

# **REGULATORY IMPROVEMENT LEGISLATION: RISK ASSESSMENT, COST-BENEFIT ANALYSIS, AND JUDICIAL REVIEW**

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## I. INTRODUCTION

As the number, cost, and complexity of federal regulations have grown over the past twenty years, there has been growing interest in the use of analytic tools such as risk assessment and cost-benefit analysis to improve the regulatory process.<sup>13</sup> The application of these tools to public health, safety, and environmental problems has become commonplace in the peer-reviewed scientific and medical literatures. Recent studies prepared by Resources for the Future, the American Enterprise Institute, the Brookings Institution, and the Harvard Center for Risk Analysis have demonstrated how formal analyses can and often do help government agencies achieve more

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protection against hazards at less cost than would otherwise occur.<sup>14</sup> Although analytic tools hold great promise, their use by federal agencies is neither consistent nor rigorous.

The 103<sup>rd</sup>, 104<sup>th</sup>, 105<sup>th</sup> and 106<sup>th</sup> Congresses demonstrated sustained interest in the passage of comprehensive legislation governing the employment of these tools in the federal regulatory process. While legislative proposals on this issue have attracted significant bipartisan interest, and recent amendments to particular enabling statutes have incorporated some of these analytical requirements, no comprehensive legislation has been enacted into law since passage of the Administrative Procedure Act in 1946.

The inability to pass such legislation has been attributed to a variety of factors, but a common substantive concern has been uncertainty and controversy about how such legislation should address judicial review issues. For example, the judicial review portion of The Regulatory Improvement Act (S. 981), the 105th Congress's major legislative initiative, was criticized simultaneously as meaningless (for allegedly offering too few opportunities for petitioners to challenge poorly reasoned agency rules) and dangerous (as supposedly enabling petitioners to paralyze even well-reasoned agency rules).<sup>15</sup> Thus, a significant obstacle to regulatory improvement legislation appears to be the conflicting opinions among legal scholars and practitioners about how judicial review issues should be addressed in such legislation.

The Clinton Administration and the authors of S. 981 believe they have crafted a workable compromise, one that accommodates the need to bring more rigor and transparency to an agency's decisional processes without imposing excessive judicial review. Nevertheless, it is clear that their agreement on this subject, if included in future legislative deliberations, will be scrutinized and contested.

Recognizing the importance of the judicial review issue to this and, indeed, any effort to improve the regulatory process, the Center for Risk Analysis at the Harvard School of Public Health convened an invitational Workshop of accomplished legal practitioners and

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14. See generally *COMPARING ENVIRONMENTAL RISKS: TOOLS FOR SETTING GOVERNMENT PRIORITIES* (J. Clarence Davies ed., 1996); *ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT* (Richard D. Morganstern ed., 1997); *RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION* (Robert W. Hahn ed., 1996); *THE GREENING OF INDUSTRY: A RISK MANAGEMENT APPROACH* (John D. Graham & Jennifer K. Hartwell eds., 1997).

15. See generally, *The Regulatory Improvement Act of 1997: Hearing on S. 981 Before the Committee on Governmental Affairs, 105<sup>th</sup> Congress, 1-64* (1997).

scholars to discuss how judicial review should be handled in legislation of this kind. The full-day Workshop was conducted in Washington, D.C. on December 17, 1998. Its purpose was to discuss principles, experiences, and insights that might inform future public debate about how judicial review should be addressed in legislative proposals that entail use of risk assessment and/or cost-benefit analysis in agency decision-making (whether the proposals are comprehensive or agency-specific).

In order to provide the Workshop a practical focus, participants analyzed the provisions of S. 981 (as modified at the request of the Clinton Administration). An exchange of letters between S. 981's chief sponsors and the Clinton Administration defining the terms of the agreement was examined as well. This Report highlights the themes of the Workshop discussion and offers some specific commentary on how proposed legislation (including but not limited to S. 981) could be improved in future legislative deliberations.

## II. BACKGROUND

This section provides some background in the form of a brief description of (a) cost-benefit analysis and risk assessment, followed by an overview of prior (b) executive and (c) legislative efforts to incorporate these tools into the regulatory process.

### A. *The Analytic Tools*

Regulatory agencies use a variety of analytic tools, including comparative risk assessment, cost-benefit analysis, and cost-effectiveness analysis, to inform their decisions and provide a degree of credibility to the decisions that are made. But before these tools are discussed, it is important to acknowledge that terminology has not been standardized and thus a phrase such as "risk analysis" or "risk assessment," without an explicit definition, may mean different things to different people.

*Risk assessment* refers to a variety of tools developed by scientists and engineers for use when threats to human health, safety, or the environment are of concern. Assessing risk entails the use of scientific data, assumptions, and mathematical models to estimate the likelihood, frequency, and severity of harm to people or natural resources exposed to a hazard. Although some risk assessments provide only a qualitative indication of whether a hazard may exist, risk assessors often seek to quantify the number of people or resources that might be adversely impacted by a hazard. *Risk* typically refers to

the probability and severity of an adverse event or outcome. *Variability* refers to differences in risk across people or resources (e.g., due to differences in susceptibility or exposure). *Uncertainty* refers to lack of knowledge about the likelihood or severity of harm.<sup>16</sup>

When multiple hazards are assessed within a common framework and combined into a single report, the phrase *comparative risk assessment* is used. The comparisons may be made to inform resource allocation (priority setting), to weigh the countervailing risks of competing policy options (risk-risk tradeoffs), or to provide a sense of perspective about relative risk (risk communication). In the environmental health field, where serious questions have been raised about current policy priorities, the push for comparative risk assessment has been particularly strong.<sup>17</sup>

*Cost-benefit analysis* is a tool developed by economists and scientists to determine whether a proposed course of action is efficient compared to alternative courses of action. The *costs* of a project are typically the time, labor, material, and capital expended; the economic value of these resources is measured by their productivity if applied to their next best alternative uses (*opportunity costs*). The *benefits* of a project are typically defined as the gain in utility of the beneficiary population, often measured by the stated or observed willingness by the beneficiary population to pay for the results of the project. A project's *net benefits* are defined as benefits minus costs as compared to a well-specified alternative.<sup>18</sup>

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16. Several textbooks are available on modern methods of risk assessment. They include: YACOV Y. HAIMES, *RISK MODELING, ASSESSMENT AND MANAGEMENT* (1998); CHARLES D. HOLLAND & ROBERT L. SIELKEN, JR., *QUANTITATIVE CANCER MODELING AND RISK ASSESSMENT* (1993); GRANGER MORGAN & MAX HENRION, *UNCERTAINTY: A GUIDE TO DEALING WITH UNCERTAINTY IN QUANTITATIVE RISK AND POLICY ANALYSIS* (1990); *QUANTITATIVE RISK ASSESSMENT IN REGULATION* (Lester B. Lave ed., 1982).

