reform of Risk Regulation: Achieving More Protection at Less Cost*.” The OSTP also issued a brief report entitled, “*Science, Risk, and Public Policy*.” In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management issued the report entitled, “*Risk Assessment and Risk Management in Regulatory Decision-Making*.” Many of the risk assessment provisions of this legislation are strongly supported by findings and recommendations of these and other reports.

Section 624 defines which agency actions must follow the basic principles in this legislation. Subsection (a)(1)(A) states that the risk assessment principles of this legislation apply to: (i) proposed and final major rules the primary purpose of which is to address

health, safety, or environmental risk; and (ii) risk assessments that the OMB Director reasonably determines will have a substantial impact on a significant public policy or on the economy. The Committee recognizes that some risk assessments can have a significant effect even though they are not associated with a major rule. Under Subsection (a)(1)(A)(ii), such “stand alone” risk assessments also would have to comply with the risk principles of S. 981 if the OMB Director determines that the risk assessment will have a substantial impact on public policy or on the economy. This could occur, for example, where a risk assessment may establish the basis for significant regulatory actions at the Federal, state, or international level.

The Committee intends to promote the most advanced and scientifically valid techniques for performing the wide variety of risk assessments covered by this legislation. The Committee does not intend to deter agencies from using the forms of risk assessment appropriate to their respective regulatory decisions. It does intend that the methodology be credible and understandable, and its limitations be made known to the public.

Subsection (a)(1)(B) sets out two general principles for risk assessments. This first principle provides that a risk assessment shall be conducted in a manner that promotes rational and informed risk management decisions and informed public input into and understanding of the process. This recognizes that risk assessments play an important role as a tool for regulatory decision making, as well as for communicating information to the public about risks.

The second general principle provides that in determining the scope and level of analysis of a risk assessment, the significance and complexity of the decision must be considered as well as the need to inform the public adequately; the need for expedition; and the nature of the risk being assessed.⁵⁸ This provision acknowledges that some risk assessments need to be done with greater rigor than others. Differently stated, the level of effort required for a risk assessment depends on what is at stake. In some cases, very severe risks can be identified and managed with relative simple risk assessments because the stakeholders agree that the danger is great enough that no further analysis is needed. Often, the risks requiring detailed analysis are those that are marginal on a cost-benefit scale: in these cases, credible, detailed analyses can be crucial to satisfying stakeholders. The Committee cautions the agencies against construing this provision as excusing noncompliance with the provisions of section 624 or other provisions of this legislation.

To avoid unnecessary duplication of effort, Subsection (a)(2) provides that an agency does not have to prepare a new risk assessment for a final rule where: (1) the final rule is substantially simi-

⁵⁸See OSTP report, “Principles in Devising Risk Policy,” at 17 (“The level of effort should be commensurate with the severity of the risks and costs to society.”) The Risk Commission Report also supports this principle. See Vol. 2, at 63 (“Deciding to go forward with a risk assessment is a risk-management decision, and scaling the effort to the importance of the problem, with respect to scientific issues and regulatory impact, is crucial.”); Vol. 2, at 21 (“The level of detail considered in a risk assessment and included in the risk characterization should be commensurate with the problem’s importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures.”).

lar to the proposed rule with respect to the risk being addressed; (2) the risk assessment performed for the proposed rule is consistent with the provisions in Subchapter II; and (3) a new risk assessment is not necessary to address comments submitted during the comment period.

Subsection (b) requires each agency to “consider * * * all reliable and relevant and reasonably available scientific information” and to describe the basis for selecting that scientific information. This subsection promotes three basic principles. First, the agency must make a thorough search for relevant data. The agency should make a reasonable attempt to gather data from informed parties and may solicit information through the Federal Register. Second, the agency should assess whether the data are reliable and relevant. And third, if the data are relevant and reliable, the agency should consider all those data as appropriate in the risk assessment. Data can be “reliable” if they are well understood and generally supported in the scientific community; come from well recognized, credible sources; or are of sufficient quality that the results could be reproduced.⁵⁹

The Committee understands that even reliable data will vary in quality, relevancy and applicability. The definition of “risk assessment” in Section 621(9) contemplates that an agency will use a careful analysis of the weight of the evidence to evaluate the information it has.⁶⁰ In considering the scientific information, the agencies should evaluate the data and apply the appropriate weight to them in the risk assessment.

Agencies make assumptions in conducting risk assessments to overcome a paucity of data or a lack of scientific understanding about such things as causality or basic biological mechanisms. As Subsection (b) establishes, the agency should consider all relevant, reliable and reasonably available data. If the agency concludes that information is not relevant or reliable, the agency should explain how and why it so concluded. When the agency needs to use assumptions in risk assessment, Subsection (c) sets out the appropriate treatment of the assumptions.

Subsection (c) does not dictate which assumptions an agency shall use. Rather, it requires the agency to disclose pertinent information about the significant assumptions so that anyone relying on the risk assessment can better evaluate the validity of the assumptions and their effect on the risk assessment. Accordingly, for a significant assumption, the agency must: (1) identify the scientific basis, and the policy basis (if any), as well as the extent to which the assumption is validated by or conflicts with empirical data; (2) explain the basis for choosing among possible assumptions and/or combining an assumption with other assumptions; and (3) describe reasonable alternative assumptions that would have had a signifi-

⁵⁹See Risk Commission Report, Vol. 1, at 38 (“Because so many judgments must be based on limited information, it is critical that all reliable information be considered. Risk assessors and economists are responsible for providing decision-makers with the best technical information available or reasonably attainable, including evaluations of the weight of the evidence that supports different assumptions and conclusions.”)

⁶⁰The Risk Commission Report provides examples of the kinds of considerations entailed in making judgments on the basis of the weight of the scientific evidence in a toxicity study: quality of the toxicity study; appropriateness of the toxicity study methods; consistency of results across studies; biological plausibility of statistical associations; and similarity of results to responses and effects in humans. See Vol. 2, at 20.

cant effect on the results of the risk assessment, and those that were considered but not selected by the agency for use in the risk assessment.

Finally, Subsection (c)(2) establishes the agency's obligation to update the assumptions it uses to reflect new data or new scientific understandings.⁶¹ It requires the agency to revise its assumptions to incorporate relevant and reliable scientific information as it becomes reasonably available. Subsection (c)(2) is intended to keep agency assumptions current. It is not intended to create a counter-productive and never-ending cycle of revisions. It is intended to promote credible and reliable risk assessments.

Subsection (d) requires that when an agency decides to conduct a risk assessment, it must notify the public and solicit relevant and reliable data from the public. The agency must consider the data in conducting the risk assessment. The purpose is to make the process more transparent and accountable.⁶²

Subsection (e) mandates some of the basic contents of the document describing the risk assessment. This subsection and subsections (c) and (f) are critical to the transparency in the risk assessment. They will allow the public and agency decision makers to understand the full scope and dimensions of the problem that the agency is addressing. Subsection (e) sets out five pieces of information the agency risk assessment must disclose:

(1) *A description of the hazard of concern.*—That is, the problem being addressed.

(2) *A description of the populations or natural resources that are the subject of the risk assessment.*—Consistent with subsection (f), “populations” would include the population that could be exposed to the hazard and, as appropriate, highly exposed or sensitive sub-populations.

(3) *An explanation of the exposure scenarios used in the risk assessment, an estimate of the population or natural resource corresponding to each exposure scenario, and an estimate of the likelihood that the exposure scenario would actually occur.*—The Committee is aware that the concept of “exposure” has been more associated with assessments of risks from pollutants or disease agents. However, the Committee believes that it also is applicable to risks from harmful events. For example, passengers in a car are exposed to passenger side airbag injuries; workers who work around electrical machinery are exposed to injuries from inadvertent start-ups during repairs; and vehicle passengers or downstream residents

⁶¹The Committee supports the conclusions of Risk Commission Report, which states: “Agencies should continue to move away from the hypothetical . . . toward more realistic assumptions based on available scientific data.” Vol. 2, at iv. As Science and Judgment in Risk Assessment clearly acknowledges, “Over time, the choice of defaults should have decreasing impact on regulatory decision-making. As scientific knowledge increases, uncertainty diminishes. Better data and increased understanding of biological mechanisms should enable risk assessments that are less dependent on default assumptions and more accurate as predictions of human risk.” (p. 90).

⁶²The Committee received comments on the need for a more transparent risk assessment process that would allow for greater public input. The Risk Commission Report strongly supports stakeholder (public) involvement at all stages of risk management. To avoid the politicization of risk assessments, however, the Commission noted that “stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns” but should not participate directly in the risk assessment itself. See Vol. 2, at 21 (“Stakeholders play an important role in providing information that should be used in risk assessments and in identifying specific health and ecological concerns they would like to see addressed.”); id., at 185.

may be exposed to the potential harm from the collapse of a bridge. The Committee broadly interprets the term “exposure.”

(4) *A description of the nature and severity of the harm that could occur as a result of exposure to the hazard.*—By “nature” the Committee means the type of adverse affect, such as disease, physical harm or ecosystem damage, that could be attributed to the hazard. By “severity” the Committee means the seriousness of the harm—not the likelihood—including whether the harm is reversible.

(5) *A description of the major uncertainties in each component of the risk assessment and their influence on the results of the assessment.*—This requirement will help inform the public and agency decision maker how certain the risk is. It also will help identify areas where additional research or data could significantly improve the quality and reliability of the risk assessment.⁶³

The final product of a risk assessment should be a set of numeric estimates which, along with the information required under Subsection (e), constitutes the risk characterization. Traditionally, agency regulatory decisions have been based on the estimate of the risk. Subsection (f) describes the form the risk estimate shall take. In the past, risk assessments resulted in risk estimates that were a single value, such as one-in-ten-thousand, or for some toxicological assessments, a “safe” dose or exposure level. The Committee believes that reliance on single point estimates may conceal important information from the public and the decision maker, such as the degree of uncertainty about the estimate, how different populations might be affected differently, or what policy judgments are embodied in the estimate. For example, to be protective, agencies routinely have used conservative assumptions where there were uncertainties or suspected variability in exposed individuals. The decision to be protective may well be the correct one, but embedding this important policy decision in the risk estimate (the “science”) is not transparent to the public or agency decision makers.⁶⁴

The tools of probabilistic risk assessments are now sufficiently well-developed that agencies often can supply a multidimensional descriptive estimate of the risk—one that fully conveys both the range and likely distribution of the risk. The risk manager should have as complete a picture of the risk as possible, avoiding, for example, the simple presentation of a single-point risk estimate that could overstate or understate the true risk. Accordingly, Subsection (f) requires that “to the extent scientifically appropriate,” which

⁶³ In “Science, Risk and Public Policy,” OSTP emphasized the importance of describing the uncertainties inherent in risk assessments, stating “Variation in risk estimates also arises from choices of assumptions and methods to address and treat uncertainty in available scientific data. Risk assessors may develop different estimates of risk because they employ different (but equally justifiable) assumptions.” (p. 9).

⁶⁴ See “Risk and the Environment: Improving Regulatory Decision Making”: “Regulatory agencies should report a range of risk estimates when assessing risk and communicating it to the public. How risk estimates, whether derived from an inventory or not, are conveyed to the public significantly affects the way citizens perceive those risks. Single-value risk estimates reported to the public do not provide an indication of the degree of uncertainty associated with the estimate. Such numbers do not convey the conservative nature of some risk estimates.” (p. 87); see also “Science and Judgment in Risk Assessment”: “EPA should make uncertainties explicit and present them as accurately and fully as is feasible and needed for risk management decision-making. To the greatest extent feasible, EPA should present quantitative, as opposed to qualitative, representations of uncertainty.” (p. 185).

should be typical, agencies must provide such estimates. Specifically, agencies are required to provide:

(1) *The estimate of risk as one or more reasonable ranges and, if feasible, probability distributions, reflecting variabilities and uncertainties.*—By “reasonable” the Committee intends that the ranges and distributions convey a reasonably accurate picture of the risk, one that neither overstates nor understates the risk. The reasonable ranges and distributions would incorporate all of the data and alternative assumptions used in the risk assessment. One of the underlying premises of this legislation is that more information leads to better decisions. Risk information should at least be presented as a range, but this bill reflects the preference that agencies should strive to obtain sufficient information to provide probability distributions. Such distributions, when accurately reflecting variability and uncertainty, give decision makers and the public a more complete picture of the risks. Accordingly, the bill requires the agency to provide a probability distribution where feasible. The reference to “one or more” ranges and distributions reflects that fact that more than one distribution may be needed to reflect fundamental uncertainties or to provide specialized information for relevant subpopulations, as described in subsection (f)(2).

(2) *The central⁶⁵ and high end estimates for each range and distribution and a description of the relevant exposure scenario for the potentially exposed population to which the range and distribution estimate applies.*⁶⁶—The Committee believes that the public and the agency decision maker will make more informed decisions if they know about the central and high-end estimates of each range and distribution and the exposure of particularly affected populations.

(3) *A description of qualitative factors that influenced the ranges, distribution and likelihood of the risk.*—Such qualitative factors may include: choice of data sets; choice of extrapolation models; choice of statistical cutoff point for validity; choice of end point; choice of default assumptions, and so on. This paragraph promotes the core philosophy of this legislation—namely, that more information and greater transparency will improve the quality of agency decision making.

To help the public and the agency decision maker to better understand the nature and magnitude of the risks that are the subject of a risk assessment, Subsection (g) requires agencies to compare the risk to other risks “familiar to and routinely encountered by the general public.” The agency should disclose the critical features of the compared risks, including whether they are voluntary

⁶⁵ A “central estimate of risk” is: the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative plausibility; or any estimate judged to be most representative of the distribution. See, e.g., Charles A. Holloway, “Decision Making Under Uncertainty: Models and Choices” (1979), at 76, 214, 91–127; Theodore Colton, “Statistics in Medicine” (1974), at 28–31. The central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk. See *Science and Judgment in Risk Assessment*, at 170–75.

⁶⁶ See EPA, Policy for Risk Characterization (March 21, 1995), at 2 (“Information should be presented on the range of exposures derived from exposure scenarios and on the use of multiple risk descriptors (e.g., central tendency, high-end of individual risk, population risk, important subgroups (if known) * * *”).

or involuntary, newly discovered or well understood, and reversible or irreversible.⁶⁷

Comparing risks in this manner helps the agency understand whether it is addressing the right problems in the most effective way. It also helps the public understand the dimensions of the risk and whether the agency is focusing its efforts on the right problems.⁶⁸ The Committee intended to underscore the public communication value of risk comparisons and therefore required that the comparison be familiar to and routinely encountered risks. The Committee expects the agencies to select appropriate comparisons that provide the best contextual information to the public.

§ 625. Peer review

This section specifies that agency heads must develop a systematic program for independent peer review of risk assessments and cost-benefit analyses conducted for major rules.⁶⁹ Central to the peer review program should be reviewed by an adequate number of individual experts from relevant scientific and technical disciplines, through formal or informal devices. Peer reviewers must be selected on the basis of their expertise in the sciences or economics relevant to the regulatory decision. The participants must be broadly representative of the scientific and technical views relevant to the decision at hand and independent⁷⁰ of the agency.⁷¹

At the same time, the bill allows for a variety of approaches to peer review, including the use of informal methods. For example, the National Science Foundation (“NSF”) uses two principal meth-

⁶⁷ See, e.g., National Research Council, “Improving Risk Communication”, 165–79 (1989).

⁶⁸ One of the key recommendations of the Commission Report was that the problems a regulation is intended to address should be placed in their “public health and ecological context.” Vol. 1, at 4. For example, in the environmental area the Report suggests four questions for an agency to ask and answer:

Is the population exposed to the same pollutant from other sources?

Is exposure to the pollutant also occurring from other environmental media?

Do other pollutants from the same sources pose additional risks to the population of concern?

How great a risk does the problem pose compared to other similar risks that the community?

Vol 1, at 9–10.

⁶⁹ Peer review is a widely endorsed component of risk assessment and cost-benefit analysis. See, e.g., Risk Commission Report, Vol 2, at 103 (“Peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information.”); National Research Council, “Valuing Health Risks, Costs, and Benefits for Environmental Decision Making” (1990), at 207 (“benefit-cost analysis should be subject to systematic, consistent, formal peer review”); American Enterprise Institute & Brookings Institution, “An Agenda for Regulatory Reform” (1997), at 13 (the president and Congress should adopt procedures to peer review regulatory analyses); John D. Graham, “Making Sense of Risk: An Agenda for Congress,” in “Risks, Costs, and Lives Saved” (Robert W. Hahn, ed. 1996); John D. Graham, “Harnessing Science for Environmental Regulation” (1991). As stated in the OSTP “Principles in Devising Risk Policy”, “Appropriate scientific peer review and guidance are essential to the risk assessment process.” (p. 17). The Carnegie Commission Report also highlights the importance of external peer review. The report states, “A key element in setting risk-based priorities is science advice, both internal (within the agency) and external (through science advisory boards and other mechanisms). External science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues.” (p. 90).

⁷⁰ Independence from the agency is not intended to preclude use of established advisory committees like the Science Advisory Board at EPA. The charter of EPA’s Science Advisory Board states that its objective is to provide “independent advice to EPA’s Administrator on the scientific and technical aspects of environmental problems and issues.” Its membership consists of persons from the private sector who serve for two year terms. No full time federal employee is permitted to be on the Science Advisory Board, although most members do serve as special government employees and are eligible by statute to be compensated for their services. Permanent advisory committees and the members of such committees, even though they serve as special government employees, are not intended to be precluded from serving as peer reviewers under S. 981.

⁷¹ See Statement of Dr. Bruce Alberts, President of the National Academy of Sciences, in Response to Senator Levin’s Questions following February 24, 1998 Hearing on S. 981.

ods for peer review of proposals, by mail and by panel. In its report to the National Science Board on the Merit Review System for FY 1997, the NSF reported that “In ‘mail only’ reviews, peers are sent proposals and asked to submit written comments to NSF by postal mail, facsimile, electronic mail, or through FastLane, NSF’s Web-based system for electronic proposal submission and review.” Many proposals peer reviewed by the National Science Foundation are done so using a combination of both mail and panel methods. The peer review requirements of S. 981 are intended to allow agencies to use peer review procedures that are appropriate for the analysis involved.