17. *See generally*, *WORST THINGS FIRST? THE DEBATE OVER RISK-BASED NATIONAL ENVIRONMENTAL PRIORITIES* (Adam M. Finkel & Dominic Golding eds., 1994); *RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND ENVIRONMENT* (John D. Graham & Jonathan B. Wiener eds., 1995); *COMPARING ENVIRONMENTAL RISKS: TOOLS FOR SETTING GOVERNMENT PRIORITIES* (J. Clarence Davies ed., 1996).

18. A variety of texts are available on cost-benefit analysis. PETER BOHM, *SOCIAL EFFICIENCY: AN INTRODUCTION TO WELFARE ECONOMICS* (1973); EDWARD M. GRAMLICH, *BENEFIT-COST ANALYSIS OF GOVERNMENT PROGRAMS* (1981); EDWARD J. MISHAN, *COST-BENEFIT ANALYSIS* (4th ed. 1988); TEVFIK F. NAS, *COST-BENEFIT ANALYSIS: THEORY AND APPLICATION* (1996). Specialized texts for applications to human health, safety and environmental problems include: PER-OLOV JOHANSSON, *EVALUATING HEALTH RISKS: AN ECONOMIC APPROACH* (1995); MAGNUS JOHANNESSON, *THEORY AND METHODS OF ECONOMIC EVALUATION OF HEALTH CARE* (1996); MICHAEL F. DRUMMOND ET AL., *METHODS FOR THE ECONOMIC EVALUATION OF HEALTH CARE PROGRAMMES* (2d ed. 1997).

The application of strict cost-benefit analysis to public health and environmental regulation presents a challenge because it requires placing a value (often expressed in monetary terms) on human health and ecological outcomes. When this proves infeasible, these outcomes are not necessarily ignored. They still may be described qualitatively by the analyst, or a *cost-effectiveness analysis* may be performed. In a cost-effectiveness analysis, the cost of a project is divided by a quantitative (yet non-monetary) measure of effectiveness, such as the number of years of human life saved or tons of pollution removed. This produces a cost-effectiveness ratio, such as cost per year of life saved or per ton of pollution removed. Cost-effectiveness ratios can be used to maximize the number of life years saved (or pollution removed) for a given budget, but it does not inform the choice of the budget level. Cost-effectiveness analysis is used instead of cost-benefit analysis for many applications in public health and medicine.<sup>19</sup>

The terminology, as defined above, is not universally accepted. Sometimes the phrase “risk analysis” is used as a broad umbrella to refer to all of these tools. Since cost-effectiveness analysis is such a close cousin to cost-benefit analysis, the latter phrase may be used to refer to both of them. The terms “economic evaluation” or “economic appraisal” have also been used to refer to cost-benefit analysis and cost-effectiveness analysis. Broader terms such as “policy analysis,” “regulatory analysis,” or “socio-economic impact analysis” are also used occasionally, but their meanings may extend beyond the scope of this Report.

Despite differences in terminology, it is well accepted that tools such as risk assessment and cost-benefit analysis offer insight and intellectual discipline to the decision-making process. They can help to identify and evaluate decision options, and achieve more benefits at less cost than otherwise would occur.<sup>20</sup> However, it is also well recognized that use of these tools is not a substitute for human judgment in decision-making. Human judgment comes into play because the structure or findings of an analysis may not be adequate to inform a decision;<sup>21</sup> for example, a serious risk may be too uncertain to quan-

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19. See DIANA B. PETITTI, *META-ANALYSIS, DECISION ANALYSIS, AND COST-EFFECTIVENESS ANALYSIS: METHODS FOR QUANTITATIVE SYNTHESIS IN MEDICINE* (2d ed. 2000); *COST-EFFECTIVENESS IN HEALTH AND MEDICINE* (Marthe R. Gold et al. eds., 1996).

20. See, e.g., *ECONOMIC ANALYSIS AT EPA: ASSESSING REGULATORY IMPACT*, *supra* note 14; *THE GREENING OF INDUSTRY: A RISK MANAGEMENT APPROACH*, *supra* note 14.

21. See KRISTIN S. SHRADER-FRECHETTE, *RISK AND RATIONALITY: PHILOSOPHICAL FOUNDATIONS FOR POPULIST REFORMS* 169-96 (1991) (explaining the relationship between the

tify, or a decision may be driven more by fairness and equity considerations than by economic efficiency.<sup>22</sup> Although these tools will have a stronger influence on some decisions than others, there is a broad consensus that they should be used to inform major regulatory decisions by federal agencies.<sup>23</sup>

### B. *Executive Orders*

Since the FDR administration, every President has sought to exert some form of executive control over agency rulemaking.<sup>24</sup> This interest has grown during the past three decades as regulatory programs have expanded in number, scope, complexity, and cost. Thus, in 1971, President Richard Nixon required the U.S. Environmental Protection Agency, which had been created just one year earlier, to conduct "Quality of Life Reviews" for certain regulations.<sup>25</sup> President Gerald Ford also sought centralized control of the rulemaking process by requiring agencies to conduct "inflationary impact analyses" of major rules.<sup>26</sup> Under President Jimmy Carter's Executive Order 12044, important regulations were to be submitted for review by the Council on Wage and Price Stability and the Regulatory Analysis Review Group and all major rules were subjected to an "economic impact analysis."<sup>27</sup>

President Ronald Reagan's use of the executive order has been described as "[p]robably the most important development in administrative law in the 1980's . . . ."<sup>28</sup> His 1981 Executive Order 12291 further centralized the rulemaking process when it required the Office of Information and Regulatory Affairs in the Office of Management and Budget to review all rules before they were issued in proposed or final form.<sup>29</sup> This Order further directed each agency to analyze the costs and benefits of each major rule, and to the extent permitted by law, it compelled agencies to issue only those rules for which potential

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subjective response of individuals and risk analysis).

22. See MISHAN, *supra* note 19, at xxiii-xxiv.

23. See Kenneth J. Arrow et al., *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles*, 272 *SCIENCE* 173, 221-222 (1996).

24. See Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 *U. CHI. L. REV.* 1 (1995).

25. See *id.* at 13.

26. See *id.* at 14.

27. See *id.*

28. See *id.* at 3 (authors' opinion).

29. See Exec. Order No. 12291, 3 *C.F.R.* 128, 133-134 (1981), *reprinted in* 5 *U.S.C.* § 601 note (Supp. 1988).

benefits exceeded potential costs.<sup>30</sup> In 1985, President Reagan signed Executive Order 12498 to require agencies to prepare a yearly agenda of all significant actions for the coming year, and to put the Vice President (then George Bush) in charge of a committee overseeing the regulatory review process.<sup>31</sup> These executive orders continued in effect throughout the Bush administration. In 1992, the White House staff drafted a new executive order on risk assessment and risk-risk tradeoffs, but President Bush never issued this order.