The Committee considered in some depth how to draw the line with respect to possible conflicts of interest of peer reviewers. S. 981 as introduced provided specifically that persons with a financial conflict of interest in a rulemaking could serve as peer reviewers so long as the conflicts were disclosed to the agency. Many persons who commented on the bill were not satisfied with that approach as a universal requirement. After consulting with individuals with expertise on the practices and conflicts standards of leading agencies that use peer review widely, including the National Institutes of Health, the National Academy of Sciences, the National Science Foundation, and EPA, the Committee concluded that agencies themselves⁷² can adequately address potential conflicts in a fair and impartial manner, which is their responsibility today. The Committee is not aware of any problems with the current conflict of interest standards being used by federal agencies with respect to peer review, and expects that agencies new to peer review under S. 981 will seek guidance from OMB, OSTP and agencies with expertise in the field.

S. 981 requires that agency peer review programs ensure that reviews are conducted on a timely basis and that they contain balanced presentations of all considerations, including minority reports and an agency response to all significant comments. In addition, adequate protection must be provided to ensure that confidential business information and trade secrets are protected. Subsection (b)(2) requires the agency to respond in writing to all significant peer review comments. The agency response must be made available to the public and be part of the rulemaking record for purposes of judicial review of any final agency action.

Where the agency head and the OMB Director agree, subsection (b)(3) allows them to exempt from the peer review requirements a cost-benefit analysis, risk assessment, or any component thereof, that previously has been subjected to adequate peer review. Subsection (c) provides for a neutral referee who can attest to the independence and quality of the peer review. For each peer review under this section, the agency head shall include in the rulemaking

⁷²For example, EPA’s approach for addressing possible conflicts of interest is contained in EPA’s recently issued Science Policy Council Handbook on peer review. It presents alternative approaches to identifying and resolving potential conflicts, depending upon the specific situation. The EPA handbook recognizes that “It is important that peer reviewers be selected for independence and scientific/technical expertise.” U.S. Environmental Protection Agency, Science Policy Council Handbook, EPA 100-B-98-001 (Jan. 1998), at p. 45. Yet EPA also acknowledges that “experts with a stake in the outcome—and therefore a potential conflict—may be some of the most knowledgeable and up-to-date experts because they have concrete reasons to maintain their expertise. Such experts could be used provided the potential conflicts of interest are disclosed and the peer review panel or group being used as whole is balanced.” *Id.*, at p. 48.

record a statement by a Federal officer or employee who is not an employee of the rulemaking office or program (1) whether the peer review participants reflect the independence and expertise required under subsection (b)(1)(A), and (2) whether the agency has adequately responded to the peer review comments as required under subsection (b)(2).

Finally, subsection (d) provides that the peer reviews required by this section shall not be subject to the Federal Advisory Committee Act. With the input of respected scientific and technical experts, the Committee determined that a FACA exemption would help expedite peer reviews as well as enhance their technical rigor. Peer review is not intended to provide policy advice or analysis to an agency, and it is not a political debate among interested parties.⁷³ Moreover, the Committee believes that the FACA exemption will reduce the rigidity, time, and expense of peer reviews.

§ 626. Deadlines for rulemaking

For a 2-year period after the effective date of the legislation, this section extends certain rulemaking deadlines for up to six months to allow agencies time needed to comply with the analytical requirements of the legislation. The affected deadlines include statutory and judicial deadlines for rulemakings, as well as rulemaking deadlines that would create an obligation to regulate through individual adjudications. To avoid any constitutional concerns about extending judicial deadlines by legislation, subsection (b) authorizes and directs the United States to ask the relevant court to extend any deadlines imposed by the court.

The sole purpose of section 626 is to give agencies time to make a reasonable effort to faithfully fulfill the requirements of this legislation. The Committee understands that the legislation asks for better quality and greater openness in many analyses already done, and in some cases, creates new obligations. The Committee intends that agencies be given a reasonable opportunity to develop policies and procedures adequate to comply with the law. The Committee does not intend this grace period to be used otherwise to delay decisions or to compromise the implementation of legal requirements.

§ 627. Judicial review

Section 627 establishes the framework for judicial review of agency compliance with the regulatory analysis, risk assessment, and peer review requirements of this legislation. Specifically, Section 627 is addressed solely to judicial review of “[c]ompliance by an agency with the provisions of [Subchapter II].” To the extent that an agency action is being challenged on grounds other than al-

⁷³See, e.g., Statement of Dr. Bruce Alberts, President of the National Academy of Sciences, in Response to Senator Levin’s questions following February 24, 1998 Hearing on S. 981. As defined by EPA, “Peer review is a documented critical review of a specific agency major scientific and/or technical work product * * * It is usually characterized by a one-time interaction or a limited number of interactions by independent peer reviewers.” See EPA, Science Policy Council Handbook, at p. 10.

leged noncompliance with the provisions of Subchapter II, Section 627 would not apply.⁷⁴

Subsection (a) sets three basic conditions for judicial review of agency compliance with the provisions of Subchapter II: The judicial review must occur—(1) in connection with review of final agency action; (2) in accordance with the provisions of Section 627; and (3) in accordance with the limitations on timing, venue, and scope of review imposed by the statute authorizing the review. In setting forth the third condition, the Committee recognizes that in some cases, the statute authorizing review may not impose any special limitations on timing, venue, or scope of review; in other cases, these matters may be addressed in several different statutes.

Subsection (b) governs the availability and standard of review of agency “major rule” determinations. An agency’s determination of whether a rule is a major rule—and thus subject to the regulatory analysis and risk assessment requirements of Subchapter II—is subject to review only in connection with review of the final agency action to which it applies. At that time, a court may set aside the agency’s determination of whether the rule is “major” only if it is shown to be arbitrary or capricious in light of information reasonably available at the time the agency made the determination.

In close cases, the Committee would expect that the agency would err on the side of good analysis and avoid the risk of remand or invalidation of the rule. As a practical matter, the agency’s major rule determination will be consequential where the agency wrongly determines that a rule is not “major” and does not bother to perform the cost-benefit analysis, cost-benefit determination, risk assessment, or peer review that Subchapter II requires for “major rules.” In such a case, Section 627(e) would require the court to remand or invalidate the rule.

By contrast, if the agency incorrectly determines that a rule is “major,” the impact on the rule itself is not likely to be adverse—since a rule would not be remanded or invalidated just because an agency performed a cost-benefit analysis and risk assessment, made a cost-benefit determination, and provided for peer review in circumstances where such action was not statutorily mandated. After all, the Executive Branch is free to undertake such actions today even where not required to do so by statute. Indeed, that is the premise of a series of executive orders on regulatory analysis and review that date back to the Carter Administration, that grew in the Reagan Administration, and that is currently embodied in Executive Order 12866.

Under subsection (c), a designation by the Director of OMB that a rule is a major rule—or the failure to make such a designation—is not subject to judicial review. If the Director has designated a rule as “major,” the requirements of Subchapter II that apply to major rules must be met. Conversely, if neither the Director nor the agency has designated a rule as “major,” and the rule does not fall within Subsection 621(7)(A), then the requirements of Subchapter II would not apply.

⁷⁴This point is underscored by the savings clause in Section 622(b), which states: “Nothing in this subchapter shall be construed to alter or modify the * * * opportunity for judicial review made applicable under other statutes.”

Subsection (d) provides that any cost-benefit analysis, cost-benefit determination, or risk assessment required under Subchapter II shall not be subject to judicial review separate from review of any final rule to which the analysis or assessment applies. Such a cost-benefit analysis, cost-benefit determination, or risk assessment, however, would be part of the rulemaking record, and if the final rule to which they apply is brought before a court for review, the court would have to consider the analysis, determination, and any assessment—to the extent relevant—in determining whether the final rule is arbitrary, capricious, an abuse of discretion, or unsupported by substantial evidence.⁷⁵

Section 627(e) states that if an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, as required under Subchapter II, the court “shall remand or invalidate the rule.” If an agency fails to perform the cost-benefit analysis, cost-benefit determination, risk assessment, or peer review, the court would be obliged to invalidate or remand the rule. In this respect, S. 981 expands the role of a reviewing court by directing that a rule be invalidated in circumstances where it might not be invalidated under current law.

Under Section 627, an agency’s failure to comply with a specific requirement of S. 981 regarding how to perform a risk assessment or cost-benefit analysis would not, in and of itself, be grounds for invalidating a rule. That is, a rule could not be invalidated simply because a “how to” requirement of Section 623 (governing cost-benefit analyses) or 624 (governing risk assessments) was not met. At the same time, however, in determining whether the final rule is arbitrary or capricious, the court would be free to consider the effect that the agency’s failure to comply with any such requirement (e.g., a failure to consider reliable and reasonably available scientific information) had on the rulemaking. In addition, of course, the cost-benefit and risk assessment information would be available to the court and could be considered in determining whether the final rule is arbitrary or capricious.

The following three scenarios illustrate how the judicial review provision of S. 981 is intended to operate.

Scenario (1): S. 981 requires an agency to identify and evaluate reasonably identifiable substitution risks. Suppose that during a rulemaking, a person submitted information to the agency on the possibility of a substitution risk and the agency ignored it. Could that person later argue in a lawsuit challenging the rule that the agency action in adopting the final rule is arbitrary or capricious simply because the agency violated a requirement of S. 981 when it failed to consider a legitimate substitution risk?

No. Failure to comply with a specific procedural requirement of S. 981 regarding how to perform a risk assessment or cost-benefit analysis would not, in and of itself, be grounds for invalidating a rule.

However, the person could argue that the agency’s failure to consider the legitimate substitution risk had the effect of making the

⁷⁵“The “substantial evidence” standard would apply in those cases where a “substantial evidence” standard of review is provided by the enabling statute—such as under the Occupational Safety and Health Act, 29 U.S.C. §655(f), or the Toxic Substances Control Act, 15 U.S.C. §2618(c)—or where it is required by the Administrative Procedure Act, 5 U.S.C. §706(2)(E).

resulting rule arbitrary or capricious—whether or not that failure also violated a specific procedural requirement of S. 981. Such an argument is available today, and would continue to be available after S. 981 is enacted.

Scenario (2): S. 981 requires agencies, when doing a risk assessment, to consider “reliable and reasonably available scientific information.” If an agency fails to consider such information which we know the agency had access to through the public comment period, can a person argue that the rule should be remanded or invalidated just because the agency violated a specific procedural requirement of S. 981 when it failed to consider such information?

No. As indicated in Scenario (1), failure to comply with the procedural requirements of S. 981 regarding how to conduct a risk assessment is not independent grounds for remanding or invalidating a rule.

On the other hand, the fact that Congress directed agencies to follow this requirement is an indication that it is important to the development of a risk estimate on which a rational and well-informed rulemaking decision can be based. Depending on the circumstances of the particular case, a court today might conclude that a rule is arbitrary or capricious where it is based on a risk assessment that did not consider reliable and reasonably available scientific information. Nothing in S. 981 is intended to preclude a court from reaching the same result in the future. To the contrary, S. 981 specifically directs agencies to consider “reliable and reasonably available scientific information” in conducting risk assessments, so it does not prevent a court from finding a rule to be arbitrary or capricious when such information is ignored.

Scenario (3): S. 981 requires the agency to make a determination as to whether the benefits of the rule justify the costs. The agency doesn’t make that determination. Can a person challenge the rule for the failure of the agency to make that determination based on the requirement of S. 981?

Yes. The bill explicitly states that the failure to make the determination requires the court to remand or invalidate the rule.

As the foregoing scenarios illustrate, an agency’s failure to comply with the specific procedural requirements of S. 981 regarding how to conduct a risk assessment or cost-benefit analysis would not, in and of itself, be grounds for invalidating a rule. That is, the rule could not be invalidated under section 627(d) simply because a procedure required by S. 981 had been violated. At the same time, the court could consider the content of the cost-benefit analysis and risk assessment, any omissions in such analyses (such as those discussed in the above scenarios), or the arbitrary treatment of the content of those analyses, in determining whether the final rule is arbitrary or capricious. This is true under current law and would continue to be true once S. 981 is enacted.

In addition, if an agency fails to perform a required cost-benefit analysis or risk assessment, does not make a cost-benefit determination, or does not provide for peer review, a court would remand or invalidate the rule. In this respect, S. 981 changes the role of a reviewing court by directing that a rule be remanded or invalidated in circumstances where it might not be remanded or invalidated under current law.

In sum, in determining whether a rule is arbitrary or capricious, a court would remain free under S. 981—as it is under current law—to consider both what the agency did do, as reflected in the cost-benefit analysis and risk assessment, and what it did not do, such as failing to consider relevant, reliable, and reasonably available scientific information. But, with the exception of cases covered by Section 627(e)—where automatic remand or invalidation of the rule is required—a court would not remand or invalidate a rule on the ground that the agency simply had not complied with a specific procedure of S. 981.

§ 628. Guidelines, interagency coordination, and research

Subsection 628(a)(1) requires the Director of the Office of Management and Budget, in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, to develop and issue uniform guidelines to implement the cost-benefit analysis, risk assessment, and peer review requirements of this legislation. Such guidelines should embody, and expand upon, principles required by this legislation. The OMB Director is responsible for overseeing the implementation of these guidelines, and periodically revising them as appropriate and as warranted by advances in risk analysis, cost-benefit analysis, and related fields.

No later than 18 months after issuance of those uniform guidelines, each agency subject to section 624 is required to adopt detailed guidelines under subsection 628(a)(2) for risk assessments as required by section 624. Such guidelines shall be consistent with the uniform guidelines issued under subsection 628(a)(1). The Committee expects each agency to revise these risk assessment guidelines as appropriate and as warranted by advances in science and risk assessment methodology.

Subsection (a)(3) requires that all guidelines developed under subsection (a) must be developed following notice and public comment. OMB and the agencies are expected to make diligent efforts to solicit input from all informed parties. Agencies are not required, however to develop the guidelines through the legislative rule-making process. The Committee was concerned that the APA rule-making process may be too rigid and time-consuming for the expeditious development and updating of risk assessment guidelines. Accordingly, Subsection (a)(3) makes clear that the development, issuance, and publication of risk assessment and risk characterization guidelines developed under this section are subject only to limited judicial review under section 706(1) of title 5. The Committee expects the agencies to develop and maintain state-of-the-art guidelines.

Subsection (b) is designed to improve the conduct, application, and practice of cost-benefit analysis and risk assessment across all relevant agencies. Subsection (b)(1) requires the OMB Director, in consultation with the Council of Economic Advisors and the Director of the Office of Science and Technology Policy, to oversee periodic evaluations of the manner in which agencies are conducting cost-benefit analyses and risk assessments. Such a survey will allow for a determination of the scope and adequacy of cost-benefit analysis and risk assessment practices of the federal agencies. It

also will promote the injection of new scientific and technical advances into the analytical practices of the agencies.

Subsections (b)(3) and (b)(4) require OMB to establish with CEA and OSTP appropriate interagency mechanisms to promote coordination between agencies and to ensure consistent use of state-of-the-art cost-benefit and risk assessment practices.

Subsection (c)(1) requires OMB, in consultation with the agencies, CEA, and OSTP, to develop and periodically evaluate a strategy to meet agency needs for research and training in cost-benefit analysis and risk assessment. This strategy should address the need for research on modeling, the development of generic data, use of assumptions, the identification and quantification of uncertainty and variability, and other areas. OMB also should identify long-term needs to adequately train individuals in risk assessment techniques.

Subsection (c)(2) requires the OMB, in consultation with OSTP, to enter a contract with an accredited scientific institution, to conduct research to: (1) develop a common basis to assist risk communication related to both carcinogens and non-carcinogens; and (2) develop methods to appropriately incorporate risk assessments into related cost-benefit analyses.⁷⁶ The OMB shall enter into the contract no later than 6 months after enactment of section 628, and the results of the research shall be submitted to OMB and to Congress no later than 24 months after the date of enactment.

§ 629. Risk-based priorities study

The Committee believes that setting risk-based priorities offers an excellent opportunity to promote better allocation of resources of both the government and the private sector to increase the protection of human health, safety and the environment. The importance of such a risk-based approach has been advocated in numerous studies and publications,⁷⁷ as well as in testimony before the Governmental Affairs Committee.⁷⁸ The Committee believes that the tool of comparative risk analysis can help us find ways to make our health, safety and environmental protection dollars go farther and provide greater overall protection, saving even more lives than the current system.⁷⁹ As the blue-ribbon Carnegie Commission panel noted in its report, *Risk and the Environment: Improving Regulatory Decision Making*, “The economic burden of regulation is

⁷⁶ See Risk Commission Report, Vol 2, at 43, 99.

⁷⁷ See, e.g., J. Clarence Davies & Jan Mazurek, *Pollution Control in the United States, Resources for the Future* (1998), at 101–22; Cass R. Sunstein, “Health-Health Tradeoffs,” *U. Chi. L. Rev.* 1533 (1996); *Resources for the Future, Comparing Environmental Risks* (J. Clarence Davies, ed. 1996); John D. Graham, “Making Sense of Risk: An Agenda for Congress,” in *Risks, Costs and Lives Saved*, (Robert W. Hahn, ed. 1996); National Academy of Public Administration, *Setting Priorities, Getting Results* (April 1995); Harvard Center for Risk Analysis, *Reform of Risk Regulation: Achieving More Protection at Less Cost* (March 1995); Carnegie Commission on Science, Technology, and Government, *Risk and Environment: Improving Regulatory Decisionmaking*, Washington, D.C. (June 1993); Stephen Breyer, “Breaking the Vicious Circle: Toward Effective Risk Regulation,” *Harv. Univ. Press* (1993).

⁷⁸ See, e.g., Testimony of John D. Graham, Director, Harvard Center for Risk Analysis, before the Senate Committee on Governmental Affairs, September 12, 1997.

⁷⁹ The need for a national comparative risk analysis was one of the chief recommendations of the Report of the Harvard Group on Risk Management Reform entitled, *Reform of Risk Regulation: Achieving More Protection at Less Cost* (March 1995). The Harvard report states that the purpose of such an analysis would be “to learn how diverse risks should be compared, how ordinary citizens should participate in risk ranking, what inherent limitations to the process might be, and how guidelines can be developed to govern a broad-based process of risk-based priority setting in the federal government.” (p. 27).

so great and the time and money available to address the many genuine environmental and health threats so limited, that hard resource allocation choices are imperative.” (p. 118).

The 1995 National Academy of Public Administration (NAPA) report to Congress, entitled *Setting Priorities, Getting Results*, recommends that the Environmental Protection Agency use comparative risk analysis to identify priorities and use the budget process to allocate resources to the agency’s priorities. The NAPA study commends EPA for having pioneered risk prioritization studies and comparative risk analyses. However, the report states that during the budgetary process, EPA did not push for shifts in resources to the higher-priority programs. The report recommends that Congress “could enact specific legislation that would require risk-ranking reports every two to three years. Congress should use the information when it passes environmental statutes or reviews EPA’s budget proposals.” (p. 49).

The purpose of the analyses required by this section is to provide Congress and the President with the information to make more informed choices. The Committee anticipates that, among other things, these analyses will be useful for identifying unaddressed risks, risks borne disproportionately by a segment of the population, and research needs. This will provide better information for deciding where to focus regulatory efforts and agency resources. Finally, conducted through an open process, these analyses are likely to enhance public debate about these choices and ultimately create greater public confidence in government policy. The comparative risk study should compare significant risks to human health, safety or the environment and make recommendations on setting priorities to reduce them. The comparison is limited to “significant” risks, and the study should examine which of those risks are the most serious and most amenable to cost-effective reduction.

Section 629 furthers the use of comparative risk analysis to inform planning and budgetary decision making. To begin, it calls for contracting with an accredited scientific institution to conduct a study with three components. The first and most important component is a comparative risk analysis, which is a process to systematically estimate, compare, and rank the size and severity of risks to provide a common basis for evaluating strategies for reducing or preventing those risks.⁸⁰

Since the purpose is to assist the Federal government in evaluating how to use its resources effectively to address the most serious problems, to the extent feasible, the comparison should include all such risks that are, or could reasonably be, addressed by the various agencies and programs whose purpose is to protect human health and safety or the environment, including natural resources. Comparative risk analysis is not purely a scientific undertaking. The Committee believes that, while hard data will form the underpinnings of the analysis, public values must also be incorporated when assessing the relative seriousness of the risks and when setting priorities. Scientific data alone cannot tell us which risks should be addressed first, for example: neurological damage,

⁸⁰ See OSTP report, *Science, Risk, and Public Policy*. The report defines policy trade-offs, and stakeholder concerns. The goal is to conduct a broad examination of governmental policies and expenditures to reduce risk. (p. 11).

heart disease, or birth defects; a plane crash or cancer. The comparative risk analysis should be conducted in a way that enables public values to be ascertained and considered. This will require public input into the comparative risk analysis. Nevertheless, when the analysis is completed, it should be clear to the public and policy makers which part of the risk comparison reflects science and which part reflects values.

The second component is a study of methodologies for using comparative risk analysis to compare dissimilar risks to further development and use of this tool. Because comparative risk analysis is still a relatively new science, particularly when used to compare dissimilar risks, subsection (a)(2) requires that, even while the comparative risk analysis is being conducted, a study be done to improve the methods and use of comparative risk analysis. The Committee anticipates that this study will draw on the analyses already conducted by numerous states. The results of this part of the study should also facilitate risk comparisons required by Section 624(g).

The third component of the study is a set of recommendations on the use of comparative risk analysis for setting priorities. These recommendations should provide sufficient guidance to enable the President, the agency heads, and Congress to evaluate how to better allocate resources across agencies and among programs to achieve the most cost-effective risk prevention and reduction.

To assure its credibility, the study must be conducted by an accredited body selected by the Director of OMB in consultation with the Office of Science and Technology Policy. Subsection (b) requires that the study provide an opportunity for public comment and public participation. For the comparative risk analysis to be reliable and credible, the Committee thinks it is important that the study be conducted through an open process, utilizing expertise in appropriate fields, such as toxicology, biology, engineering, medicine, industrial hygiene and environmental effects. The Committee also recognizes that experts in the relevant social sciences may be needed to help incorporate public values into the process. The analysis should be conducted consistent with the risk assessment principles in Section 624. The methodologies and scientific determinations made in the analysis are to be subjected to external peer review, in compliance with Section 625, and made available for public comment. The results of the comparative risk analysis under subsection 629(a)(1) should be presented in a manner that distinguishes between the scientific conclusions and any policy or value judgments embodied in the comparisons.⁸¹

The study must be completed within three years following enactment of this section. Within one year thereafter, agencies are to

⁸¹The Carnegie Commission report, *Risk and the Environment*, recommends that agencies “experiment with different mechanisms for integrating societal values into the process of setting risk-based regulatory priorities.” (p. 89). The report states that value choices should not be made covertly by unaccountable “experts.” The report offers that “One possibility is for the experts to make explicit, to the extent possible, all value judgments and their relative weights in the ranking process.” (p. 89).

The 1995 NAPA report supports the Carnegie Commission recommendation: “Because comparing risks is a value-laden process as well as a technical challenge, EPA should conduct its comparative risk analyses as policy exercises with the active engagement of the public or its representatives. Doing so would provide legitimate results that would become a base for agency priorities and budget proposals.” (p. 49).

use the results of the study to inform the agencies in the development of their budgets and strategic plans and performance plans under the Government Performance and Results Act, which should provide an excellent framework for achieving more cost-effective risk reduction.

Finally, to implement any lessons learned from the exercise, Subsection 629(d) directs the President to recommend legislative changes to assist in setting priorities so that the federal government can more effectively and efficiently reduce risks to human health, safety, or the environment. The Committee views this report to Congress as an important element in setting the federal government's priorities so that we can achieve the greatest degree of protection for health, safety and the environment with our resources. Congress needs this information to evaluate its agenda.

Subchapter III. Review of rules

The Committee believes that for regulatory reform to be effective it must not be prospective only. Agencies must also look back and review existing regulations to eliminate outdated, duplicative, or unnecessary rules, and to reform and streamline others. With the passage of time, outmoded government decisions need review and revision.

Review of existing rules has been required since 1981 under Executive Orders 12291, 12498, and 12866; it has met with varying degrees of failure. Clearly, getting agencies to review existing rules is much easier said than done.

In the first annual report on Executive Order 12866, released in November 1994, OIRA Administrator Sally Katzen admitted that bureaucratic incentives make such review a difficult undertaking. While the "lookback" process had begun under E.O. 12866, she said, "it had proven more difficult to institute than we had anticipated. . . . [A]gencies are focused on meeting obligations for new rules, often under statutory or court deadlines, at a time when staff and budgets are being reduced; under these circumstances, it is hard to muster resources for the generally thankless task of rethinking and rewriting current regulatory programs" (p. 36). Much the same point was made in OIRA's May 1, 1994, report to the Vice President on the first six months of implementation of E.O. 12866 (pp. 22, 25), and in Ms. Katzen's testimony before the Committee on May 19, 1994.

After extensive review of the regulatory process, Vice President Gore concluded that "thousands upon thousands of outdated, overlapping regulations remain in place."⁸² The Vice President then launched his "Cutting Red Tape" initiative under the National Performance Review. Unfortunately, that too proved unsuccessful.⁸³

⁸²National Performance Review, *From Red Tape to Results: Creating a Government that Works Better and Costs Less* (1993).

⁸³See, e.g., GAO, *Regulatory Reform: Agencies' Efforts to Eliminate and Revise Rules Yield Mixed Results* (Oct. 1997). See also, Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, General Accounting Office, before the Subcommittee in Financial Management and Accountability, Senate Committee on Governmental Affairs, September 25, 1996; Testimony of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, General Accounting Office, before the Senate Committee on Governmental Affairs, September 12, 1997; Statement of L. Nye Stevens, Director, Federal Management and Workforce Issues, General Government Division, Gen-

The long but disappointing record of Executive Branch review efforts necessitates a legislative mandate.

The Committee believes that it is time that agencies deliver on the now long-standing requirement to review existing rules. Accordingly, Subchapter III and Section 3(b), discussed later in this report, require agencies to review their current rules.

Subchapter III requires the periodic review of economically significant rules. The definition of “economically significant rules” in Section 631 mirrors the definition of “major rule” in Subsection 621(7) with one important difference—Section 631 has no exceptions. All economically significant rules should be considered by all agencies for possible review.⁸⁴

Section 632 requires each agency, within 1 year after enactment, to publish 5-year plans for the review of the economically significant rules the agency selects for review. Each schedule must be subject to public comment, and published in the Federal Register within 120 days after the close of the comment period. The Committee believes the 5-year time frame (with an extension of up to 1 year for good cause) is a reasonable period of time for an agency to review the rules it has selected for review.

In setting priorities and in selecting which rules to review, the agencies must consider the extent to which (1) the rule could be revised to be more cost-effective or to increase net benefits; (2) the rule is important relative to other rules being considered for review; (3) the agency has discretion under the statute authorizing the rule to modify or repeal the rule. The agency should schedule its reviews so that they are reasonably distributed over time, with rules most in need of scrutiny reviewed first. Agencies should also try to review related rules at the same time.

Each schedule, preliminary and final, must include: (1) a brief identification and description of each rule selected for review; (2) an explanation for selecting each such rule; and (3) deadlines for the review of each rule on the schedule—no later than 5 years after the publication of the final schedule. Subsection (a)(4) requires the agency to publish, no later than 6 months after each deadline, its determinations about what action it will take on each rule, and an explanation for each determination. If an agency determines to amend or repeal a rule, subsection (a)(5) requires the agency to complete final agency action on such rule no later than 2 years after the deadline for the rule under subsection (a)(3). The OMB Director may extend a deadline for no more than 1 year if the Director for good cause finds that compliance with such deadline is impracticable and publishes such finding, and a succinct explanation therefor, in the Federal Register.

Subsections (b) and (c) parallel section 5 of Executive Order 12866. Subsection (b) requires each agency to identify any legislative mandates that require the agency to impose rules that are unnecessary, outdated, or unduly burdensome. Subsection (c) requires the OIRA Administrator to work with interested entities, including

eral Accounting Office, before the Senate Committee on Governmental Affairs, February 24, 1998.

⁸⁴ See ACUS Recommendation 95-3, “Review of Existing Agency Regulations” (1995) (all agencies (executive branch or “independent”) should develop processes for systematic review of existing regulations to determine whether such regulations should be retained, modified, or revoked).

small entities and State, local and tribal governments, to pursue the objectives of subchapter III. Consultation with representatives of State, local, and tribal governments shall be governed by the process established under section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. § 1534) and shall be exempt from the Federal Advisory Committee Act. Nothing in this section relieves any agency from its obligation to respond to a petition to issue, amend, or repeal a rule, for an interpretation regarding the meaning of a rule, or for a variance or exemption from the terms of a rule, submitted pursuant to any other provision of law.

To ensure that the basic requirements of Subchapter III are met, judicial review is available under Section 706(1) of this title in the event that the agency flaunts these basic requirements. The Committee believes that this Subchapter establishes a reasonable and effective requirement and finally will set agencies on the road of revisiting forgotten, but still burdensome, rules.

Subchapter IV. Executive oversight

This subchapter establishes in law the responsibility of the President to supervise the regulatory process of the federal agencies. Such responsibility includes coordinating agency regulatory policies and procedures, including those required by this legislation; developing a process for the review of rules covered by this legislation; and developing and overseeing an annual government-wide regulatory planning process.

Oversight of the federal regulatory process by the President, including review of proposed rules by an office designated by the President, has been in effect in one form or another for about twenty years. Since 1981, it has been conducted in a centralized process by OMB through the Office of Information and Regulatory Affairs under Executive Order Nos. 12291, 12498, and, most recently, 12866. The bill recognizes that centralized regulatory review has become an integral part of the Federal regulatory process and provides an important double-check on the work of the regulatory agencies in the effort to achieve efficient and effective regulations. The Committee is mindful that in the past, presidents have argued against regulatory review legislation because of potential inroads on presidential prerogatives. The Committee believes, however, that placing a regulatory review mandate into this legislation will help put to rest arguments about the fundamental nature or need for effective and transparent regulatory review. Nonetheless, respectful of separation of powers, the Committee has placed into statute only a general framework of executive oversight, with basic guidelines for regulatory review and public disclosure. This allows the President the flexibility to craft the details and scope of any regulatory review scheme, consistent with the requirements of this legislation.

Subchapter IV has four sections: Section 641, definitions; Section 642, presidential regulatory review; Section 643, public disclosure of information; and Section 644, judicial review.

Section 641 provides several definitions for Subchapter IV. First, it applies the same definitions in Section 551 of current law and Section 621 of the bill to the provisions in Subchapter IV. The section also defines the term “regulatory action” to include advance

notice of proposed rulemaking, notice of proposed rulemaking, and final rulemaking, including interim final rulemaking. These are the activities for which the Director of OMB, acting through the OIRA Administrator, is responsible to review and coordinate under this subchapter.

Section 642 requires the President in 642(a) to establish a process for such review and coordination and requires that the day-to-day responsibility for that reside in the Director of OMB, acting through the Administrator of OIRA. Section 642(b) enumerates specific activities that the Director/Administrator is required to carry out, namely: the development and oversight of uniform regulatory policies and procedures throughout the federal government, including those by which each agency shall comply with the requirements of this chapter; the development of policies and procedures for the review of rulemakings or regulatory actions by the Director/Administrator; and the development and oversight of an annual government-wide regulatory planning process. The planning process in 642(b)(3) is to include:

A summary of and schedule for the promulgation of major rules;

Agency specific schedules for the review of existing rules required under this legislation;

A summary of regulatory review actions undertaken in the prior year;

A list of major rules promulgated in the prior year for which an agency could not make the determinations that the benefits of a rule justify the costs under section 623(d);

An identification of significant agency noncompliance with this chapter in the prior year; and

Recommendations for improving compliance with this chapter and increasing the efficiency and effectiveness of the regulatory process.

Subsection 642(c)(1) limits the length of time for OMB review of regulatory actions to 90 calendar days. But subsection (c)(2) provides that the 90-day period can be extended by either the Administrator of OIRA or at the request of the rulemaking agency to the Administrator and that such extension must be published promptly in the Federal Register.

Section 643 mandates important disclosure requirements for the OMB review process. This has been an area of particular concern to the Committee for almost 20 years, beginning with President Reagan's issuance of E.O. 12291. Many in Congress were concerned about guaranteeing the openness of the regulatory review process to instill public confidence and equal access in such review. The Committee held numerous hearings over the years on OMB's review process, culminating in an agreement in 1986 with then OIRA Administrator, Wendy Gramm, over basic disclosure procedures specifically identified in a Memorandum to all agencies and made available to the public. This debate reemerged in connection with oversight of the Council on Competitiveness in 1991-92 and consideration of legislation to require disclosure in regulatory review. In 1996, Senator Thompson, then Chairman of the Subcommittee on Financial Management and Accountability, conducted oversight on President Clinton's E.O. 12866 on regulatory review. That over-

sight, and related GAO investigations, showed that agencies were not complying with the disclosure requirements of E.O. 12866.⁸⁵

The disclosure procedures in the 1986 Gramm memo were included in E.O. 12866 when it was issued in 1993. Also included in E.O. 12866 was the additional requirement that the public be informed on an ongoing basis as to the status of regulatory actions undergoing review (a requirement never resolved in the 1986 Gramm memo). Section 643 would codify those disclosure procedures developed and agreed to over time. Generically, Subsection 643(a) requires the Director of OMB, acting through the OIRA Administrator, to establish procedures for public and agency access to information concerning the review of regulatory actions. Specifically it requires that certain elements must be included in such procedures. These are:

Disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review.

Disclosure to the public no later than publication of a regulatory action of—

(1) all written communications relating to the substance of a regulatory action (including the drafts of proposed and final rules and the associated analyses) between the OIRA Administrator or employees of the Administrator and the regulatory agency;

(2) all written communications relating to the substance of a regulatory action between the Administrator and employees of the Administrator and any person not employed by the executive branch of the Federal Government;

(3) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive meetings and telephone conversations relating to the substance of a regulatory action between the OIRA Administrator or employees of the Administrator and any person not employed by the Executive Branch; and

(4) a written explanation of any review action and the date of any such action.

Disclosure to the regulatory agency, on a timely basis of—

(1) all written communications relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government;

(2) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive meetings and telephone conversations, relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the Executive Branch; and

(3) a written explanation of any review action taken concerning an agency regulatory action and the date of such action.

⁸⁵ See GAO, *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (Jan. 1998).

Subsection 643(b) requires the rulemaking agency, before publication of any proposed or final rule, to include in the rulemaking record the following—

A document identifying in a complete, clear, and simple manner, the substantive changes between the draft submitted to the Administrator for review and the rule subsequently announced.

A document identifying and describing those substantive changes in the rule that were made as a result of the regulatory review and a statement if the Administrator suggested or recommended no changes.

All written communications relating to the substance of a regulatory action between the Administrator and the agency during the review of the rule, including drafts of all proposals and associated analyses.

Finally, Subsection 643(c) requires that a representative of the agency submitting the regulatory action shall be invited to any meeting relating to the substance of a regulatory action under review between the Administrator or employees of the Administrator and any person not employed by the Executive Branch.

Section 644 states the exercise of the authority granted under this Subchapter by the President, the OMB Director, or the OIRA Administrator shall not be subject to judicial review.

Section 3(b). Periodic review of rules

Subsection 3(b) amends Section 610 of the Regulatory Flexibility Act of 1980 (P.L. 96–354) (“RFA”) to reaffirm and refine the nearly 18-year statutory responsibility of the agencies to review rules with a significant economic impact on a substantial number of small entities. As demonstrated by testimony and statements provided to this Committee and others, the need for periodic review of rules under Section 610 is as strong today, if not stronger, than in 1980 when President Carter signed the RFA into law.

In April 1994, the General Accounting Office reviewed 11 years of Small Business Administration (“SBA”) annual reports on the RFA and reported that agency compliance “varied widely.” In particular, GAO noted that many agencies had failed to issue the plans for periodic review of rules under Section 610. Moreover, some of the plans that were issued were inadequate.⁸⁶

In 1995, the White House Conference on Small Business adopted recommendation #183, calling on Congress to provide judicial review of agencies’ compliance with the RFA. Senator Christopher Bond, Chairman of the Senate Committee on Small Business, authored legislation to provide judicial review and several other important RFA reforms. This legislation, the “Small Business Regulatory Enforcement Fairness Act” of 1995 (P.L. 104–121), passed the Senate by a 100–0 vote, and President Clinton signed it into law on March 29, 1996.