Centralizing control of the rulemaking process in the Office of Management and Budget (“OMB”) reflected a desire to enhance both political accountability and technical competence. Not surprisingly, the Reagan-Bush executive orders triggered a number of criticisms. These included charges that the OMB’s regulatory oversight process was overly stringent, ineffective, and/or unduly secretive.<sup>32</sup> They also triggered the more substantive objections that the influence of cost benefit analysis would overstate costs, understate benefits, and preclude the weighing of political interests and concerns which is a political reality in agency decision-making.

President Reagan’s Executive Order 12291 was replaced in 1993 when President Clinton issued Executive Order 12866. Unlike Executive Order 12291, which required centralized review of “all” rules, Executive Order 12866 necessitates such review only for “significant” rules, which primarily consist of those rules expected to have an annual impact on the economy of at least \$100 million.<sup>33</sup> Like its predecessor, it too requires a cost-benefit analysis of such significant rules—it directs agencies to maximize net benefits, issue regulations only when the benefits justify the costs and use the most cost-effective policy instruments.<sup>34</sup> It also perpetuates the requirement that each agency submit an annual regulatory plan, and continues to place the Vice President in charge of the regulatory review process, a role that Vice Presidents Bush and Quayle had played to some extent in previous Republican Administrations.<sup>35</sup> Executive Order 12866 differed

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30. See Exec. Order No. 12498, 3 C.F.R. 323 (1985), *reprinted in* 5 U.S.C. § 601 note (Supp. 1988).

31. See Pildes & Sunstein, *supra* note 24, at 14.

32. See *Role of the Council on Competitiveness in Regulatory Review: Hearings before the Senate Committee on Governmental Affairs*, 102nd Cong. 2 (1991) (statement of John Glenn, Senator, U.S. Senate).

33. See Exec. Order No. 12866, 3 C.F.R. 638, 641 (1993), *reprinted in* 5 U.S.C. § 601 note (Supp. 1998).

34. See *id.*

35. See *id.*

from the Reagan-Bush orders in several respects. It accorded more attention to qualitative measures of benefits and costs as well as the equitable distribution of the risk. It further required more emphasis on risk-risk tradeoffs and greater openness in the process of regulatory review. Continuing this trend, S. 981 would authorize the ongoing role of presidential review as a vehicle to enhance S. 981's goals of improving the regulatory process.

### C. *Recent Congressional Deliberations*

In 1946, Congress enacted the Administrative Procedure Act<sup>36</sup> ("APA") to guide agency rulemaking. As both agencies and their rules have grown in number since the 1960's, Congress has considered whether and how to supplement the APA to improve both the process and outcomes of administrative rulemakings. Thus, during the 103<sup>rd</sup>, 104<sup>th</sup>, and 105th Congresses, efforts have been made to pass legislation that would improve the regulatory process by making the use of science and economics more consistent, rigorous, and transparent. Of particular interest to Congress has been the appropriate use of risk assessment and cost-benefit analysis by those federal agencies responsible for protecting public health, safety, and the environment. These agencies include, for example, the Consumer Product Safety Commission (CPSC), Environmental Protection Agency (EPA), Food and Drug Administration (FDA), National Highway Traffic Safety Administration (NHTSA), Occupational Safety and Health Administration (OSHA), Mine Safety and Health Administration (MSHA), and Nuclear Regulatory Administration (NRC).

Although congressional interest in regulatory analysis can be traced to the early 1980s and even earlier, recent interest in the roles of both risk assessment and cost-benefit analysis is rooted in the Democrat-controlled 103<sup>rd</sup> Congress. Since then, members of both parties have participated in drafting and advocating legislation concerning risk assessment and cost-benefit analysis.

#### 1. The 103<sup>rd</sup> Congress

Proposals regarding risk assessment and cost-benefit analysis were an important part of the legislative agenda of the 103<sup>rd</sup> Congress. The Science Committee held a number of hearings on related issues and reported H.R. 4306, the Risk Assessment Improvement Act.<sup>37</sup>

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36. 5 U.S.C. §§ 551-552, 702-706 (1994).

37. See Risk Assessment Improvement Act, H.R. 4306, 103rd Cong. (1994).

H.R. 4306 only applied to the EPA and contained provisions designed to address the perceived problems with federal risk assessment and characterization practices.<sup>38</sup> H.R. 4306 was not brought up for a vote on the floor. Representative Walker, now Chairman of the Science Committee, did offer a subset of H.R. 4306 as an amendment to H.R. 3870, the Environmental Technologies Act of 1994.<sup>39</sup> The Walker amendment was approved 286 to 139.

During the 103<sup>rd</sup> Congress, the Energy and Commerce Committee adopted several Republican amendments requiring unbiased presentation of risk information during markups of the Superfund Reform Act of 1994,<sup>40</sup> the Safe Drinking Water Act Amendments of 1994,<sup>41</sup> the Radon Awareness and Disclosure Act,<sup>42</sup> and the Indoor Air Act of 1994.<sup>43</sup> The Safe Drinking Water and Radon bills were both approved on the House floor but did not become law. These provisions reflected requirements for transparency and objectivity in agency rulemaking. The Superfund bill also contained provisions for a National Risk Protocol designed, in part, to address the perceived problems of unreasonable risk estimates in the Superfund program.<sup>44</sup>

Based on concerns over both risk assessments at the EPA and the perceived failure of EPA regulations to reflect costs and benefits, the Senate also approved risk and cost-benefit language in the Johnston amendment by a vote of 95-3 during floor consideration of legislation to elevate EPA to Cabinet status in early 1993.<sup>45</sup> A less demanding version of the Johnston amendment was also attached to legislation reauthorizing the Safe Drinking Water Act in the Senate.<sup>46</sup> The Johnston amendment basically required: (1) cost-benefit analysis for major rules; (2) comparative risk analysis to place the risk reduction into perspective; and (3) certifications that the science used was the best reasonably available scientific information and that the benefits of the rule justified the costs.<sup>47</sup> It did not authorize judicial review of agency compliance with these requirements. A similar amendment

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38. *See id.* §§ 2-3.

39. *See* Environmental Technologies Act of 1994, H.R. 3870, 103rd Cong., 140 CONG. REC. 6212 (1994) (enacted).

40. *See* Superfund Reform Act of 1994, H.R. 3800, 103rd Cong. § 101 (1994).

41. *See* Safe Drinking Water Act Amendments of 1994, S. 2019, 103rd Cong. § 18 (1994).

42. *See* Radon Awareness and Disclosure Act, H.R. 2448, 103rd Cong. § 310 (1994).