Section 610(c) of the RFA requires that each agency publish in the Federal Register a list of the rules which have “a significant economic impact on a substantial number of small entities, which

⁸⁶ GAO, Regulatory Flexibility Act: Status of Agencies’ Compliance, GAO/GGD–94–105 (April 27, 1994).

are to be reviewed” under the RFA during the following 12 month period. The list is to include a “brief description of each rule and the need for and legal basis of such rule” and then the agency must ask the public to comment on the rule. Despite the latest improvements to the RFA, new GAO reports show that few, if any, lists of rules under Section 610(c) complied with the law. In testimony provided this Committee,⁸⁷ GAO reports that in the October 1997 Unified Agenda, seven agencies identified a total of 34 entries as Section 610 review actions. However, only three entries satisfied all the requirements of Subsection 610(c). Similarly, GAO reported that in the November 1996 Unified Agenda, three agencies identified a total of 21 entries as Section 610 reviews. None of these entries satisfied the requirements of Subsection 610(c). In sum, GAO found that agencies had identified only 55 rules for review in these two editions of the Unified Agenda.

As GAO has found over the years, the agencies have reviewed relatively few rules under Section 610 of the RFA. Given the large number of rules that significantly affect small entities, the Committee concludes that more rigorous review is needed under Section 610.

Therefore, S. 981 includes an amendment to Section 610 to provide the benefits intended by Congress in 1980. Section 3(b) of the bill amends the RFA to require agencies to publish new plans for the review of rules. Beginning 60 days after the effective date, which is 180 days after enactment, and every subsequent fifth year, Section 3(b) requires each agency to submit to the OIRA Administrator and to the SBA Chief Counsel for Advocacy a proposed plan describing the procedures and timetable for Section 610 reviews. Sixty days later, proposed plans are to be published in the Federal Register for 60-day comment. Within 120 days of the proposed plan’s publication, agencies must submit final plans to OIRA and Advocacy, and publish them in the Federal Register 60 days later.

Adding the requirement that agencies share their draft and final plans with OIRA and SBA’s Chief Counsel for Advocacy will better ensure that agencies consistently interpret the requirements of Section 610. This coordination will assist OIRA and Advocacy in fulfilling their new statutory responsibility in Section 3(b), to work with small entities to help achieve the objectives of Section 610. The Committee notes that the GAO has recommended that Congress require OIRA and SBA to work together to improve agency compliance.⁸⁸

Section 3(b) substitutes the requirement that agencies review rules within 10 years with the requirement that agency plans provide for the review of rules that have a significant economic impact on a substantial number of small entities no later than 5 years after publication of the plan. If the agency head certifies in the Federal Register that more than 5 years is needed to review a spe-

⁸⁷ GAO, Comments on S. 981—The Regulatory Improvement Act of 1998, GAO/T-GGD/RCED-98-95 (Feb. 24, 1998). See also, GAO, Regulatory Flexibility Act: Agencies’ Use of the October 1997 Unified Agenda Often Did Not Satisfy Notification Requirements, GAO/GGD-98-61R (Feb. 12, 1998); GAO, Regulatory Flexibility Act: Agencies’ Use of the November 1996 Unified Agenda Often Did not Satisfy Notification Requirements, GAO/GGD/OGC-97-77R (April 22, 1997)

⁸⁸ GAO, Regulatory Flexibility Act: Status of Agencies’ Compliance, GAO/GGD-94-105 (April 27, 1994).

cific rule in the plan, up to two extensions of 1 year each can be obtained.

Section 3(b) does not amend Subsection 610(b) of the RFA, which sets forth the criteria for each Section 610 review. Upon completion of the review, Section 3(b) requires the agency to “determine whether the rule should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rule upon a substantial number of small entities.”

Section 3(b) amends subsection 610(c) to require agencies to publish the annual list of the rules to be reviewed under the plan during the next fiscal year, rather than during the next 12 months. Consistent with Congress’ original intent in 1980, this requires agencies to provide small entities with advanced notice and the opportunity to participate in the review process.⁸⁹ The annual list published by the agency must include: a brief description of each rule, the need for and legal basis for each rule, and an invitation for public comment. Section 3(b) enhances the notice provided small entities by requiring agencies to include the basis for the determination that a rule has or will have a significant economic impact on a substantial number of small entities. This determination should be based on all available information about the rule’s impact on small entities at the time the rule is being considered for inclusion on the fiscal year list.

Improving upon the RFA, Section 3(b) ensures that small entities are advised of the outcome of each review conducted under Section 610. Not later than 18 months after publication of the annual list, the agency is required to publish in the Federal Register the determinations made on each rule on the list and an explanation of the determination. Agencies should include in the Federal Register notice the legal and factual basis for their determinations, establishing a record of each Section 610 review.

Section 3(c). Presidential authority

Section 3(c) provides that nothing in this Act shall limit the exercise by the President of the authority and responsibility that the President otherwise possesses under the Constitution and other laws of the United States with respect to regulatory policies, procedures, and programs of departments, agencies, and offices. The President retains the authority to extend regulatory analysis and review requirements beyond those established in this Act.

Section 3(d). Technical and conforming amendments

Section 3(d) provides the technical and conforming amendments to Chapter 6 of title 5, United States Code. Up to this point, Chapter 6 consisted of the Regulatory Flexibility Act. With this legislation, Chapter 6 is substantially amended to create Subchapter I, which includes the regulatory flexibility analysis with revisions to the periodic review of rules covered by the Regulatory Flexibility Act. It also creates three new subchapters: Subchapter II—Regulatory Analysis; Subchapter III—Review of Rules; and Subchapter IV—Executive Oversight.

⁸⁹ Senate Report No. 96–878, at 15.

Section 4. Compliance with the Unfunded Mandates Reform Act of 1995

To avoid duplicative cost-benefit analyses under the Unfunded Mandates Reform Act of 1995, Section 4 states that compliance with the cost-benefit provisions of this legislation constitutes compliance with the cost-benefit provisions applicable to the private sector in sections 202, 205(a)(2) and 208 of UMRA (2 U.S.C. §§ 1532, 1535(a) and 1538).

Section 5. Effective Date

Except as otherwise provided in this legislation, this Act shall take effect 180 days after the date of the enactment of this Act, but shall not apply to any agency rule for which a notice of proposed rule making is published on or before 60 days before the date of enactment of this Act.

VI. REGULATORY IMPACT STATEMENT

Pursuant to paragraph 11(b), rule XXVI of the Standing Rules of the Senate, the Committee, after due consideration, concludes that S. 981 will have a significant regulatory impact.

VII. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

S. 981—Regulatory Improvement Act of 1998

Summary: S. 981 would amend chapter 6 of Title 5, U.S. Code, to require federal agencies to complete specific studies as part of the regulatory analysis performed before major rules are issued. (The bill would define a major rule as a regulatory action expected to have an impact on the economy of \$100 million or more annually.) It would require agencies to conduct cost-benefit studies, risk assessments, and peer reviews before finalizing certain major rules. In addition, the bill would require that agencies select existing major rules for review to determine if modifying such rules would reduce the cost of compliance for state and local governments and private-sector entities. Agency compliance with the regulatory analysis provisions of S. 981 would be subject to judicial review in certain circumstances.

Enacting the bill would increase the cost of regulatory analysis at federal agencies that regulate health, safety, and the environment. Based on information from these agencies, on our review of the number and type of major rules issued in fiscal year 1997, and on past costs of regulatory analyses, CBO estimates that implementing S. 981 would increase the government's cost to perform regulatory analyses by between \$20 million and \$30 million annually, subject to appropriation of the necessary amounts.

In addition, the bill would increase costs at the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) to write regulations and contract for a pair of studies, and at agencies that regulate health, safety, and the environment to devise detailed guidelines for performing risk-assessment analyses. CBO estimates that enacting S. 981 would increase such administrative costs by about \$5 million over the 1999–2003 period.

S. 981 could result in additional costs to federal agencies beyond those we have estimated. Under S. 981, OMB could require that agencies perform risk assessments according to the bill's detailed procedures for agency actions, other than major rules, that it believes could have a substantial impact on a significant public policy or on the economy. CBO assumes, however, that the bill's procedures for conducting risk assessments would be applied only in the case of major rules. If OMB were to require that agencies apply the bill's risk assessment procedures to other agency actions that include an assessment of risk, the additional costs could be substantial.

CBO also has not included costs that might be incurred as the result of additional judicial review because we have no basis for predicting how many regulatory actions might be challenged under this bill. While the bill would require that agencies review past rules, CBO estimates that such costs would not be significant over the next five years because agencies are required to review existing rules periodically under current law.

CBO estimates that enacting the bill would not affect direct spending or receipts; therefore, pay-as-you-go procedures would not apply. The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act of 1995 (UMRA) and would not affect the budgets of state, local, or tribal governments.

Estimated cost to the Federal Government

Much of the regulatory analysis and review that would be required by S. 981 is already performed to some degree by federal agencies. In addition, the bill would exempt many federal regulatory actions from its requirements, including rules that apply to or regulate: (1) governmental receipts, (2) certain commerce activities, including wages and prices, mergers and acquisitions, and accounting practices, (3) securities trading, (4) monetary and federal fiscal policy, (5) banking, and (6) new products. In addition, the bill would exempt certain regulations of the Federal Communications Commission and any rule that an agency must issue at least annually. Based on a preliminary review of the approximately 60 major rules issued in fiscal year 1997, CBO estimates more than half would be exempt from the bill's requirements because they involve some form of economic regulation.

Agencies also could exempt rules from the bill's provisions where the more detailed reviews are either not practical or contrary to an important public interest. In such cases, the bill would direct the agency to comply with its provisions as soon as possible after adopting the rule, unless the rule is set to expire.

CBO expects that enacting S. 981 would have a small impact on the cost to perform regulatory analyses for most agencies because the bill: (1) would codify much of existing practice, (2) would generally not apply to so-called "minor" rules, (3) would exempt many regulatory provisions from its review, and (4) would allow agencies to opt out of its requirements in certain situations. The bill, however, could significantly increase costs for agencies that issue major rules governing health, safety, and the environment, such as the Environmental Protection Agency (EPA), the Occupational Safety

and Health Administration (OSHA), and the Departments of Health and Human Services, Transportation, and Agriculture.

CBO estimates that S. 981 would increase the costs of issuing new major rules for federal agencies by between \$20 million and \$30 million a year. In addition, we estimate the bill would increase administrative costs by about \$5 million over the 1999–2003 period. All costs would be subject to the availability of appropriated funds.

Finally, the bill would establish procedures for agencies to review past rules. Periodic review of major rules already is required under current law (section 610 of the Regulatory Flexibility Act of 1980) and current policy (section 5 of the Executive Order 12866), although not as frequently as would be called for under S. 981. Under the bill, agencies would have considerable discretion in deciding which rules to examine and whether to revise or repeal a rule. Based on information provided by various agencies, we expect that agencies would revise or repeal a rule only if strong and compelling evidence existed that a core assumption was in error. Because most such regulatory revisions would likely be made under current law, CBO expects that agencies would not incur significant additional costs over the 1999–2003 period for the review of existing regulations.

Impact on EPA

Based on information from EPA, CBO estimates the agency spends about \$120 million annually on regulatory analysis, and S. 981 would add \$1 million to \$2 million to each major regulatory action that would be covered by the bill to pay for added or improved economic studies and risk assessments. In 1997, EPA finalized seven major rules that would appear to be covered by S. 981. Since the provisions of the bill would also apply to preliminary rules, and because the volume of regulatory activity fluctuates, we estimate that implementing S. 981 would increase the cost of EPA's regulatory analyses by \$10 million to \$15 million annually, assuming appropriation of the necessary amounts.

Impact on other agencies

In 1997, CBO published a paper that examined the costs of 85 regulatory impact analyses (RIAs) conducted by selected agencies (Regulatory Impact Analysis: Costs at Selected Agencies and Implications for the Legislative Process, March 1997). The cost of these RIAs ranged from as low as \$14,000 to as high as \$6 million, with the time required to complete them ranging from six weeks to more than 12 years. (Because the paper did not attempt to obtain a representative sample of RIAs, it does not indicate the cost of a "typical" or "average" RIA.)

In addition, the paper showed that RIAs were more expensive at EPA than at other agencies. Based on that paper, as well as on information provided by OSHA and the National Highway Traffic Safety Administration (NHTSA), we expect that the increase in costs under S. 981 would be greater at EPA than at other regulatory agencies. Specifically, we estimate the bill would add, on average, less than \$1 million per rule to the cost of the regulatory

analysis for most major rules promulgated by agencies other than EPA.

The increase in cost per rule would likely vary, depending on the complexity of the rule. For instance, in fiscal year 1997, NHTSA issued two major rules, one of which S. 981 would exempt. Based on information from NHTSA, CBO estimates that the agency spent less than \$1 million on the nonexempt rule. Because we expect that, on average, the bill would increase the costs to perform the regulatory analysis for a rule by less than one-half, the additional costs under S. 981 for this rule would have amounted to less than \$500,000.

By comparison, OSHA issued one major rule in fiscal year 1997 and the agency spent about 10 years to complete that rule. Based on information from OSHA, CBO estimates that the agency spent as much as \$5 million performing regulatory analysis of the rule. As part of this analysis, OSHA performed numerous risk assessments, although those assessments did not include all of the information that S. 981 would require, such as providing additional information on the ranges and distributions of risks addressed by the rule, requesting and considering data submitted by the public, and fully documenting each assumption. Based on this information, we estimate that by broadening the scope and effort of OSHA's analysis, S. 981 would have added \$1 million to \$2 million in total over several years to the rule's cost. For most major rules issued by OSHA, however, we expect that implementing the bill would increase costs by less than \$1 million per rule.

Based on our review of the type and number of major rules issued during fiscal year 1997, we expect the bill's provisions would apply to about 25 rules a year (including those promulgated by EPA), although the volume of regulatory activity can fluctuate depending on the demands on regulatory agencies. (As noted above, agencies issued about 60 major rules in 1997, and at least half of those would have been exempt from the new review requirements of S. 981. A similar number of major rules were issued in 1996.) Thus, CBO estimates that enacting S. 981 would increase costs for the 15 to 20 nonexempt rules issued by agencies other than EPA by between \$10 million and \$15 million annually—about the same amount as the estimated increase in EPA's costs.

Reporting, Oversight, and Implementation Costs

In addition to the increase in costs to issue new major rules, S. 981 would impose several, reporting and oversight requirements on the Administration, which would be carried mostly by OIRA. Specifically, the bill would require that OIRA: (1) issue guidelines for cost-benefit analyses, risk assessments, and peer reviews and periodically evaluate agency efforts in implementing these guidelines, (2) periodically evaluate and develop a strategy to meet agency needs for research and training in performing regulatory-impact analyses, and (3) contract with accredited scientific institutions to study the use of risk assessments and comparative-risk analysis in performing regulatory analyses. The bill would require that the results of the research on risk assessments be forwarded to OMB and the Congress within two years of enactment and that the results of the research on comparative-risk analyses be forwarded within

three years of enactment. CBO estimates that implementing these provisions would cost OIRA about \$2 million over the 1999–2003 period, assuming appropriation of the necessary funds.

In addition, under the bill, the roughly one-half dozen agencies that issue health, safety, and environmental regulations would have 18 months to adopt detailed guidelines for performing risk assessments as part of their regulatory impact analyses. In total, CBO estimates that these agencies would incur costs of about \$3 million over fiscal years 2001 and 2002 to develop those guidelines.

Pay-as-you-go considerations: None.

Intergovernmental and private-sector impact: S. 981 contains no intergovernmental or private-sector mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

Previous CBO estimate: CBO prepared an estimate of the costs of S. 981 on April 20, 1998. This revised estimate clarifies the discussion of the bill's provisions and CBO's assumptions, but the estimated costs of S. 981 are unchanged.

Estimate prepared by: Kim Cawley and John R. Righter.

Estimate Approved by: Robert A. Sunshine, Deputy Assistant Director for Budget Analysis.

VIII. ADDITIONAL VIEWS

ADDITIONAL VIEWS OF SENATOR GLENN

I am pleased to be an original co-sponsor of the Regulatory Improvement Act of 1998. This legislation, introduced by my colleagues Senators Carl Levin and Fred Thompson, reflects a bipartisan effort to establish a comprehensive set of analytic standards to inform and improve Federal agency rulemaking.

The hearings held by the Committee on September 12, 1997, and on February 24, 1998, established a legislative record supporting the need for the legislation and the balance reflected in it. The hearings also produced critical commentary that led to a number of improvements in the legislation. The resulting bill, that has now been ordered reported by the Committee, is a good bill that deserves support by the full Senate.

I believe that S. 981 can improve our government and reduce regulatory burdens without harming important public protections. As I have said many times during our long-running regulatory reform debate, true regulatory reform must strike a balance between the public's concern over too much government and the public's strong support for regulations to protect public health and safety, and the environment.

S. 981 strikes the needed balance, but I must emphasize that it is a delicate balance. For example, while I am a firm believer in improving the rigor of agency rulemaking decisions, both through analysis and OMB review, I also believe that both are far from exact sciences and are vulnerable to manipulation and bias. I have been convinced of this fact by two decades of Committee oversight of the regulatory process.

First, cost-benefit analysis and risk assessment can help an agency in its quest for better rulemaking, but if they become controlling factors, their inherently subjective limitations, when combined with the prospects of judicial review, can stifle important regulatory activity. For example, while better estimation of regulatory costs is important, studies have found that even after fifteen years or more of experience with presidentially required cost-benefit analysis, agency practices are inconsistent in substance and procedure. *Regulatory Reform: Changes Made to Agencies' Rules Are Not Always Clearly Documented*, GAO/GGD-98-31 (January 1998), and *Air Pollution: Information Contained in EPA's Regulatory Impact Analyses Can Be Made Clearer*, GAO/RCED-97-38 (April 1997). Specific estimates of future costs, themselves, have been shown to be significantly miscalculated. *Gauging Control Technology and Regulatory Impacts in Occupational Safety and Health*, U.S. Congress, Office of Technology Assessment, September 1995.

Second, while OMB regulatory review is also needed to coordinate and improve the quality of agency rulemaking, it too has its weaknesses. This Committee has documented, for example, a lengthy record in previous administrations of undisclosed lobbying, undocumented decisions, and unaccountable pressures on agencies to change rulemaking decisions. "Regulatory Review Sunshine Act," S. Report 102-256 (1992); "Risk-Risk Analysis," S. Hearing 102-1144 (1992); Risk-Risk Analysis: OMB's Review of a Proposed OSHA Rule, GAO/PEMD-92-33 (May 1992); "The Role of the Council on Competitiveness in Regulatory Review," S. Hearing 102-1135 (1991); "Federal Management Reorganization and Cost Control Act of 1986," S. Report 99-347 (1986); and "Oversight of the OMB Regulatory Review and Planning Process," S. Hearing 99-839 (1986).

These concerns, in fact, led the Committee to craft many of the provisions found in S. 981, from consideration of nonquantifiable as well as quantifiable costs and benefits, to cost-benefit determination explanations (instead of mandatory decisional criteria), to transparency in OMB regulatory review.

Again, I believe that the provisions of S. 981 are sufficiently clear and sufficiently balanced to improve the regulatory process, while protecting agency discretion to provide needed public protections. My caution is intended only to more clearly state, than is set forth in the majority report, the need to recognize potential flaws in the regulatory process that can jeopardize public protections.

For this same reason, if changes are made to the bill that would restrict agency discretion more than that provided in S. 981, I would probably find it difficult to support it. On the other hand, if it proves legislatively feasible, I believe the bill could be strengthened, for example, by the incorporation of a number of suggestions made by OMB Director Frank Raines in his March 6, 1998, letter to the Committee.

In conclusion, whatever the outcome of debate on S. 981 by the full Senate, at this point, I believe this legislation meets my goal of providing a balanced approach to improving the Federal regulatory process, while ensuring continued protections of public health and safety, and the environment. S. 981 is a worthy accomplishment and should be supported.

JOHN GLENN.

IX. MINORITY VIEWS

MINORITY VIEWS OF SENATORS LIEBERMAN, AKAKA, DURBIN, TORRICELLI, CLELAND

We understand and respect that the goal of our colleagues in crafting S. 981 is to improve the regulatory process. Senators Lieberman and Akaka, who were members of this Committee in the 104th Congress, supported the Roth-Glenn and Glenn-Chafee regulatory reform bills; and some of us made clear during the markup that it is the specific provisions of S. 981 that we cannot support because we believe they do not achieve the goal of improving the regulatory process.

We fear that, despite the good intentions of the sponsors, the unintended consequences of S. 981 will be to threaten the ability of our health and safety agencies to act in a timely and decisive manner to protect us and our children. We agree with the conclusion reached by OMB Director Franklin Raines in his March 6, 1998 letter to Chairman Thompson: the bill does not meet the simple test of truly improving the regulatory system while not impairing—by creating more litigation, more red tape, and more delay—the agencies' ability to do their job. In fact, we believe that the provisions of the bill in its current form run contrary to the goal of truly improving the regulatory system. We do not believe that the American people would support such a result. For this reason, we voted against S. 981.

The number one responsibility we have, and what people demand from us, is to protect the public we serve from harm. That means guarding our national security with a strong defense, and keeping our streets safe from crime. But that also means protecting people from breathing polluted air, from drinking poisonous water, from eating contaminated food, from unsafe toys, from hazards in the workplace and on our roads and in our air, from being exposed to consumer fraud—in other words, protecting people from harms from which they cannot protect themselves. And it means ensuring that the laws we have passed to provide opportunity for access and participation for all our citizens or to protect wildlife are not weakened.

We often fail to think of these problems as being a threat to our safety and well-being because, for the most part, the federal government has done a good job in guaranteeing that we have clean water and clean air and safe toys. Interestingly, on the day in March when this bill was marked up, the Pew Research Center for the People and the Press released a survey showing that the public actually has a very high degree of confidence in the civil servants who run our health, safety, and environmental agencies: the favorable ratings of agencies such as the Environmental Protection

Agency, the Federal Aviation Administration, the Federal Drug Administration, and the Centers for Disease Control, ranged from 69 percent to 79 percent. Many politicians would envy these favorable ratings for people they sometimes criticize as “nameless bureaucrats”—particularly since the same poll found a favorable rating for politicians of only 16 percent.

We all agree that there are problems with the regulatory process. For example, the process is often too slow, and it can be inaccessible to the ordinary American trying to understand either how to comply with the law or how to take advantage of the benefits of a regulation. But when it comes to health and safety, the people want a government that works better, not a government that does too little too late. When we travel around our states, no one comes up to us and says, “stop trying to regulate unsafe children’s toys.” No one says, “our meat and poultry supply is too safe.” Even business owners, who have legitimate concerns about the way in which some regulations are written and enforced, say to us, “I’m a citizen and a parent, too. I want to live in a clean environment. I want my kids to have safe toys and drink clean water.”

It is also important to recognize that our laws provide a host of procedural protections to make certain that all individuals have an opportunity to participate in the rulemaking process and then challenge decisions that they believe are wrong in a federal court. These procedural due process protections are designed to ensure that the “truth” will emerge from our regulatory process. Guaranteeing that all citizens have procedural due process rights with respect to rulemaking makes the process of issuing regulations a lengthy one. It is, therefore, rare that citizens object that a health or safety agency has acted with too much speed on their behalf. On the contrary, citizens often complain that agencies do not act rapidly enough. Sue Doneth, the mother of a hepatitis A victim, and Nancy Donley, whose child died from eating an E. Coli contaminated hamburger, spoke eloquently to the Committee on this point. So did Dr. Franklin Mirer, Director of the Health and Safety Department of the United Automobile, Aerospace & Agricultural Implement Workers of America, who testified that the current standard setting process at OSHA to protect workers from chemical exposure is stalled and failing to protect workers.

THERE IS A BETTER WAY TO IMPROVE REGULATIONS

Our point is that when it comes to environmental, consumer, and public health protection we need to try to achieve better protection in a smarter, more efficient way. We concur with the conclusion of our colleagues, Senator Chafee and Senator Baucus, the Chairman and Ranking Member of the Environment and Public Works Committee in their March 6, 1998 letter to Chairman Thompson, that such reforms are generally better accomplished within the framework of a specific regulatory statute, rather than in an across the board omnibus bill such as S. 981. (A copy of the letter is attached hereto.)

During the markup, Senator Torricelli provided an excellent example of one of the problems with an omnibus bill. He pointed out that regulations designed to protect civil rights would be included within the scope of the bill; therefore, a cost-benefit analysis would

be required for these regulations. But when Senator Torricelli asked how a cost-benefit analysis could possibly apply to these type of regulations, the sponsors did not have an answer. We believe that is because our nation's commitment to civil rights is one of the major ways we define what is good about our society. This commitment is not "purchased" like a TV set, where cost factors may drive the decision. Regardless of any costs, all Americans are entitled to the protection of our civil rights laws and regulations. Similarly, Director Raines points to another example of the dangers of over-inclusiveness: some of the provisions in S. 981 governing how to do a risk assessment may be ill-suited to objectives such as an evaluation of risks related to airworthiness, environmental and natural resources and worker safety. Why would we want to enact a law that forces air safety risks to be analyzed by methods that are ill-suited to the problem at hand?

In contrast, statute-by-statute reform does not create problems of over-inclusiveness. And it works. Last Congress' Safe Drinking Water Act Amendments is an outstanding example of a piece of regulatory reform legislation which was very targeted and dealt with features unique to the problem of drinking water quality. The Congress carefully considered how risk assessment and cost-benefit analysis could make the law more effective, and incorporated those principles based on the overall objectives and operation of that law. For example, an issue unique to the Safe Drinking Water Act is the different capacities of large and small water systems. As a result, the law specifically tailored the EPA Administrator's authority to use cost-benefit analysis based on differences in these systems. We are concerned that such refinement and targeting may be missed in this type of broad government-wide proposal and, as our colleagues Senators Chafee and Baucus have stated, serious unintended consequences may result.

Last Congress we also passed and the President signed the Food Quality Protection Act and the Pipeline Reauthorization Act, two bills providing for banking reform, legislation providing interstate trucking deregulation, procurement reform and pension reform.

There is no doubt that the statute-by-statute approach may be more time-consuming and difficult in the short-run than an omnibus bill. The Environment and Public Works Committee spent three years on the reauthorization process for the Safe Drinking Water Act, listening to all views on how this law was or wasn't working. But the result was worth it: the bill passed the Senate unanimously with the support of virtually every interested group. The importance of that type of consensus cannot be overstated. Among other advantages, it makes everyone want to work to implement effectively a law that they supported and have a stake in. On the other hand, there is no consensus with respect to this bill. The testimony of one Committee witness, Dr. Frank Mirer of the UAW, indicates just how far from consensus we are. He testified that S. 981 "will make it harder to protect workers from serious safety and health hazards. It will result in preventable injuries, illnesses and deaths on the job."

In addition to the statute-by-statute approach, last Congress we passed and President Clinton signed a number of more targeted regulatory reform bills to address some of the problems that mem-

bers of the business community and state and local governments raised about the regulatory process. These included the Small Business Regulatory Enforcement Fairness Act, the Unfunded Mandates Reform Act, and the 1996 Amendment to the Paperwork Reduction Act. The Small Business Regulatory Enforcement Fairness Act was designed to increase agency sensitivity to the needs and concerns of small businesses. Agencies are required to write their regulations so that those affected can more easily understand them and know how to comply, and agencies must establish programs to provide for the reduction and, in some circumstances, for the waiver of penalties for violation of requirements by a small entity. It provided for enhanced judicial review for decisions affecting small businesses. And it also contained provisions for Congressional review of agency rulemaking whereby Congress acknowledged and assumed more responsibility for the rules that agencies issue. The Unfunded Mandates Reform Act includes provisions for cost-benefit analysis of major rules. The Paperwork Reduction Act was designed, in part, to assure that collections of information included in regulations by Federal agencies minimize the burden on respondents and maximize their usefulness to agencies.

The Clinton Administration has also undertaken a number of initiatives to improve the Federal regulatory system. In 1993, President Clinton issued Executive Order No. 12866 setting forth a regulatory philosophy that, consistent with existing law, regulations should be issued only where necessary and be based on a full assessment of costs and benefits of reasonable alternatives. This Executive Order is a powerful tool for OMB to ensure that agencies' regulations both protect public health and make good economic sense, but the Order does not put at risk existing laws or add new judicial hurdles for agencies to overcome.

We believe that the appropriate next step for this Committee is to conduct oversight hearings to determine if all these laws are working to address the concerns raised, if more needs to be done and where the gaps, if any, may be.

Finally, Senator Lieberman has advocated another approach to regulatory reform based on an outstanding program at EPA, known as X-L (standing for excellence and leadership), that allows EPA to grant waivers of environmental requirements if companies demonstrate superior environmental performance. S. 1348, introduced by Senators Lieberman, Daschle, Moynihan, Kerrey, and Landrieu and endorsed by the Clinton Administration, would provide a statutory framework for a pilot program adopting this approach. The goal is to achieve real changes in the way we do business in the environmental arena. Companies will have lower costs, but we will also have a guarantee that the environment will be improved.

CONCERNS WITH S. 981

Despite our misgivings about this legislation, we have remained willing and open to working with the sponsors to try and achieve a bill that meets the test articulated by Director Raines in his letter and earlier by OIRA Director Sally Katzen in her September 27, 1997 testimony before the Committee. In his letter, which we attach to these views, Director Raines sets forth specific reasons why S. 981 does not meet the test of truly improving the regulatory

process while not impairing—by creating more litigation, more red tape and more delay—the agencies’ ability to do their job. We agree with Director Raines. The letter also sets forth specific proposals to address the problem areas. At the markup, Senator Lieberman discussed (but filing requirements prevented him from offering) an amendment that included legislative language incorporating all of the Administration proposals.

I. Supermandate

We believe that the American people strongly oppose any efforts which would override, alter or compromise—whether explicitly or implicitly—our public health, environmental, wildlife, consumer, food safety, disability, automobile and air traffic safety laws. For this reason, we sought specific guarantees at the markup that this would not be the result of S. 981.

At the markup, Senator Cleland offered an amendment designed to ensure that “nothing in this subchapter shall be construed to alter or modify the substantive standards otherwise applicable to a rulemaking under other statutes, or to limit the range of discretion available under, or in construing, other statutes.” This amendment also was proposed in Director Raines’ letter. Chairman Thompson offered a second-degree amendment striking the second part of the amendment relating to discretion. Over our objections, the Thompson second-degree amendment was adopted and then the Cleland amendment passed.

Obviously, we are pleased that the first portion of this amendment was adopted. Although Senator Thompson indicated a willingness to continue to work with Senator Cleland, we are very concerned about the failure to adopt the second portion of the amendment dealing with agency discretion. As Director Raines stated: “The range of discretion available to agencies under current law must be expressly preserved to avoid an implicit supermandate.”

What is the danger of an implicit supermandate? Suppose Congress enacts a law requiring an agency to set standards to ensure that children are protected from unsafe cribs with an adequate margin of safety. Our laws generally grant agencies discretion in implementing their statutory mandates to protect public health, safety, or the environment because Congress does not possess the necessary detailed information or expertise to make the decision about the most effective approach. In other words, an agency might have the discretion to meet the statutory mandate in a number of ways: it might determine that children can be protected from unsafe cribs by requiring a recall if a problem arises with a particular type of crib, by requiring warning labels be posted in pediatricians’ offices if a problem arises, by requiring that warnings be mailed to each person who purchased a crib if a problem arises, or by requiring new design standards for cribs which will ensure that all cribs are safe. We are concerned that the provisions of this bill, taken together, would limit the ability of an agency head—whether directly or through new pressures created on agencies—to select the option that will provide the best protection for children: redesigning the crib, despite claims that other riskier options are more “cost-effective”.

Senator Cleland's amendment sought to make very clear that the agency's ability to choose the redesign option would be fully preserved. We think the American people would want nothing less. At the same time, Senator Cleland's amendment made clear that agencies would still be required to perform the cost-benefit and other analyses required under S. 981, but that existing law determines the degree to which these analyses should affect the outcome of the rulemaking.

The sponsors of this bill repeatedly have indicated that they do not intend to change the ability of agencies to make the decisions they would make under current law. We are puzzled and troubled, therefore, by their rejection of the second part of Senator Cleland's amendment.

2. Judicial review

We think that most members of the Senate would agree that we do not want to create more opportunities for litigation. Unfortunately, that is what would happen under S. 981.

We fully support the thorough judicial review that the Administrative Procedure Act (APA) provides for all rules. Under that Act, an agency's decision will be set aside if it is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. Under the current judicial interpretation, courts will find that an agency has passed these tests if the agency's analyses, assessment and responses to comments have provided the court with a reasoned discussion of choices the agency has made, and a sufficient explanation of the reasons for those choices so that the court can conclude that the agency had a reasonable basis for making its decision. Any risk assessment or cost-benefit analysis that is prepared must be sufficient to withstand this APA test.

Our concern about S. 981 is that it provides agencies with new, much more burdensome hurdles to overcome. The court is given new authority for overturning a rule, based on the fact that the cost-benefit or risk assessment did not meet the many new requirements of this bill relating to how to perform a cost-benefit or risk assessment. In other words, courts must judge the quality of these analyses not by the traditional APA yardstick of a reasonable explanation, but by a much tougher yardstick that is based on an item-by-item examination of whether each of the bill's many analytical and procedural requirements have been properly carried out. We fear that regulated entities will use these new hurdles to tie the agency up in litigation for years and that the court will be given new authority to overturn rules that today would be judged reasonable.

Of equal importance, we are concerned that S. 981 allows a court to review an agency's determination about whether it selected the alternative that was more cost-effective or had greater net benefits than other alternatives that the agency has identified. The bill, therefore, provides another wholly new basis for overturning an agency's good rule.

Let's look at a simple example. Suppose an agency is setting standards for reducing lead in drinking water, and it has discretion to set the level anywhere from Option 1 (least stringent) to Option 5 (most stringent). The costs are quantifiable; assume it will cost

\$100 million to reach Option 1 and \$500 million to reach Option 5. Let's say we can quantify some benefits at \$120 million, but the most significant benefit—avoiding a reduction in a child's IQ—cannot be quantified. Let's say the EPA Administrator selects Option 5 because she believes removing a greater quantity of lead is critical to avoiding a reduction in a child's IQ. In other words, she says that Option 5 is the alternative with the greater net benefits than Option 1 because of the weight she accords to protecting a child's IQ, even though the quantified net benefits of Option 1 are clearly greater.

We do not believe that regulated entities should be able to challenge the Administrator's determination that Option 5 provided the greater net benefits than other alternatives or that the court should be second-guessing whether the Administrator gave proper weight to the value of a child's IQ. There is no such standard in current law, we see no reason to provide litigants with a new basis for overturning good rules, and we oppose giving courts the ability to be the arbiters of fundamental value decisions such as the value of a child's IQ, the value of avoiding birth defects, or the value of seeing a clear Grand Canyon. But this is what might occur under S. 981.

There is another concern raised by the judicial review provisions of S. 981. It's what we've previously referred to as unintended consequences. The agencies may choose a less protective option in order to avoid the risks of a court fight. This could lead to regulations that will be unnecessarily weakened, resulting in potential dangers to the public.

Finally, one of the ironies of this bill is that it could actually discourage use of voluntary, incentive-based programs, despite the sponsors' clear intention to encourage these programs. One of the Committee witnesses, Karen Florini of the Environmental Defense Fund, testified that the cost-effectiveness or net benefits test, combined with judicial review, may actually discourage the use of information-based and incentive oriented approaches such as the very popular Right-to-Know laws. She testified: "It's typically difficult to predict just how, and to what extent, incentives will lead to a particular outcome because, by definition, compliance isn't mandatory. But if you can only generally describe the benefits, how can you do a 'net benefits' or 'cost-effectiveness' determination with enough specificity to withstand attacks by lawyers seeking to derail the rule."

Senator Lieberman offered an amendment at markup to make clear that this bill does not give rise to any new bases for overturning an agency's rule. The text of the amendment was identical to the judicial review provisions in S. 291, the regulatory reform bill reported unanimously by this Committee in the 104th Congress. Unfortunately, the amendment was rejected. The sponsors contend that their intent is to have limited judicial review. We, therefore, remain troubled and puzzled by their rejection of an amendment which would make that intent very clear.

3. Peer review

We urge our colleagues in the Senate to consult with scientists in their states about the peer review provisions in this bill. We

strongly support a process for ensuring that the agencies' approaches to risk assessment are vetted on a regular basis with those who are the best in their field and willing to devote the time to such a review. But we are concerned that this bill does not achieve such a goal and instead will result in new processes for peer review without any benefits. The reaction of many scientists we have heard from has been strongly negative. For example, in a March 3, 1998 letter to the sponsors, a group of scientists including representatives from all of our states, concluded that S. 981 "particularly the provisions governing participation on 'peer review' panels, takes a peculiar—and even damaging—approach to science."