43. *See* Indoor Air Act of 1994, H.R. 2919, 103rd Cong. §§ 2702, 2704 (1994).

44. *See* Superfund Reform Act of 1994, H.R. 3800, 103rd Cong. §§ 106-108 (1994).

45. *See* Safe Drinking Water Act Amendments of 1994, S. 2019, 103rd Cong. (1994).

46. *See* Safe Drinking Water Act Amendments of 1993, S. 1547, 103rd Cong. (1993).

47. *See* Safe Drinking Water Act Amendments of 1994, S. 2019, 103rd Cong., § 18 (1994).

was gaining bipartisan support in the House when the House Democratic leadership made a strategic decision not to bring the EPA Cabinet-evaluation bill to a vote on the House floor.<sup>48</sup>

Legislative interest in the ranking of risks and risk communication also emerged in the 103<sup>rd</sup> Congress. The Risk Reduction Act of 1993, emphasizing the ranking of risks for priority-setting purposes at the EPA, was introduced in the Senate as S. 110 by Daniel Patrick Moynihan (D-NY)<sup>49</sup> and in the House as H.R. 3111 by Dick Zimmer (R-NJ) and Jim Slattery (D-KS).<sup>50</sup> The bills were not marked up although a version was adopted as part of Safe Drinking Water legislation on the Senate floor.<sup>51</sup> Risk communication based on sound science and transparent assumptions was emphasized in several bills introduced by Carlos Moorhead (R-CA), Herb Klein (D-NJ), Robert Walker (R-PA) and others. Their Risk Communication Act of 1993 applied only to the EPA and, while it did not pass into law, it did build a significant amount of support for legislation of this kind.<sup>52</sup>

## 2. The 104<sup>th</sup> Congress

During the fall 1994 election campaign, specific references to risk assessment and cost-benefit analysis were featured in the Republican "Contract with America." When Republicans won control of Congress in November 1994, it took only one month after the House reconvened for the Risk Assessment and Cost-Benefit Act of 1995, led by Thomas Bliley (R-VA), to pass the House on a vote of 286 to 141.<sup>53</sup> This bill combined many of the risk-related ideas from the 103<sup>rd</sup> Congress into a single comprehensive bill that applied to all covered Federal agencies that implement regulatory programs designed to protect human health, safety, or the environment.<sup>54</sup> The risk assessment and cost-benefit provisions in the Bliley bill were modified prior to floor debate in order to clarify that the new bill would supersede any decisional criteria in existing statutes (e.g., the Clean Air Act, the Occupational Safety and Health Act, and the Federal Food, Drug, and Cosmetic Act). Unlike the Johnston Amendment in the 103<sup>rd</sup> Congress which proscribed judicial review, the Bliley bill contained new

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48. *See id.*

49. *See* Risk Reduction Act of 1993, S. 110, 103rd Cong. (1993).

50. *See* Environmental Risk Reduction Act of 1993, H.R. 3111, 103rd Cong. (1993).

51. *See* Safe Drinking Water Act Amendments of 1994, S. 2019, 103rd Cong., § 18 (1994).

52. *See* Risk Communication Act of 1993, H.R. 2910, 103rd Cong. (1993).

53. *See* Risk Assessment and Cost-Benefit Act of 1995, H.R. 1022, 104th Cong. (1995).

54. *See id.* § 103.

opportunities for petitioners to seek judicial reversal of agency actions.<sup>55</sup>

During the 104<sup>th</sup> Congress, the Senate proved to be less hospitable toward legislation that would make such major changes to public health, safety, and environmental laws. Republicans became splintered, as different bills were developed in three separate Committees (Judiciary, Governmental Affairs, and Natural Resources). Democrats did not generally oppose risk assessment and cost-benefit analysis—indeed, John Glenn (D-OH) and John Chafee (R-RI) crafted an alternative to the major Republican proposals.<sup>56</sup> Nevertheless, key Democrats fought the provisions in Republican bills that would have overturned decisional criteria in existing laws or offered petitioners new grounds to seek judicial reversal of agency actions.

Senate Majority Leader Robert Dole (R-KS) and Senator Bennett Johnson (D-LA) ultimately crafted a compromise bill that was debated on the floor of the Senate in July 1995.<sup>57</sup> Determined opposition from Democrats and the Clinton Administration culminated in a filibuster threat that could not be broken. Even after the sponsors agreed to several amendments that weakened the Dole bill, a third and final cloture vote received 58 votes—two votes shy of the 60 necessary to stop a filibuster. The Clinton Administration was also threatening a veto, in which case it would have been necessary to attract 67 votes in order to override such a veto.

The 104<sup>th</sup> Congress did pass bills concerning risk assessment and cost-benefit analysis in narrow pieces of legislation concerning, for example, the Safe Drinking Water Act<sup>58</sup> and the Oil Pipeline Safety Act.<sup>59</sup> The Food Quality Protection Act also passed with strong risk assessment provisions.<sup>60</sup> Yet broad-based legislation never passed in the Senate, even though several Senate Democrats who had opposed Dole's initiative worked, without success, to fashion a compromise later in the session.

### 3. The 105<sup>th</sup> Congress

Proponents of risk assessment and cost-benefit analysis took a different approach in the 105<sup>th</sup> Congress. Action began in the Senate

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55. *See id.* § 401.

56. *See* Regulatory Accountability Act of 1995, S. 100, 104th Cong. (1995).

57. *See* Comprehensive Regulatory Reform Act of 1995, S. 343, 104th Cong. (1995).

58. *See* Safe Drinking Water Act Amendments of 1996, S. 1316, 104th Cong. §§ 5-6 (1995)

59. *See* Pipeline Safety Act of 1995, H.R. 1323, 104th Cong. § 3 (1995).

60. *See* Food Quality Protection Act of 1995, H.R. 1627, 104th Cong. § 102 (1995).

where a single Committee, Governmental Affairs, crafted S. 981, The Regulatory Improvement Act of 1998, under the leadership of the new chairman, Fred Thompson (R-TN), and senior Democrats Carl Levin (D-MI) and John Glenn (D-OH).<sup>61</sup> Committee staff and members worked diligently to rebuild bipartisan interest in risk assessment and cost-benefit analysis. The bill ultimately passed the Committee on a vote of 8 to 4 but there were two ominous signs. First, four Committee Democrats, Joseph Daniel Akaka (D-HI), Max Cleland (D-GA), Joseph Lieberman (D-CT) and Robert Torricelli (D-NJ) opposed the measure. Second, Majority Leader Trent Lott (R-MS) decided to introduce his own bill, which included the risk assessment provisions in the Thompson-Levin bill but omitted any mention of cost-benefit analysis.<sup>62</sup>

Despite these complications, Senators Levin and Thompson worked with White House officials to revise the bill so that it would be acceptable to the Clinton Administration and more attractive to additional Senate Democrats. Written letters of agreement with the Clinton Administration were secured late in the 105th Congress. With these revisions, several additional Democrats, including Minority Leader Tom Daschle (D-SD) and Daniel Patrick Moynihan (D-NY), agreed to become co-sponsors of a modified version of the Regulatory Improvement Act.<sup>63</sup> Toward the end of the 105th Congress, it became apparent that a floor vote on the Thompson-Levin initiative might attract 60 or more favorable votes in the Senate. When Thompson and Levin approached Majority Leader Lott about floor time, it was late in the session and the November 1998 elections were only a few months away. There were concerns about whether the Levin-Thompson bill, as modified to satisfy the Clinton Administration, was meaningful enough to justify precious floor time, especially since it would attract significant opposition. Lott discussed with Daschle an approach to floor consideration that would sharply limit time for floor debate and amendments (several Democratic Senators, including Edward Kennedy (D-MA), expressed interest in proposing multiple amendments to S. 981 that were likely to provoke controversy). When Daschle refused to agree to sharp limits on floor debate, Lott declined further consideration of the Levin-Thompson initiative. No action had been taken in the House because leadership

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61. *See* Regulatory Improvement Act of 1997, S. 981, 105th Cong. (1997).

62. *See* Federal Regulatory Risk Assessment Act of 1997, S. 1728, 105th Cong. (1998).

63. *See* Regulatory Improvement Act of 1998, S. 981, 105th Cong. (1998).

for the passage of the bill had been expected to come from the Senate.

#### 4. The 106<sup>th</sup> Congress

Early in 1999, Senator Carl Levin (D-MI) reintroduced the Regulatory Improvement Act of 1999 to the Senate.<sup>64</sup> This bill is very similar to its predecessor that Senator Thomson and Levin had introduced in the 105<sup>th</sup> Congress. Additionally, on November 10, 1999, Republican George W. Gekas (R-PA) introduced a regulatory improvement bill to the House.<sup>65</sup> The fate of both bills is uncertain, and they may be lost in the partisan, election-year struggle.

### III. S. 981: THE REGULATORY IMPROVEMENT ACT AND ITS CORE PROVISIONS

Whether or not S. 981 stands a reasonable chance of ultimate enactment, it provides a useful vehicle to address the various issues involved in attempting to legislate the use of certain analytic tools in the rulemaking process. Accordingly, this section delineates the relevant provisions of S. 981 (see Table 1 for a summary). Following this account of the overall structure and content of the bill, we provide a closer analysis of what we see as the more salient provisions and discuss specific concerns.

**Table 1: Basic Structure of S. 981: Analytical Provisions**

<b>Section 621: Definitions of Key Terms</b>
<b>622: Applicability and Relationship to Existing Laws</b>
<b>623: Cost-Benefit Analysis and Cost-Benefit Determination</b>
<b>624: Principles of Risk Assessment</b>
<b>625: Requirements for Peer Review</b>
<b>626: Deadlines and Scheduling</b>
<b>627: Judicial Review</b>
<b>628: OMB's Role in Agency Coordination, Guidelines, and Research</b>
<b>629: National Study of Risk-Based Priorities</b>

64. See Regulatory Improvement Act of 1999, S. 746, 106th Cong. (1999).

65. See Regulatory Improvement Act of 2000, H.R. 3311, 106th Cong. (1999).

### A. Sections 621 and 622: Definitions, Applicability and Effect

Rules with a likely effect on the economy of \$100 million or more in “reasonably quantifiable costs” are defined as “major” under section 621(7)(A).<sup>66</sup> Such a determination should be made by the agency or the Director of the Office of Management and Budget (the Director) acting through the Office of Information and Regulatory Affairs.<sup>67</sup> Section 621(7)(B) also gives the Director, but not the agency, the discretionary authority to designate a proposed rule as “major” if it is likely to adversely affect the economy “in a material way.”<sup>68</sup> Section 621 also exempts a variety of proposed rules from S. 981’s regulatory analysis requirements, such as rules pertaining to banking, securities, taxes, or fiscal policy as well as rules which are otherwise exempt from notice and comment rulemaking.<sup>69</sup>

Under section 622(a), S. 981 applies to all proposed and final major rules with certain exceptions.<sup>70</sup> Furthermore, it states that the subchapter shall not be construed to alter or modify: (1) the substantive standard applicable to rulemaking under other statutes; (2) the range of regulatory options that an agency has the authority to adopt under the statute authorizing the agency to promulgate the rule, or the deference otherwise accorded to the agency in construing such statute; or (3) any opportunity for judicial review made applicable under other statutes.<sup>71</sup>

### B. Section 623: Cost-Benefit Analysis of “Major” Rules

Section 623 of the Regulatory Improvement Act states that before publishing a notice of a proposed rulemaking of *any* rule, the agency must first determine whether the rule should be designated a “major rule” under S. 981.<sup>72</sup> Once a rule is determined to constitute a major rule, the agency must perform an “initial” regulatory analysis.<sup>73</sup> In doing so, the agency must consider the benefits and costs (both quantifiable and non-quantifiable), for both the proposed rule and for a “reasonable number of reasonable alternatives to the rule” which,

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66. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 621(7)(A) (1998).

67. See *id.*

68. See *id.* § 621(7)(B).

69. See *id.* § 621(10).

70. See *id.* §§ 622(a), 623(f).

71. See Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 622(b) (1999). (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this language).

72. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 623(a)(1) (1998).

73. See *id.* § 623(b)(1)(B)(i).

in turn, must include evaluation of “flexible regulatory options.”<sup>74</sup> The agency must also explain how the respective benefits and costs are expected to result from the proposed rule and describe the persons or classes of persons likely to sustain such benefits or costs.<sup>75</sup>

Under section 623(c), a final regulatory analysis must accompany publication of a final major rule.<sup>76</sup> It must address each component of the initial regulatory analysis and indicate any material changes made since the initial analysis of the rule itself, the cost-benefit analysis, or the risk assessment.<sup>77</sup> The final regulatory analysis must also reflect agency consideration of “significant comments” regarding the proposed rule and the initial regulatory analysis.<sup>78</sup>

Section 623(d) provides that a final regulatory analysis must also contain a cost-benefit determination.<sup>79</sup> Here, the agency must state whether the rule is likely to provide benefits that “justify” its costs and is likely to do so in “a more cost effective manner or with greater net benefits than the other reasonable alternatives considered by the agency.”<sup>80</sup> Pursuant to the Clinton agreement, “net benefits” is specifically defined to include both quantifiable and nonquantifiable effects.<sup>81</sup>

Should the agency head conclude that the rule being issued is not likely to yield net benefits or achieve its objectives in a cost-effective manner, section 623(d) requires the agency head to explain the grounds for adopting the rule.<sup>82</sup> The agency must identify “any statutory provision that required the agency to select such rules” despite the lack of positive net benefits or superior cost-effectiveness.<sup>83</sup> Again, the regulatory analysis outlined in S. 981 is not intended to function as a decision rule but, rather, is only supposed to provide a framework for the process that should be employed in making rules. Thus, while the regulatory examination must be conducted, the analytical findings do not automatically dictate the agency’s ultimate decision.