The bill requires that the peer review panels that will pass judgment on the validity of risk assessments and cost-benefit analyses be independent of the agency. We are concerned that the requirement will simply duplicate or displace many well-established and well-respected processes already in place in agencies for peer review. We note that the Majority Report states that the "independence" requirement will not preclude use of established advisory committees, like EPA's Science Advisory Committee. But we are also concerned about the interaction of this peer review requirement with other established approaches that may not currently be called peer review, but serve to provide a similar type of review. For example, we heard testimony that under OSHA procedures, proposed standards must be presented in a public hearing. OSHA must present evidence supporting the proposed standard including the health risks, control measures, cost analyses and other details. Other participants such as scientific experts, unions, and employers also are allowed to testify in the OSHA process. Additionally, peer review of cost-benefit analysis would be very similar to review already undertaken by OMB's review of agency analyses.

The requirement that the peer review panel be independent of the agency could also mean that a scientist from a particular university would not be able to participate in the peer review if he or she were funded by another part of the agency for unrelated research or even if another scientist in another part of the university was funded by the agency. Additionally, the federal government has some of the best scientists in the world and there is no reason to exclude a scientist working in one office from serving on the peer review panel reviewing a risk assessment done by another office or agency. Director Raines pointed out that the independence requirement could mean that in some highly specialized areas, such as nuclear safety, good peer review would become virtually impossible.

On the other hand, the bill provides no assurance that a person with a direct financial interest in the outcome of the rulemaking or employed by an entity with a direct financial interest in the outcome of the rulemaking will not be allowed to serve on a peer review panel. This raises serious concerns about potential conflicts of interest.

The Majority Report indicates that decisions about conflicts of interest are best left to agencies. But during the September 12 hearing, Senator Lieberman discussed his concern about conflict of interest issues that previously had arisen with respect to EPA's internal peer review rules relating to pesticides.

Senator Cleland offered an amendment at markup designed to address some of these concerns. We were disappointed that the sponsors did not accept this amendment, but we are encouraged that they indicated a willingness to continue to work with Senator Cleland on these issues.

We are also concerned about the interaction of peer review and judicial review. We believe that peer review can play an important role in improving an agency's risk assessment prior to the notice of proposed rulemaking. But we do not believe that the peer reviewers' comment should be entitled to special deference by a court in determining whether an agency's actions are arbitrary or capricious. Why should the peer reviewers' comments with respect to a rule on food safety be given any more weight than the comments of a mother whose child died of E. Coli poisoning? Why should the peer reviewers' comments be entitled to any more weight with respect to a rule implementing the Americans With Disabilities Act than the comments of a handicapped person? We are concerned that the Majority Report is unclear about the relationship between peer review and judicial review, and may, whether intentional or not, accord special weight to the peer reviewers.

4. Risk assessment, review of past rules, needless burdens, key definitions, adequate resources

There are other significant concerns about this bill raised in Director Raines' letter (and in a similar manner in Senator Chafee's and Senator Baucus' letter) which we share, but will not repeat in detail here. Changes to address these areas are included in the amendment drafted by Senator Lieberman. They are aimed at ensuring that:

The red tape of reviewing rules does not prevent agencies from acting to protect public health. Director Raines' letter expresses concern that the provisions in the bill "creates two different, uncoordinated and likely duplicative processes for the review of past regulations, imposing a major burden on agencies and needless expense on taxpayers."

Risk assessment provisions do not impose burdensome requirements where those requirements do not enhance major rules, would result in endless and costly analytical processes, and are ill-suited to objectives such as airworthiness;

The risk assessment provisions of this bill apply not only to rules, but to any risk assessment that the Director of OMB determines may have a "significant impact on public policy or the economy." We fear this provision might be used to significantly delay important actions to protect public health and the environment, such as warnings with respect to food safety or unsafe beaches.

The Majority Report adds to our concerns by stating that OMB might require application of these provisions where a risk assessment "may establish the basis for a regulatory action at the Federal, State or International level." If this requires our health, safety and environmental agencies to demonstrate that their risk assessments may not at some date be the basis for a regulatory action somewhere in the world, the provisions of this bill might apply to hundreds of risk assessments each year and delay important health and safety actions.

Needless burdens on agencies are avoided where there would be no conceivable benefit to the public or regulated entities;

The definitions ensure clarity, discourage unwarranted litigation that would delay new safeguards, and eliminate unwarranted burdens on agencies. For example, the bill defines benefits to include nonquantifiable benefits. But the term net (as in “net benefits”) is not defined anywhere. Dictionaries define the adjective net in mathematical terms, such as the amount left over after deductions and allowances have been made. It is critical to make clear that the cost-benefit tests in the bill do not require a mathematical or numerical analysis.

We are also concerned that the bill and the Majority Report may skew the cost-benefit analysis in several ways, such as narrowing the range of benefits considered (which could result from the detailed instructions on how an agency should conduct a benefit analysis) but leaving the cost analysis too open. We fear this could lead to results which most of us would find wrong. For example, at the markup, Senator Durbin expressed his concern that some cost-benefit analyses of anti-smoking measures have defined “costs” to include society’s medical bills associated with elderly persons because people will live longer if they smoke less. In other words, under this analysis, it would be more expensive for people to live longer.

Second, the Majority Report fails to acknowledge many of the uncertainties associated with cost analyses. In a 1995 study, the Congressional Office of Technology Assessment reviewed seven major OSHA regulatory programs and found that in no case had regulated companies spent significantly more than OSHA had predicted—and in five to the seven they had spent less. The study found that industries often adopt advanced or innovative control measures which bring down costs significantly, but are not anticipated at the time of the rulemaking.

Finally, the Majority Report includes the concept of “opportunity costs” within the definition of costs. Without further guidance, this term could lead to very speculative costs estimates because it might involve forecasts into the future concerning how a project not in existence today would have worked out, but for government restrictions. Projections of opportunity costs could also lead to time-consuming and extensive government information-gathering and analyses about companies’ financial structures, which some might view as intrusive. Difficult confidentiality claims might also arise in the context of a public rulemaking, potentially resulting in litigation.

In addition, we are concerned with ensuring that agencies have adequate funding to carry out new burdens imposed on them and do not have to choose between these new burdens and protecting public health, safety, and the environment. Senator Durbin offered an amendment at markup that would have ensured the availability of adequate resources be established in conjunction with the new requirements, but it was rejected.

In conclusion, we do not question that the sponsors of S. 981 seek to improve the regulatory process through this bill. But we disagree that this result has been achieved in the Committee-reported version of this legislation.

JOSEPH LIEBERMAN.

DANIEL K. AKAKA.
DICK DURBIN.
ROBERT TORRICELLI.
MAX CLELAND.

EXECUTIVE OFFICE OF THE PRESIDENT,
OFFICE OF MANAGEMENT AND BUDGET,
Washington, DC, March 6, 1998.

Hon. FRED THOMPSON,
*Chairman, Committee on Governmental Affairs,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: I am writing to provide the Administration's views on S. 981, the Regulatory Improvement Act of 1998. The Administration commends the thoughtful effort by both you and Senator Levin to address numerous concerns raised by the Administration and by others about the bill as introduced.

The Administration believes strongly in responsible regulatory reform. President Clinton's issuance of Executive Order No. 12866 was predicated on his belief that government should do a better job of assessing risks and evaluating costs and benefits before issuing major rules. While we have been skeptical of the need for further comprehensive regulatory reform legislation at this time, we have sought to work with the Committee to ensure that any bill advances the President's regulatory reform principles without creating unwarranted costs to taxpayers or needless burdens on agencies acting to protect human health, safety, or the environment.

The substitute bill issued earlier this month contains significant improvements over last summer's draft. We very much appreciate this effort. While the substitute is responsive to many of our concerns, there are still serious issues remaining. One of the problems with comprehensive legislation is that so many different kinds of rulemaking are affected. We want to be sure that any new law meets a simple test: that it truly improves the regulatory system, and does not impair—by creating more litigation, more red tape, and more delay—the agencies' ability to do their jobs. We are interested in working with you to see if we can find the common ground.

After a full review of the substitute to S. 981, we have concluded that the bill does not yet meet the test we have articulated, and therefore the Administration would oppose the bill if it were to be adopted in its current form. Our concerns are briefly outlined below, and we have developed and enclosed for your consideration a set of modifications to the bill that would remedy these and other concerns while remaining faithful to the sponsors' intent. As you know from our past conversations, many of these are critical to achieving an acceptable result.

1. Judicial Review. The Administration remains concerned that the judicial review provisions would promote tactical litigation over errors that were not material to the outcome of a particular rulemaking. We know that this conflicts with the sponsors' intent, as reflected in earlier hearing discussions. To avoid additional litigation over major rules, the troubling ambiguity in the current version of the bill should be eliminated.

2. Implicit Supermandate. We have been pleased that the sponsors of S. 981 consistently have agreed with the view that regu-

latory reform legislation should not alter or modify the substantive reach of particular statutes designed to protect human health, safety, or the environment. We remain concerned that the current language of the bill would be construed to narrow the range of discretion available to agencies under their existing statutory mandates to protect human health, safety, or the environment. The range of discretion available to agencies under current law must be expressly preserved to avoid an implicit supermandate.

3. Risk Assessment. The Administration believes that, while there have been improvements in Section 624, this section needs to be revised still further to eliminate the imposition of burdensome requirements where those requirements will not enhance major rules. For example, section 624 includes in its sweep an unbounded category of agency actions that are not rulemakings, as well as major rules where Congress has not predicated regulatory standards on risk assessment. These should be excluded. In addition, the requirement for revision of risk assessments threatens an endless and costly analytical process, reopened with each new study, that would provide additional fodder for protracted litigation. We also remain concerned that certain provisions are too specifically tailored to analysis of cancer risks, and are thus ill-suited to other objectives, such as an evaluation of risks related to environmental and natural resource protection, worker safety, or airworthiness.

4. Peer Review. The Administration is very concerned about requiring peer review in contexts where the process would add significantly to costs and delays of the regulatory process without any foreseeable benefit. For example, the requirement that cost-benefit analyses be subject to peer review would add little to the review already performed by the Office of Management and Budget in our regulatory review process. In addition, the requirement that peer review be entirely independent of the regulating agency would displace well-established and credible peer review mechanisms, while making good peer review virtually impossible in highly specialized subject areas (e.g. nuclear safety). We also believe that the statute should require no more than one round of peer review for each major rule.

5. Review of Past Regulations. While the Committee responded to many of the Administration's earlier concerns about review of past regulations, the current version of the bill creates two different, uncoordinated and likely duplicative processes for the review of past regulations, imposing a major burden on agencies and needless expense on taxpayers. The second of these should be deleted, and the cycle of review in the first should be set at 10 years.

6. Needless Burdens. A number of the bill's requirements would impose substantial costs on agencies where there would be no conceivable benefit to the public or regulated entities. For example, the bill imposes its analytical requirements and review requirements even where the costs of compliance with the regulation have been incurred by the regulated community and no costs can be avoided by selecting a different regulatory option. Our proposed changes address other examples as well.

7. Definitions and other issues. There are several definitions and other provisions that need to be added or modified to ensure clarity, to discourage unwarranted litigation that would delay new

safeguards, to protect the constitutional prerogatives of the President and the deliberative process within the Executive Branch, and to eliminate unwarranted burdens on agencies. While many of these changes appear minor, it would be difficult to overstate their importance to us in evaluating the cumulative effect of this bill.

In developing revisions to the bill that would address our concerns, we have sought to suggest changes that are consistent with our understanding of the sponsors' intent and with the spirit of our very constructive discussions with the Committee staff. We would welcome a further opportunity to work with you before the bill is reported by the Committee.

Sincerely,

FRANKLIN D. RAINES, *Director*.

Enclosure.

PROPOSED REVISIONS TO THE SUBSTITUTE S. 981

1. Judicial review

a. Delete section 627(d) and substitute the Glenn-Chafee review language (modification in italic):

“(d) In any proceeding involving judicial review under Section 706 or under the statute granting the rulemaking authority, the information contained in any cost-benefit analysis or risk assessment required under [sections 623, 624, . . .] may be considered by the court as part of the administrative record as a whole solely for the purpose of determining *under the statute granting rulemaking authority* whether the final agency action is arbitrary, capricious, or an abuse of discretion or unsupported by substantial evidence where that standard is otherwise provided by law. The adequacy of compliance or the failure to comply with [sections 623, 624, * * *] shall not be grounds for remanding or invalidating a final agency action, unless the agency entirely failed to perform a required cost-benefit analysis or risk assessment.”

b. In 627(e), change “shall” to “may,” delete reference to peer review, and add prejudicial error language (to ensure that only errors material to the regulatory outcome are a basis for remand).

c. Provide that judicial review is not applicable to Subchapter III other than under section 706(1) of the APA.

d. Clarify that section 627(b) is not subject to an interlocutory order.

2. Implicit supermandate

a. Delete section 622(b) and replace as follows: “Nothing in this subchapter shall be construed to alter or modify the substantive standards otherwise applicable to a rulemaking under other statutes, or to limit the range of discretion available under, or in construing, other statutes.”

3. Risk assessment

a. Delete section 624(a)(1)(A)(ii), which broadens the applicability of the risk assessment provisions beyond rulemaking.

b. Delete section 624(c)(2) to prevent unending cycle of revision, or clarify that new studies must only be considered if they are rea-

sonably available before the agency prepares the initial risk assessment.

c. Delete the requirement in section 624(d) requiring public notice of intent to perform a risk assessment.

d. Exclude from the coverage of section 624 those major rules that are not premised on the outcome of a risk assessment (e.g. MACT, BACT).

4. Peer review

a. Delete cost-benefit analysis from the coverage of requirements for peer review (section 625).

b. Modify section 625(b)(1)(A)(ii), so that peer review participants are independent of the "program office," rather than independent of the "agency."

c. Clarify that only one round of peer review is required, and that it should be performed at the NPRM stage.

5. Other

a. Narrow definitions, procedures and disclosure provisions to protect the constitutional prerogatives of the President and the deliberative process.

Delete section 641;

In section 642(a) after "Such process shall be * * *" add "determined by the President and shall be * * *"

In section 643(a) after "subchapter" add "as determined by the President." Delete 643(a)(1) through 643(c).

b. Regarding "look back" reviews, delete section 644(b) (amending section 610 of title V), which duplicates the review of rules section, and delete other references to section 610 in the bill. In section 632(a)(1), change "5th" to "10th." In section 631(1), incorporate the definitions in 621 by reference (to capture rule exclusions) and limit to major rules.

c. Modify post-promulgation analysis requirements (section 623(f)(2)) by striking everything after "* * * unreasonable."

d. Delete section 628(c)(2) requiring OMB and OSTP to contract for research studies.

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC, March 6, 1998.

Hon. FRED THOMPSON,
Chairman, Committee on Governmental Affairs,
U.S. Senate, Washington, DC 20510.

DEAR SENATOR THOMPSON: As Chairman and Ranking Member of the Environment and Public Works Committee, we are writing regarding the Regulatory Improvement Act of 1998, S. 981.

We are confident that, in your hands, regulatory reform is not a disguised effort to roll back environmental laws, but instead a sincere effort to make regulations, including environmental regulations, more effective. We share that goal.

At the same time, we generally believe that such reforms are best accomplished within the framework of a specific regulatory statute, rather than in an across-the-board omnibus bill. Our Committee recently has developed legislation to reauthorize the Safe

Drinking Water Act and the Endangered Species Act. In each case, we considered how risk assessment, requirements for sound scientific analysis, and cost-benefit analysis could make the law more effective. And in each case, we reached different conclusions. For example, in the case of the Safe Drinking Water Act, we provided for cost-benefit analysis up front, during the process of selecting maximum contaminant levels. In the case of the Endangered Species Act, we limit the use of cost-benefit analysis to the recovery planning process. In each case, the decision was based on a careful consideration of the overall objectives and operation of the law. We are concerned that an omnibus approach, which makes changes across a wide range of statutes, may have serious unintended consequences. For this reason, we are particularly concerned about the potential impact of S. 981 on environmental laws.

More specifically, we have six main concerns about the provisions of the substitute amendment version of S. 981, described below.

Decisional criteria

Section 623(d) of S. 981 requires an agency to determine whether a major rule is likely to produce benefits that justify the costs. This standard, which is similar to the standard that was used in the new Safe Drinking Water Act, should improve decision making. However, section 623(d) also requires an agency to determine whether the rule is likely to achieve the rule making objective “in a more cost-effective manner, or with greater net benefits,” than other reasonable alternatives.

We are concerned that this second set of tests could distort decision making, for two reasons.

First, a cost-effectiveness test may be biased against more protective rules. In environmental regulation, marginal costs often rise as protectiveness rises. As a result, a more protective regulation often is not as cost-effective as a less protective one. For example, assume that one alternative environmental standard costs \$500 million and saves one thousand lives (\$500,000/life saved); a second costs \$1.5 billion and saves two thousand lives (\$750,000 per life saved). The first would be considered more cost effective, even though the second may, as a matter of public health policy, be preferable, because it saves many more lives at a reasonable and justified cost.

Second, the use of the “greater net benefits” standard may be biased against regulations, like many environmental regulations, that provide substantial non-quantifiable benefits. Although S. 981’s definition of benefit includes nonquantifiable benefits, we are concerned that it will be difficult or impossible to take nonquantifiable benefits into account as part of a “netting” calculation that seems inherently focused on quantification.

We appreciate that section 623(d)(2) allows an agency to override the preference for the alternative that is most cost effective or provides greater net benefits, as long as the agency provides an explanation. However, we believe that the preference itself will give agencies an incentive to select alternatives that, in some cases, short-change protection of human health and the environment. Therefore, we recommend that section 623 be modified to either delete the second set of tests or, at least, define cost-effectiveness

(i.e., as the least costly means of achieving a certain level of benefits).

Savings clause

As you know, we have long been concerned that regulatory reform legislation could modify the existing statutory standards of environmental laws—in some cases simply producing confusion, in other cases seriously weakening existing standards. We understand that this is not your intention. However, we remain concerned about the absence of a strong savings clause along the lines of the 1995 Glenn-Chafee amendment, which provided that “nothing in this Act shall be construed to modify any statutory standard or requirement designed to protect human health, safety, or the environment.”