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74. *See id.* § 623(b)(1)(B)(ii).

75. *See id.*

76. *See id.* § 623(c)(1).

77. *See id.* § 623(c)(2).

78. *See id.*

79. *See id.* § 623(d)(1)(A).

80. *See id.* § 623(d)(1)(B).

81. *See id.* § 621(2).

82. *See id.* § 623(d)(2)(A).

83. *See id.* § 623(d)(2)(B).

In some instances, a major rule can be adopted without prior compliance with S. 981's regulatory analysis provisions. Under section 623(f), an agency may adopt a rule without a prior S. 981 regulatory analysis if it finds that it is "impracticable or contrary to an important public interest" to conduct the analysis before the rule's effective date.<sup>84</sup> In such instances, however, the agency must perform the S. 981 analysis *after* adoption and do so as promptly as possible unless "the Director determines that compliance would be clearly unreasonable."<sup>85</sup>

### C. Section 624: Risk Assessment

As it does for cost-benefit analysis, the statute articulates the objectives of a risk assessment as promoting rational agency decision-making that is both understandable to, and informed by, the public.<sup>86</sup> Consequently, section 624(d) obliges the agency to inform the public when it is performing a risk assessment as well as to solicit relevant and reliable data from the public for consideration in the risk assessment.<sup>87</sup>

Proposed and final major rules addressing health, safety, or environmental risk must undergo risk assessment in accordance with the provisions of section 624.<sup>88</sup> Where a section 624 risk assessment has been conducted for a proposed rule, a new risk assessment need not be conducted for the final rule if the agency determines that: (1) the final rule is substantially similar to the proposed rule for which a section 624 risk assessment has already been done; and (2) a new risk assessment for the final rule is not needed in order to respond to comments received on the proposed rule.<sup>89</sup>

Section 624 requirements can also apply to what we have termed a "free-standing risk assessment," in other words, a risk assessment that is not associated with a rulemaking.<sup>90</sup> Such an assessment must comply with the statute if the Director anticipates that the free-standing assessment is likely to have "an annual effect on the economy of \$100,000,000 or more in reasonably quantifiable costs"<sup>91</sup> *and*

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84. *See id.* § 623(f)(1)(A).

85. *See id.* § 623(f)(2).

86. *See id.* § 624(a)(1)(B)(i).

87. *See id.* § 624(d).

88. *See id.* § 624(a)(1)(A)(i).

89. *See id.* § 624(a)(2).

90. *See id.* § 624(a)(1)(A)(ii).

91. *See id.* § 621(7)(A)

the Director also determines that S. 981's requirements should apply.<sup>92</sup> Thus, whether a free-standing risk assessment must satisfy section 624 is ultimately a matter of the Director's discretion.

Risk assessments subject to section 624 must comply with a series of "disclosure" requirements which, again, are intended to maximize informed and transparent rulemaking. Risk assessments under section 624(b) and significant assumptions used in such assessments under section 624(c)(2) must consider "all relevant, reliable and reasonably available scientific information"<sup>93</sup> and must explain the basis for selecting the information relied upon in the risk assessment.<sup>94</sup> Any significant choice of assumptions must be identified along with its basis in science or policy, the basis for the agency's choice and any combination of assumptions must be explained, and the extent to which the assumption has been validated by or conflicts with empirical data must be disclosed.<sup>95</sup> A risk assessment should also describe reasonable alternative assumptions that were considered but not selected by the agency that would have significantly affected the outcome of the risk assessment.<sup>96</sup>

Section 624(e) specifies that the actual content of risk assessment "shall include, as appropriate," descriptions of: (1) the hazard; (2) the populations or natural resources that are the subject of the risk assessment; (3) exposure scenarios, including estimates of the population or natural resource risk and the likelihood of such scenarios; (4) the nature and severity of the harm from exposure to the hazard; and (5) the major uncertainties in each component of the risk assessment and their impact on the assessment's outcome.<sup>97</sup> The bill provides further specifics for expressing risk estimates in subsection (f)<sup>98</sup> and for analyzing risks in subsection (g) "in relationship to other reasonably comparable risks familiar to and routinely encountered by the general public."<sup>99</sup>

#### D. Section 625: Peer Review

An independent peer review is required for a cost benefit analy-

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92. *See id.* § 624(a)(1)(A)(ii).

93. *See id.* § 624(b).

94. *See id.* § 624(c)(2).

95. *See id.* §§ 624(c)(1)(A),(B).

96. *See id.* § 624(c)(1)(C).

97. *See id.* §§ 624(e)(1)-(5).

98. *See id.* § 624(f).

99. *See id.* §§ 624(g).

sis of a major rule under subsection (a)(1), when: (1) the agency or Director anticipates that the rule is likely to have an annual effect on the economy of “\$500 million in reasonably quantifiable costs”<sup>100</sup> or, (2) there is a section 624 risk assessment.<sup>101</sup> Under such circumstances, only one peer review is required and should be conducted, when feasible, *prior* to the notice of proposed rulemaking.<sup>102</sup> Furthermore, if an agency head, with the Director’s concurrence, publishes a determination in the rulemaking file that adequate peer review has been conducted for a cost-benefit analysis or risk assessment, no further peer review can be required under this section for that cost-benefit analysis, risk assessment, or component thereof.<sup>103</sup>

The actual mechanism for conducting peer review is not described with the degree of specificity contained in other sections of the bill. Section 625(b)(1) permits “panels, expert bodies, or other formal or informal devices” that involve participants who carry with them relevant expertise, independence of the agency, and a broad and balanced “presentation of all considerations . . . .”<sup>104</sup> The formality of the peer review process, however, “shall be commensurate with the significance and complexity of the subject matter” under subsection (d).<sup>105</sup>

#### E. Section 627: Judicial Review

The availability of judicial review of agency compliance with S. 981’s requirements is addressed in section 627. Under section 627(a), compliance with the provisions of S. 981 is 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.”<sup>106</sup> An *agency’s* determination of whether a rule is a major rule is subject to the “arbitrary and capricious” standard of review under section 627(b).<sup>107</sup> In contrast, section 627(c) states ex-

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100. See Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 625(a)(1) (1999). (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this language).

101. See *id.*, S. 746, § 625(a)(2).

102. See *id.*, S. 746, § 625(h).

103. See *id.*, S. 746, § 625(b)(3).

104. See *id.*, S. 746, § 625(b)(1)(A)-(D).

105. See *id.*, S. 746, § 625(d).

106. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 627(a)(1)-(3) (1998).