Judicial review

One of our fundamental concerns about omnibus regulatory reform legislation has been concern that the legislation not create a host of new issues for litigation. This can have two harmful consequences. First, it can shift important policy decisions inappropriately to the courts (for example, determining the value of a human life or cleaner lakes and rivers for purposes of cost-benefit analysis). Second, it can create new opportunities to delay the implementation of regulations necessary to protect human health and the environment.

We appreciate that the judicial review provisions of S. 981 are significant improvements over those of previous regulatory reform bills. But we believe the best approach is to preclude judicial review of the application of the new decisional criteria and procedural requirements. Alternatively, we recommend an approach that more clearly limits the scope of judicial review, along the lines of the 1995 Glenn-Chafee Amendment.

Peer review

We believe that peer review can improve the scientific information used in developing rules. But we are concerned about the peer review provisions of S. 981, for two reasons. First, the requirements that peer reviewers be “independent of the agency” is too broad, and could exclude any scientists who have ever been funded by that agency, even for research on subjects unrelated to the rule. It could also exclude scientists who serve on agencies’ own science advisory boards. On the other hand, it does not exclude any entity who may simply oppose the rule because it will bear substantial compliance costs. This is of particular concern under this bill, which would apply peer review not only to risk assessments, but also to the cost-benefit analysis, which can often be highly debatable. We recommend that the bill exclude from peer review those “with significant involvement or interest in the outcome of the rule.”

Second, we are concerned with the new procedural requirements of peer review, particularly in light of the fact that the agency’s compliance with these provisions may be subject to judicial review. We acknowledge that an agency’s failure to perform peer review should be reviewable by the court. However, the bill contains spe-

cific requirements that should not be subject to review, such as the requirement that agencies certify the expertise and independence of reviewers, and that they certify the adequacy of their own response to peer review comments. Accordingly, we recommend that it be made explicitly clear that judicial review of compliance with peer review requirements applies only to whether or not peer review is performed. Further, we recommend that the agency certification requirements with regard to peer review be deleted.

Other priorities

We are concerned that the bill emphasizes the economic impacts of rules, without also emphasizing other important national priorities. For example, in the types of alternatives agencies must consider in regulatory analysis, the bill specifically lists the “no action” or “voluntary compliance” alternatives, but does not list alternatives that emphasize protection of children or sensitive subpopulations. To the extent that the bill mandates the consideration of specific regulatory options, these priorities should be reflected in the list in § 623(b)(2). Similarly, there is consideration of costs and benefits that accrue to people, without similar consideration of cost and benefits that accrue to the environment, including natural resources. We recommend that the relevant provisions of the bill be amended to correct this.

Cost and delay

Finally, we are concerned that the various new requirements of the bill, taken cumulatively, will make the regulatory process more costly, and delay the implementation of regulations important to public health and safety. We know that you are sensitive to this point, and we recommend that the bill be amended to further streamline the provisions regarding risk assessment, peer review, and the “lookback” process.

Thank you for considering our concerns. We look forward to working with you to address them.

Sincerely,

MAX BAUCUS.
JOHN H. CHAFEE.

MINORITY VIEWS OF SENATOR AKAKA

As a supporter of the Glenn/Roth and Glenn/Chafee regulatory reform bills offered in the 104th Congress, I do not object to reforming the regulatory process. Given the unanimous support the latter received during this Committee's markup on March 23, 1995, it is evident that there is bipartisan support for effective and responsible regulatory reform that balances the need to protect the environment and public health and safety.

However, I felt that despite the good intentions of the authors of S. 981, the Regulatory Improvement Act of 1998, there could be unintended harmful consequences from such a comprehensive approach and, therefore, voted against the bill during markup on March 10, 1998. S. 981, as reported out of Committee, would require any agency proposing a regulation to conduct a peer-reviewed, cost-benefit analysis and risk assessment if the rule would have an impact on the economy of \$100 million or more per year. In addition, the Director of the Office of Management and Budget could also designate a proposed rule a "major rule," thus requiring an agency to follow the provisions of S. 981.

During markup of this measure, amendments were offered by Democratic members that would have addressed some of the concerns that I have with the bill—concerns that I believe could weaken environmental, consumer, and public health protections that Americans now enjoy. I have also associated myself with the views expressed by Senators Lieberman, Durbin, Torricelli, and Cleland relating to our specific concerns with S. 981 as detailed in our dissenting minority views. I wish to note that Senator Cleland voted against S. 981 in Committee for reasons that parallel my views as stated above.

Given my past support of regulatory reform legislation, the decision to support or not support this measure was difficult. However, knowing that both Senator John Chafee and Senator Max Baucus, the chair and ranking Democrat, respectively, of the Senate Committee on Environment and Public Works, expressed serious reservations with S. 981 prior to the Committee's markup helped tip the balance. Added to the objections of my well-respected colleagues, who oversee the Senate Committee that is charged with protection of the environment, were the concerns of my constituents who opposed various provisions in the bill. Unfortunately, the rejection of a broad-range of amendments during the Committee's markup failed to address my concerns.

Just prior to the markup, the Administration provided a draft substitute bill. Obviously, it was too late to consider this substitute, but I am hopeful that the sponsors of S. 981 will continue to work with the Administration and others to craft an acceptable bill. The Clinton Administration has been serious in its efforts to initiate actions to improve the federal regulatory process, including Executive

Order No. 12866. I am hopeful that the supporters of S. 981 will review the Administration substitute proposal presented by Senator Lieberman at the markup.

DANIEL K. AKAKA.

X. CHANGES IN EXISTING LAW

In compliance with paragraph 12 of rule XXVI of the Standing Rules of the Senate, changes in existing law made by S. 981 as reported are shown as follows (existing law proposed to be omitted is enclosed in brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

UNITED STATES CODE

**TITLE 5—GOVERNMENT ORGANIZATION
AND EMPLOYEES**

PART I—THE AGENCIES GENERALLY

Chapter	Sec.
1. Organization	101
* * * * *	
7. Judicial Review	701
8. Congressional Review of Agency Rulemaking	801
9. Executive Reorganization	901

**[CHAPTER 6—THE ANALYSIS OF REGULATORY
FUNCTIONS**

- [Sec.
- [601. Definitions.
- [602. Regulatory agenda.
- [603. Initial regulatory flexibility analysis.
- [604. Final regulatory flexibility analysis.
- [605. Avoidance of duplicative or unnecessary analyses.
- [606. Effect on other law.
- [607. Preparation of analyses.
- [608. Procedure for waiver or delay of completion.
- [609. Procedures for gathering comments.
- [610. Periodic review of rules.
- [611. Judicial review.
- [612. Reports and intervention rights.]

**CHAPTER 6—THE ANALYSIS OF REGULATORY
FUNCTIONS**

Subchapter I—Analysis of Regulatory Flexibility

- Sec.
- 601. *Definitions.*
- 602. *Regulatory agenda.*
- 603. *Initial regulatory flexibility analysis.*
- 604. *Final regulatory flexibility analysis.*
- 605. *Avoidance of duplicative or unnecessary analyses.*
- 606. *Effect on other law.*
- 607. *Preparation of analysis.*
- 608. *Procedure for waiver or delay of completion.*

- 609. *Procedures for gathering comments.*
- 610. *Periodic review of rules.*
- 611. *Judicial review.*
- 612. *Reports and intervention rights.*

Subchapter II—Regulatory Analysis

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SUBCHAPTER I—REGULATORY ANALYSIS

§ 601. Definitions

For purposes of this chapter—

* * * * *

§ 610. Periodic review of rules

[(a) Within one hundred and eighty days after the effective date of this chapter, each agency shall publish in the Federal Register a plan for the periodic review of the rules issued by the agency which have or will have significant economic impact upon a substantial number of small entities. Such plan may be amended by the agency at any time by publishing the revision in the Federal Register. The purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of such small entities. The plan shall provide for the review of such rules adopted after the effective date of this chapter within ten years of the publication of such rules as the final rule. If the head of the agency determines that completion of the review of existing rules is not feasible by the established date, he shall so certify in a statement published in the Federal Register and may extend the completion date by one year at a time for a total of not more than five years.]

(a)(1)(A) No later than 60 days after the effective date of this section (and every fifth year following the year in which this section takes effect) each agency shall submit to the Administrator of the Office of Information and Regulatory Affairs and the Chief Counsel for Advocacy of the Small Business Administration a proposed plan describing the procedures and timetables for the periodic review of rules issued by the agency that have or will have a significant eco-

conomic impact on a substantial number of small entities. No later than 60 days after the submission of the proposed plan to the Administrator and the Chief Counsel, such plan shall be published in the Federal Register and shall be subject to public comment for 60 days after the date of publication.

(B) No later than 120 days after the publication of the plan under subparagraph (A), each agency shall submit a final plan to the Administrator and the Chief Counsel. No later than 60 days after the date of such submission of the plan to the Administrator and Chief Counsel, each agency shall publish the agency's final plan in the Federal Register.

(C) Each agency's plan shall provide for the review of such rules no later than 5 years after publication of the final plan.

(2)(A) Each year, each agency shall publish in the Federal Register a list of rules that will be reviewed under the plan during the succeeding fiscal year.

(B) The publication of the list under subparagraph (A) shall include—

- (i) a brief description of each rule and the basis for the agency's determination that the rule has or will have a significant economic impact on a substantial number of small entities;
- (ii) the need for and legal basis of each rule; and
- (iii) an invitation for public comment on each rule.

(3)(A) Each agency shall conduct a review of each rule on the list published under paragraph (2) in accordance with the plan maintained under paragraph (1) and pursuant to the factors under subsection (b). After the completion of the review, the agency shall determine whether the rule should be continued without change, or should be amended or rescinded, consistent with the stated objectives of the applicable statutes, to minimize any significant economic impact of the rule upon a substantial number of small entities.

(B) No later than 18 months after the date of the publication of the list of rules referred to under paragraph (2)(A), each agency shall publish in the Federal Register the determinations made with respect to such rules under subparagraph (A) and an explanation for each determination.

(4) If the head of an agency determines that the completion of a review of a rule under this subsection is not feasible within the period described under paragraph (1)(C), the head of the agency

(A) shall certify such determination in a statement published in the Federal Register; and

(B) may extend the completion date of the review by 1 year at a time for a total of not more than 2 years.

(b) In reviewing rules to minimize any significant economic impact of the rule on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the agency shall consider the following factors—

- (1) the continued need for the rule;
- (2) the nature of complaints or comments received concerning the rule from the public;
- (3) the complexity of the rule;
- (4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

[(c) Each year, each agency shall publish in the Federal Register a list of the rules which have significant economic impact on a substantial number of small entities, which are to be reviewed pursuant to this section during the succeeding twelve months. The list shall include a brief description of each rule and the need for and legal basis of such rule and shall invite public comment upon the rule.]

(c) *The Administrator and the Chief Counsel shall work with small entities to achieve the objectives of this section.*

* * * * *

SUBCHAPTER II—REGULATORY ANALYSIS

§ 621. Definitions

For purposes of this subchapter the definitions under section 551 shall apply and—

(1) *the term “Administrator” means the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget;*

(2) *the term “benefit” means the reasonably identifiable significant favorable effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;*

(3) *the term “cost” means the reasonably identifiable significant adverse effects, quantifiable and nonquantifiable, including social, health, safety, environmental, economic, and distributional effects, that are expected to result from implementation of, or compliance with, a rule;*

(4) *the term “cost-benefit analysis” means an evaluation of the costs and benefits of a rule, quantified to the extent feasible and appropriate and otherwise qualitatively described, that is prepared in accordance with the requirements of this subchapter at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into consideration uncertainties, the significance and complexity of the decision, and the need to adequately inform the public;*

(5) *the term “Director” means the Director of the Office of Management and Budget, acting through the Administrator of the Office of Information and Regulatory Affairs;*

(6) *the term “flexible regulatory options” means regulatory options that permit flexibility to regulated persons in achieving the objective of the statute as addressed by the rule making, including regulatory options that use market-based mechanisms, outcome oriented performance-based standards, or other options that promote flexibility;*

(7) *the term “major rule” means a rule that—*

(A) *the agency proposing the rule or the Director reasonably determines is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs; or*

(B) is otherwise designated a major rule by the Director on the ground that the rule is likely to adversely affect, in a material way, the economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities;

(8) the term “reasonable alternative” means a reasonable regulatory option that would achieve the objective of the statute as addressed by the rule making and that the agency has authority to adopt under the statute granting rule making authority, including flexible regulatory options;

(9) the term “risk assessment” means the systematic, objective process of organizing hazard and exposure information, based on a careful analysis of the weight of the scientific evidence, to estimate the potential for specific harm to an exposed population, subpopulation, or natural resource including, to the extent feasible, a characterization of the distribution of risk as well as an analysis of uncertainties, variabilities, conflicting information, and inferences and assumptions;

(10) the term “rule” has the same meaning as in section 551(4), and shall not include—

(A) a rule exempt from notice and public comment procedure under section 553;

(B) a rule that involves the internal revenue laws of the United States, or the assessment or collection of taxes, duties, or other debts, revenue, or receipts;

(C) a rule of particular applicability that approves or prescribes for the future rates, wages, prices, services, corporate or financial structures, reorganizations, mergers, acquisitions, accounting practices, or disclosures bearing on any of the foregoing;

(D) a rule relating to monetary policy proposed or promulgated by the Board of Governors of the Federal Reserve System or by the Federal Open Market Committee;

(E) a rule relating to the operations, safety, or soundness of federally insured depository institutions or any affiliate of such an institution (as defined in section 2(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1841(k)); credit unions; the Federal Home Loan Banks; government-sponsored housing enterprises; a Farm Credit System Institution; foreign banks, and their branches, agencies, commercial lending companies or representative offices that operate in the United States and any affiliate of such foreign banks (as those terms are defined in the International Banking Act of 1978 (12 U.S.C. 3101)); or a rule relating to the payments system or the protection of deposit insurance funds or Farm Credit Insurance Fund;

(F) a rule relating to the integrity of the securities or commodities futures markets or to the protection of investors in those markets;

(G) a rule issued by the Federal Election Commission or a rule issued by the Federal Communications Commission under sections 312(a)(7) and 315 of the Communications Act of 1934 (47 U.S.C. 312(a)(7) and 315); FY 19(H) a rule

required to be promulgated at least annually pursuant to statute;

(I) a rule or agency action relating to the public debt or fiscal policy of the United States; or

(J) a rule or agency action that authorizes the introduction into commerce, or recognizes the marketable status of, a product; and

(11) the term “substitution risk” means a significant increased risk to health, safety, or the environment reasonably likely to result from a regulatory option.

§ 622. Applicability and effect

(a) Except as provided in section 623(f), this subchapter shall apply to all proposed and final major rules.

(b) Nothing in this subchapter shall be construed to alter or modify the substantive standards otherwise applicable to a rule making under other statutes or opportunity for judicial review made applicable under any other Federal statute.

§ 623. Regulatory analysis

(a)(1) Before publishing a notice of a proposed rule making for any rule, each agency shall determine whether the rule is or is not a major rule covered by this subchapter.

(2) The Director may designate any rule to be a major rule under section 621(7)(B), if the Director—

(A) makes such designation no later than 30 days after the close of the comment period for the rule; and

(B) publishes such designation in the Federal Register, together with a succinct statement of the basis for the designation, within 30 days after such designation.

(b)(1)(A) When an agency publishes a notice of proposed rule making for a major rule, the agency shall prepare and place in the rule making file an initial regulatory analysis, and shall include a summary of such analysis consistent with subsection (e) in the notice of proposed rule making. (B)(i) When the Director has published a designation that a rule is a major rule after the publication of the notice of proposed rule making for the rule, the agency shall promptly prepare and place in the rule making file an initial regulatory analysis for the rule and shall publish in the Federal Register a summary of such analysis consistent with subsection (e).

(ii) Following the issuance of an initial regulatory analysis under clause (i), the agency shall give interested persons an opportunity to comment under section 553 in the same manner as if the initial regulatory analysis had been issued with the notice of proposed rule making.

(2) Each initial regulatory analysis shall contain—

(A) a cost-benefit analysis of the proposed rule that shall contain—

(i) an analysis of the benefits of the proposed rule, including any benefits that cannot be quantified, and an explanation of how the agency anticipates that such benefits will be achieved by the proposed rule, including a description of the persons or classes of persons likely to receive such benefits;

(ii) an analysis of the costs of the proposed rule, including any costs that cannot be quantified, and an explanation of how the agency anticipates that such costs will result from the proposed rule, including a description of the persons or classes of persons likely to bear such costs;

(iii) an evaluation of the relationship of the benefits of the proposed rule to its costs, including the determinations required under subsection (d), taking into account the results of any risk assessment;

(iv) an evaluation of the benefits and costs of a reasonable number of reasonable alternatives reflecting the range of regulatory options that would achieve the objective of the statute as addressed by the rule making, including, where feasible, alternatives that—

(I) require no government action or utilize voluntary programs;

(II) provide flexibility for small entities under subchapter I and for State, local, or tribal government agencies delegated to administer a Federal program;

(III) employ flexible regulatory options; and

(IV) assure protection of sensitive subpopulations, or populations exposed to multiple and cumulative risks; and

(v) a description of the scientific or economic evaluations or information upon which the agency substantially relied in the cost-benefit analysis and risk assessment required under this subchapter, and an explanation of how the agency reached the determinations under subsection (d);

(B) if required, the risk assessment in accordance with section 624; and

(C) when scientific information on substitution risks to health, safety, or the environment is reasonably available to the agency, an identification and evaluation of such risks.

(c)(1) When the agency publishes a final major rule, the agency shall prepare and place in the rule making file a final regulatory analysis.

(2) Each final regulatory analysis shall address each of the requirements for the initial regulatory analysis under subsection (b)(2), revised to reflect—

(A) any material changes made to the proposed rule by the agency after publication of the notice of proposed rule making;

(B) any material changes made to the cost-benefit analysis or risk assessment; and

(C) agency consideration of significant comments received regarding the proposed rule and the initial regulatory analysis, including regulatory review communications under subchapter IV.

(d)(1) The agency shall include in the statement of basis and purpose for a proposed or final major rule a reasonable determination, based upon the rule making record considered as a whole—

(A) whether the rule is likely to provide benefits that justify the costs of the rule;

(B) whether the rule is likely to substantially achieve the rule making objective in a more cost-effective manner, or with great-

er net benefits, than the other reasonable alternatives considered by the agency; and

(C) whether the rule adopts a flexible regulatory option.