107. See *id.* § 627(b).

plicitly that the *Director's* decision regarding whether a rule is or is not a major rule is *not* subject to judicial review.<sup>108</sup>

Whether the cost-benefit analysis, cost-benefit determination, risk assessment, or peer review required as part of an S. 981 regulatory analysis can be grounds for judicial review is treated with some delicacy and complexity in subsections (d) and (e) of section 627—reflecting, perhaps, the inevitable tightrope one walks when seeking to incorporate new analytic procedures without unduly increasing opportunities for judicial wrangling. Section 627(d) directs that risk analysis “shall be considered by a court to the extent relevant in . . . determining whether the final rule is arbitrary, capricious, an abuse of discretion . . . .”<sup>109</sup>

An agency’s *failure to perform* a required cost-benefit analysis, cost-benefit determination, risk assessment, or peer review may constitute grounds for remand or invalidation of the rule (“giving due regard to prejudicial error”).<sup>110</sup> Would judicial review be available when a cost-benefit analysis, a cost-benefit determination, a risk assessment, or peer review has been performed but its *adequacy* is in question? Once performed, any risk assessment, cost-benefit analysis, or cost-benefit determination is subject to judicial review only insofar as it is relevant to 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.”<sup>111</sup>

Thus, section 627(d) forecloses judicial challenges to an agency’s use of these analytical tools during the rulemaking process prior to final rulemaking. This bill also appears to limit the ability of petitioners to assert inadequate compliance with analytical requirements alone as an independent basis for a court to set aside the entire rule. Perhaps to clarify this point, subsection (e) specifically addresses challenges based on adequacy of compliance—it states that “[t]he adequacy of compliance with the specific requirements for this subchapter shall not otherwise be grounds for remanding or invalidating a rule under this subchapter. If the court allows the rule to take effect, the court shall order the agency to promptly perform such analysis, determination, or assessment or provide for peer review.”<sup>112</sup>

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108. *See id.* § 627(c).

109. *See id.* § 627(d).

110. *See id.* § 627(e).

111. *See id.* § 627(d).

112. *See* Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 627(e) (1999). (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this language).

Both subsections (d) and (e) of section 627 had been the subject of extended debate and a fair amount of revision during negotiations between Senate staff and representatives of the Clinton Administration. And, not surprisingly, these portions of the statute provoked much discussion and some disagreement during the Workshop regarding section 627's impact on judicial review as currently available under the Administrative Procedure Act. Accordingly, the meaning and application of section 627 will be addressed in greater detail in the "Analysis and Commentary" which follows in Section V.

#### F. *Section 629: Mandatory Study of Risk Based Priorities*

Within one year of its enactment, section 629 requires the Director of OMB, in consultation with the Director of Science and Technology Policy, to "contract with an accredited scientific institution" to conduct a risk-based priorities study.<sup>113</sup> Basically, this study must include a comparative risk analysis, which entails the "systematic comparison of the extent and severity of significant risks to human health, safety or the environment."<sup>114</sup> It also must study methods for comparing dissimilar risks, and formulate recommendations regarding the use of comparative risk analysis "in setting priorities for the reduction of risks to human health, safety, or the environment."<sup>115</sup> This report is to be finalized and delivered to Congress and the President within 3 years of section 629's enactment; all relevant agencies must use the report's results in budgetary and strategic planning within 4 years of enactment; and finally, 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" within 5 years of enactment and periodically thereafter.<sup>116</sup>

### IV. JUDICIAL REVIEW IN ADMINISTRATION LAW

While the extent to which S. 981 permits judicial review is somewhat ambiguous, it seems to maintain judicial review in order to safeguard against agency failure to perform specified analytical functions, but imposes certain limitations upon it to avoid judicial intrusion into agency decision-making and to ensure timely promulgation of regula-

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113. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 629(a) (1998).

114. See *id.* § 629(a)(1).

115. See *id.* § 629(a)(2).

116. See *id.* §§ 629(b)(c)(d)

tions. To appreciate the significance of what S. 981 does and does not do in this regard, a brief overview of judicial review as currently available under the APA is necessary.

#### *A. The General Role and Purpose of Judicial Review*

Judicial review of agency action plays a critical and distinctive role in the oversight of agency rulemaking. In contrast to legislative oversight, which focuses on an agency's budget and effectiveness, or executive supervision through the selection of agency leadership and policy, review of agency conduct by a court focuses on legality and reasoned decision-making. In this way, judicial oversight supplements political controls on administration by checking whether the agency is acting in accordance with the will of the political branches as expressed in its enabling legislation. Judicial oversight can also serve as a second look at the exercise of reasoning and expertise by agencies. As an independent check on the validity of administrative decisions, judicial review also contributes to the political legitimacy of regulation.

Specifically, judicial review seeks to ensure that agency action violates no constitutional command (e.g., due process), is authorized by statute or other law, observes procedural requirements, and has a substantial basis in fact and reason.<sup>117</sup> The agency's adoption of substantive rules (i.e., legally binding rules for the implementation of delegated legislative authority) must give affected persons notice of the rule and an opportunity for comment, and state the basis and purpose of the final rule.<sup>118</sup> Changes in agency policy or in an agency's interpretation of its organic act must be justified, and departures from agency precedent must be explained.<sup>119</sup>

Thus, an important aim of judicial review is to foster reasoned decision-making by forcing the agency decision-maker to explain why a particular action was taken and why it is warranted. This can yield more careful and rational rulemaking decisions. Of course, not all substantive administrative rules are reviewed; indeed most are somewhat routine and uncontroversial. Nonetheless, the prospect of judicial review and the possibility of reversal provide meaningful incentives for an agency to stay within authorized boundaries. Accordingly, judicial review is intended to assure that a rule is

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117. See Administrative Procedure Act, 5 U.S.C. § 706(2)(A)-(E) (1994).

118. See 5 U.S.C. § 553 (1994).

119. See *Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 30-31 (1983).

authorized, well reasoned, and supported by an opportunity for public participation in its formulation.

A judicial reversal under arbitrary and capricious review may have little impact on administrative policy if there are strong bureaucratic or political reasons for the agency to persist in its view. On remand, the agency may simply produce a better rationalization for its actions, reach the same result using different methods, or misinterpret the court's directives (intentionally or otherwise). But experience teaches that judicial review can and often does have a profound effect on agency behavior and its decision process. Changes in the past two decades in the analytical rigor of EPA rulemaking and in the sensitivity of the U.S. Army Corps of Engineers to the environmental impact of its actions are prime examples of the effect judicial review can have.