(2) If the agency head determines that the rule is not likely to provide benefits that justify the costs of the rule or is not likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the other reasonable alternatives considered by the agency, the agency head shall—

(A) explain the reasons for selecting the rule notwithstanding such determination, including identifying any statutory provision that required the agency to select such rule;

(B) describe any reasonable alternative considered by the agency that would be likely to provide benefits that justify the costs of the rule and be likely to substantially achieve the rule making objective in a more cost-effective manner, or with greater net benefits, than the alternative selected by the agency; and

(C) describe any flexible regulatory option considered by the agency and explain why that option was not adopted by the agency if that option was not adopted.

(e) Each agency shall include an executive summary of the regulatory analysis, including any risk assessment, in the regulatory analysis and in the statement of basis and purpose for the proposed and final major rule. Such executive summary shall include a succinct presentation of—

(1) the benefits and costs expected to result from the rule and any determinations required under subsection (d);

(2) if applicable, the risk addressed by the rule and the results of any risk assessment;

(3) the benefits and costs of reasonable alternatives considered by the agency; and

(4) the key assumptions and scientific or economic information upon which the agency relied.

(f)(1) A major rule may be adopted without prior compliance with this subchapter if—

(A) the agency for good cause finds that conducting the regulatory analysis under this subchapter before the rule becomes effective is impracticable or contrary to an important public interest; and

(B) the agency publishes the rule in the Federal Register with such finding and a succinct explanation of the reasons for the finding.

(2) If a major rule is adopted under paragraph (1), the agency shall comply with this subchapter as promptly as possible unless compliance would be unreasonable because the rule is, or soon will be, no longer in effect.

(g) Each agency shall develop an effective process to permit elected officers of State, local, and tribal governments (or their designated employees with authority to act on their behalf) to provide meaningful and timely input in the development of regulatory proposals that contain significant Federal intergovernmental mandates. The process developed under this subsection shall be consistent with section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1534).

§ 624. Principles for risk assessments

(a)(1)(A) Subject to paragraph (2), each agency shall design and conduct risk assessments in accordance with this subchapter for—

(i) each proposed and final major rule the primary purpose of which is to address health, safety, or environmental risk; or

(ii) any risk assessment that is not the basis of a rule making that the Director reasonably determines is anticipated to have a substantial impact on a significant public policy or on the economy.

(B)(i) Risk assessments conducted under this subchapter shall be conducted in a manner that promotes rational and informed risk management decisions and informed public input into and understanding of the process of making agency decisions.

(ii) The scope and level of analysis of such a risk assessment shall be commensurate with the significance and complexity of the decision and the need to adequately inform the public, consistent with any need for expedition, and designed for the nature of the risk being assessed.

(2) If a risk assessment under this subchapter is otherwise required by this section, but the agency determines that—

(A) a final rule subject to this subchapter is substantially similar to the proposed rule with respect to the risk being addressed;

(B) a risk assessment for the proposed rule has been carried out in a manner consistent with this subchapter; and

(C) a new risk assessment for the final rule is not required in order to respond to comments received during the period for comment on the proposed rule, the agency may publish such determination along with the final rule in lieu of preparing a new risk assessment for the final rule.

(b) Each agency shall consider in each risk assessment all relevant, reliable, and reasonably available scientific information and shall describe the basis for selecting such scientific information.

(c)(1) When a risk assessment involves a choice of assumptions, the agency shall, with respect to significant assumptions—

(A) identify the assumption and its scientific and policy basis, including the extent to which the assumption has been validated by, or conflicts with, empirical data;

(B) explain the basis for any choices among assumptions and, where applicable, the basis for combining multiple assumptions; and

(C) describe reasonable alternative assumptions that—

(i) would have had a significant effect on the results of the risk assessment; and

(ii) were considered but not selected by the agency for use in the risk assessment.

(2) As relevant and reliable scientific information becomes reasonably available, each agency shall revise its significant assumptions to incorporate such information.

(d) The agency shall notify the public of the agency's intent to conduct a risk assessment and, to the extent practicable, shall solicit relevant and reliable data from the public. The agency shall consider such data in conducting the risk assessment.

(e) *Each risk assessment under this subchapter shall include, as appropriate, each of the following:*

(1) *A description of the hazard of concern.*

(2) *A description of the populations or natural resources that are the subject of the risk assessment.*

(3) *An explanation of the exposure scenarios used in the risk assessment, including an estimate of the corresponding population or natural resource at risk and the likelihood of such exposure scenarios.*

(4) *A description of the nature and severity of the harm that could reasonably occur as a result of exposure to the hazard.*

(5) *A description of the major uncertainties in each component of the risk assessment and their influence on the results of the assessment.*

(f) *To the extent scientifically appropriate, each agency shall—*

(1) *express the estimate of risk as 1 or more reasonable ranges and, if feasible, probability distributions that reflects variabilities, uncertainties, and lack of data in the analysis;*

(2) *provide the ranges and distributions of risks, including central and high end estimates of the risks, and their corresponding exposure scenarios for the potentially exposed population and, as appropriate, for more highly exposed or sensitive subpopulations; and*

(3) *describe the qualitative factors influencing the ranges, distributions, and likelihood of possible risks.*

(g) *When scientific information that permits relevant comparisons of risk is reasonably available, each agency shall use the information to place the nature and magnitude of a risk to health, safety, or the environment being analyzed in relationship to other reasonably comparable risks familiar to and routinely encountered by the general public. Such comparisons should consider relevant distinctions among risks, such as the voluntary or involuntary nature of risks, well understood or newly discovered risks, and reversible or irreversible risks.*

§625. Peer review

(a) *Each agency shall provide for an independent peer review in accordance with this section of the cost-benefit analysis and risk assessment required by this subchapter.*

(b)(1) *Peer review required under subsection (a) shall—*

(A) *be conducted through panels, expert bodies, or other formal or informal devices that are broadly representative and involve participants—*

(i) *with expertise relevant to the sciences, or analyses involved in the regulatory decisions; and*

(ii) *who are independent of the agency;*

(B) *be governed by agency standards and practices governing conflicts of interest of nongovernmental agency advisors;*

(C) *provide for the timely completion of the peer review including meeting agency deadlines;*

(D) *contain a balanced presentation of all considerations, including minority reports and an agency response to all significant peer review comments; and*

(E) provide adequate protections for confidential business information and trade secrets, including requiring panel members or participants to enter into confidentiality agreements.

(2) Each agency shall provide a written response to all significant peer review comments. All peer review comments and any responses shall be made—

(A) available to the public; and

(B) part of the rule making record for purposes of judicial review of any final agency action.

(3) If the head of an agency, with the concurrence of the Director, publishes a determination in the rule making file that a cost-benefit analysis or risk assessment, or any component thereof, has been previously subjected to adequate peer review, no further peer review shall be required under this section for such analysis, assessment, or component.

(c) For each peer review conducted by an agency under this section, the agency head shall include in the rule making record a statement by a Federal officer or employee who is not an employee of the agency rule making office or program—

(1) whether the peer review participants reflect the independence and expertise required under subsection (b)(1)(A); and

(2) whether the agency has adequately responded to the peer review comments as required under subsection (b)(2).

(d) The peer review required by this section shall not be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

§ 626. Deadlines for rule making

(a) All statutory deadlines that require an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section shall be suspended until the earlier of—

(1) the date on which the requirements of this subchapter are satisfied; or

(2) the date occurring 6 months after the date of the applicable deadline.

(b) In any proceeding involving a deadline imposed by a court of the United States that requires an agency to propose or promulgate any major rule during the 2-year period beginning on the effective date of this section, the United States shall request, and the court may grant, an extension of such deadline until the earlier of—

(1) the date on which the requirements of this subchapter are satisfied; or

(2) the date occurring 6 months after the date of the applicable deadline.

(c) In any case in which the failure to promulgate a major rule by a deadline occurring during the 2-year period beginning on the effective date of this section would create an obligation to regulate through individual adjudications, the deadline shall be suspended until the earlier of—

(1) the date on which the requirements of this subchapter are satisfied; or

(2) the date occurring 6 months after the date of the applicable deadline.

§ 627. Judicial review

(a) *Compliance by an agency with the provisions of this subchapter shall be subject to judicial review only—*

(1) in connection with review of final agency action;

(2) in accordance with this section; and

(3) in accordance with the limitations on timing, venue, and scope of review imposed by the statute authorizing judicial review.

(b) Any determination of an agency whether a rule is a major rule under section 621(7)(A) shall be set aside by a reviewing court only upon a showing that the determination is arbitrary or capricious.

(c) Any designation by the Director that a rule is a major rule under section 621(7), or any failure to make such designation, shall not be subject to judicial review.

(d) The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment required under this subchapter shall not be subject to judicial review separate from review of the final rule to which such analysis or assessment applies. The cost-benefit analysis, cost-benefit determination under section 623(d), and any risk assessment shall be part of the rule making record and shall be considered by a court to the extent relevant, only in determining whether the final rule is arbitrary, capricious, an abuse of discretion, or is unsupported by substantial evidence where that standard is otherwise provided by law.

(e) If an agency fails to perform the cost-benefit analysis, cost-benefit determination, or risk assessment, or to provide for peer review, a court shall remand or invalidate the rule.

§ 628. Guidelines, interagency coordination, and research

(a)(1) No later than 9 months after the date of enactment of this section, the Director, in consultation with the Council of Economic Advisors, the Director of the Office of Science and Technology Policy, and relevant agency heads, shall issue guidelines for cost-benefit analyses, risk assessments, and peer reviews as required by this subchapter. The Director shall oversee and periodically revise such guidelines as appropriate.

(2) As soon as practicable and no later than 18 months after issuance of the guidelines required under paragraph (1), each agency subject to section 624 shall adopt detailed guidelines for risk assessments as required by this subchapter. Such guidelines shall be consistent with the guidelines issued under paragraph (1). Each agency shall periodically revise such agency guidelines as appropriate.

(3) The guidelines under this subsection shall be developed following notice and public comment. The development and issuance of the guidelines shall not be subject to judicial review, except in accordance with section 706(1) of this title.

(b) To promote the use of cost-benefit analysis and risk assessment in a consistent manner and to identify agency research and training needs, the Director, in consultation with the Council of Economic Advisors and the Director of the Office of Science and Technology Policy, shall—

(1) oversee periodic evaluations of Federal agency cost-benefit analysis and risk assessment;

(2) provide advice and recommendations to the President and Congress to improve agency use of cost-benefit analysis and risk assessment;

(3) utilize appropriate interagency mechanisms to improve the consistency and quality of cost-benefit analysis and risk assessment among Federal agencies; and

(4) utilize appropriate mechanisms between Federal and State agencies to improve cooperation in the development and application of cost-benefit analysis and risk assessment.

(c)(1) The Director, in consultation with the head of each agency, the Council of Economic Advisors, and the Director of the Office of Science and Technology Policy, shall periodically evaluate and develop a strategy to meet agency needs for research and training in cost-benefit analysis and risk assessment, including research on modelling, the development of generic data, use of assumptions and the identification and quantification of uncertainty and variability.

(2)(A) No later than 6 months after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter a contract with an accredited scientific institution to conduct research to—

(i) develop a common basis to assist risk communication related to both carcinogens and noncarcinogens; and

(ii) develop methods to appropriately incorporate risk assessments into related cost-benefit analyses.

(B) No later than 24 months after the date of enactment of this section, the results of the research conducted under this paragraph shall be submitted to the Director and Congress.

§ 629. Risk based priorities study

(a) No later than 1 year after the date of enactment of this section, the Director, in consultation with the Director of the Office of Science and Technology Policy, shall enter into a contract with an accredited scientific institution to conduct a study that provides—

(1) a systematic comparison of the extent and severity of significant risks to human health, safety, or the environment (hereafter referred to as a comparative risk analysis);

(2) a study of methodologies for using comparative risk analysis to compare dissimilar risks to human health, safety, or the environment, including development of a common basis to assist comparative risk analysis related to both carcinogens and noncarcinogens; and

(3) recommendations on the use of comparative risk analysis in setting priorities for the reduction of risks to human health, safety, or the environment.

(b) The Director shall ensure that the study required under subsection (a) is—

(1) conducted through an open process providing peer review consistent with section 625 and opportunities for public comment and participation; and

(2) no later than 3 years after the date of enactment of this section, completed and submitted to Congress and the President.

(c) No later than 4 years after the date of enactment of this section, each relevant agency shall, as appropriate, use the results of

the study required under subsection (a) to inform the agency in the preparation of the agency's annual budget and strategic plan and performance plan under section 306 of this title and sections 1115, 1116, 1117, 1118, and 1119 of title 31.

(d) No later than 5 years after the date of enactment of this section, and periodically thereafter, the President shall submit a report to Congress recommending legislative changes to assist in setting priorities to more effectively and efficiently reduce risks to human health, safety, or the environment.

Subchapter III—Review of Rules

§ 631. Definitions

For purposes of this subchapter—

- (1) the definitions under section 551 shall apply; and
- (2) the term “economically significant rule” means a rule that—

(A) is likely to have an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs; or

(B) is likely to adversely affect, in a material way, the economy, a sector of the economy, including small business, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, or communities.

§ 632. Review of rules

(a)(1) No later than 1 year after the date of enactment of this section (and no later than every 5th year following the year in which this section takes effect) each agency shall publish in the Federal Register a preliminary schedule for the review of economically significant rules previously promulgated by the agency. The preliminary schedule shall be subject to public comment for 60 days after the date of publication. Within 120 days after the close of the public comment period, each agency shall publish a final schedule in the Federal Register.

(2) In selecting which economically significant rules it shall review, each agency shall consider the extent to which—

(A) the rule could be revised to be substantially more cost-effective or to substantially increase net benefits, including through flexible regulatory options;

(B) the rule is important relative to other rules being considered for review; and

(C) the agency has discretion under the statute authorizing the rule to modify or repeal the rule.

(3) Each preliminary and final schedule shall include—

(A) a brief description of each rule selected for review;

(B) a brief explanation of the reasons for the selection of each such rule for review; and

(C) a deadline for the review of each rule listed thereon, and such deadlines shall occur no later than 5 years after the date of publication of the final schedule.

(4) No later than 6 months after the deadline for a rule as provided under paragraph (3)(C), the agency shall publish in the Fed-

eral Register the determination made with respect to the rule and an explanation of such determination.

(5)(A) If an agency makes a determination to amend or repeal a rule, the agency shall complete final agency action with regard to such rule no later than 2 years after the deadline established for such rule under paragraph (3).

(B) The Director may extend a deadline under this section for no more than 1 year if the Director—

(i) for good cause finds that compliance with such deadline is impracticable; and

(ii) publishes in the Federal Register such finding and a succinct explanation of the reasons for the finding.

(b) The agency shall include with the publication under subsection (a) the identification of any legislative mandate that requires the agency to impose rules that the agency determines are unnecessary, outdated or unduly burdensome.

(c)(1) The Administrator shall work with interested entities, including small entities and State, local, and tribal governments, to pursue the objectives of this subchapter.

(2) Consultation with representatives of State, local, and tribal governments shall be governed by the process established under section 204 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1534).

Subchapter IV—Executive Oversight

§ 641. Definitions

For purposes of this subchapter—

(1) the definitions under sections 551 and 621 shall apply; and

(2) the term “regulatory action” means any one of the following:

(A) Advance notice of proposed rule making.

(B) Notice of proposed rule making.

(C) Final rule making, including interim final rule making.

§ 642. Presidential regulatory review

(a) The President shall establish a process for the review and coordination of Federal agency regulatory actions. Such process shall be the responsibility of the Director.

(b) For the purpose of carrying out subsection (a), the Director shall—

(1) develop and oversee uniform regulatory policies and procedures, including those by which each agency shall comply with the requirements of this chapter;

(2) develop policies and procedures for the review of regulatory actions by the Director; and

(3) develop and oversee an annual government-wide regulatory planning process that shall include review of planned significant regulatory actions and publication of—

(A) a summary of and schedule for promulgation of planned agency major rules;

(B) agency specific schedules for review of existing rules under subchapter III and section 610;

(C) a summary of regulatory review actions undertaken in the prior year;

(D) a list of major rules promulgated in the prior year for which an agency could not make the determinations that the benefits of a rule justify the costs under section 623(d);

(E) identification of significant agency noncompliance with this chapter in the prior year; and

(F) recommendations for improving compliance with this chapter and increasing the efficiency and effectiveness of the regulatory process.

(c)(1) The review established under subsection (a) shall be conducted as expeditiously as practicable and shall be limited to no more than 90 days.

(2) A review may be extended longer than the 90-day period referred to under paragraph (1) by the Director or at the request of the rule making agency to the Director. Notice of such extension shall be published promptly in the Federal Register.

§ 643. Public disclosure of information

(a) The Director, in carrying out the provisions of section 642, shall establish procedures to provide public and agency access to information concerning review of regulatory actions under this subchapter, including—

(1) disclosure to the public on an ongoing basis of information regarding the status of regulatory actions undergoing review;

(2) disclosure to the public, no later than publication of a regulatory action, of—

(A) all written communications relating to the substance of a regulatory action, including drafts of all proposals and associated analyses, between the Administrator or employees of the Administrator and the regulatory agency;

(B) all written communications relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government;

(C) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive meetings and telephone conversations relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

(D) a written explanation of any review action and the date of such action; and

(3) disclosure to the regulatory agency, on a timely basis, of—

(A) all written communications relating to the substance of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government;

(B) a list identifying the dates, names of individuals involved, and subject matter discussed in substantive meetings and telephone conversations, relating to the substance

of a regulatory action between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government; and

(C) a written explanation of any review action taken concerning an agency regulatory action and the date of such action.

(b) Before the publication of any proposed or final rule, the agency shall include in the rule making record—

(1) a document identifying in a complete, clear, and simple manner, the substantive changes between the draft submitted to the Administrator for review and the rule subsequently announced;

(2) a document identifying and describing those substantive changes in the rule that were made as a result of the regulatory review and a statement if the Administrator suggested or recommended no changes; and

(3) all written communications relating to the substance of a regulatory action between the Administrator and the agency during the review of the rule, including drafts of all proposals and associated analyses.

(c) In any meeting relating to the substance of a regulatory action under review between the Administrator or employees of the Administrator and any person not employed by the executive branch of the Federal Government, a representative of the agency submitting the regulatory action shall be invited.

§ 644. Judicial review

The exercise of the authority granted under this subchapter by the President, the Director, or the Administrator shall not be subject to judicial review in any manner.