Chapter 7 of the Administrative Procedure Act (APA)<sup>120</sup> establishes the availability and scope of judicial review for both “[a]gency action made reviewable by statute” and other “final agency action for which there is no other adequate remedy in a court.”<sup>121</sup> The 1967 opinion in *Abbott Laboratories v. Gardner* inaugurated the modern practice of liberal review by instructing courts to give the APA's “generous review provisions” an “hospitable interpretation” in light of “a congressional intention that it cover a broad spectrum of administrative actions.”<sup>122</sup> In particular, *Abbott* read the APA as embodying a “basic presumption of judicial review,” such that “only on a showing of *clear and convincing evidence* of a contrary legislative intent should the courts restrict access to judicial review.”<sup>123</sup>

Reflecting this strong presumption that review will be available, the cases have tended to interpret narrowly the two circumstances in which the APA explicitly denies review: when an organic “statute . . . preclude[s] review” or when “agency action is committed to agency discretion by law.”<sup>124</sup> *Abbott's* recognition of a strong norm of judicial review—to be departed from only in demonstrably exceptional instances—has proved remarkably durable. Indeed, in a unanimous 1986 opinion that explicitly reaffirmed much of *Abbott's* language, the Supreme Court firmly grounded the “modern presumption of judicial

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120. See 5 U.S.C. §§ 701-706 (1994).

121. See *id.* § 704.

122. See 387 U.S. 136, 140-41 (1967) (internal quotes omitted).

123. See *id.* (emphasis added; internal quotes omitted).

124. See 5 U.S.C. § 701(a)(1) (1994), (a)(2). See, e.g., *McNary v. Haitian Refugee Center*, 498 U.S. 479 (1991); *Traynor v. Turnage*, 485 U.S. 535 (1988).

review” in *Marbury v. Madison* and described it as a constitutive element of “a government of laws and of principle.”<sup>125</sup>

There is, however, a deep ambivalence in contemporary reactions to judicial review. While courts and many commentators see APA review as essential to the legitimacy of the administrative state,<sup>126</sup> others perceive review as a prime contributor to regulatory ossification. Scholars examining both specific regulatory programs and general regulatory trends have charged that the current practice of APA review entails such inevitable delays and such appreciable risks of at least temporary reversal that agencies are abandoning rulemaking in favor either of more ad hoc and covert forms of regulation, or of inaction.<sup>127</sup> From this perspective, judicial review is altering agency behavior in ways that diminish regulatory rationality, efficacy, and transparency or that jeopardize the energetic accomplishment of the agency’s statutory mission.

### B. *Standards of Judicial Review Under the APA*

Both the legitimating and the ossifying potential of APA review stem from section 706, the directions on scope of review. This section identifies certain sorts of alleged errors that can be inquired into by a reviewing court: e.g., whether agency action is “unlawfully withheld or unreasonably delayed;”<sup>128</sup> “contrary to constitutional right, power, privilege, or immunity;”<sup>129</sup> “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;”<sup>130</sup> or “without observance of procedure required by law.”<sup>131</sup> With respect to an agency’s factual and policy determinations, section 706 provides three possible standards of review: arbitrary and capricious, substantial evidence, and de novo review.<sup>132</sup> Due to a combination of textual direc-

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125. See *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986) (Rehnquist, J., not participating), quoting *United States v. Nourse*, 34 U.S. 9 Pet. 8, 28-29 (1835).

126. In addition to Bowen, see, for example, *INS v. Chadha*, 462 U.S. 919, 953 n. 16 (1983); *Yakus v. United States*, 321 U.S. 414, 426 (1944); *Amalgamated Meat Cutters & Butcher Workmen of North America, AFL-CIO v. Connally*, 337 F.Supp. 737, 746 (D.D.C. 1971); LOUIS JAFFE, *JUDICIAL CONTROL OF ADMINISTRATIVE ACTION* 320 (1965).

127. See e.g., JERRY L. MASHAW & DAVID L. HARFST, *THE STRUGGLE FOR AUTO SAFETY* (1990); Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1453 (1992); Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59 (1995).

128. See 5 U.S.C. § 706(1).

129. 5 U.S.C. § 706(2)(B).

130. 5 U.S.C. § 706(2)(C).

131. 5 U.S.C. § 706(2)(D).

132. See 5 U.S.C. §§ 706(2)(A), (2)(E), and (2)(F).

tion and judicial gloss, the latter two standards play a relatively small role in shaping contemporary judicial review of rulemaking.<sup>133</sup> The real workhorse of APA review is section 706(2)(A)'s direction that the reviewing court "shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>134</sup>

Behind the deceptively simple language of section 706(2)(A) lies a complex judicial practice that defies easy description—or outcome-prediction. Pre-APA Supreme Court precedent had suggested that arbitrary and capricious review of administrative action might resemble the highly deferential "rationality" review of legislative actions challenged under the equal protection or due process clauses.<sup>135</sup> The landmark 1971 decision in *Overton Park* firmly rejected that possibility.<sup>136</sup> A unanimous Court interpreted section 706(2)(A) review as entailing multiple inquiries: whether the agency properly understood its statutory directives; whether its decision was based on "consideration of the relevant factors"; whether it made a "clear error of judgment."<sup>137</sup> Equally important, the context for each of these inquiries is what the agency *in fact* did and said about its reasons, in light of the material *actually* before it at the time of its action—no post-hoc rationalizations by the agency or its counsel, no new supporting material brought in at the point of review, and no hypothesizing what factual conclusions or policy objectives a "rational" rulemaker might have had in mind.<sup>138</sup>

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133. The Court has characterized these two standards as available in only "narrow" circumstances. See *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 414 (1971). Section 706(2)(E) specifies substantial evidence review for agency proceedings conducted "on the record" – i.e., formal adjudication or the rarely-used formal rulemaking. Some organic statutes also provide for substantial evidence review, typically as part of a package of hybrid rulemaking procedures. See, e.g., *FTC Improvement Act of 1975*, 15 U.S.C. § 57a (1994). Even in proceedings that trigger substantial evidence review, there is a judicial tendency to employ this standard for *factual* issues, while using the arbitrary and capricious rubric for reviewing policy judgments and inferences. See, e.g., *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 31 (1983).

134. See 5 U.S.C. 706(2)(A).

135. See, e.g., *Pacific States Box & Basket Co. v. White*, 296 U.S. 176, 186 (1935) (rejecting, in the context of a constitutional challenge, the argument that administrative rules ought bear a more rigorous burden on review than legislative enactments: "Where the regulation is within the scope of authority legally delegated, the presumption of the existence of facts justifying its specific exercise attaches alike to statutes . . . and to orders of administrative bodies . . .").

136. See *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971).

137. See *id.* at 416.

138. See *id.* at 419-20.

Ultimately, however, *Overton Park* was more successful in establishing what section 706(2)(A) review is *not* (i.e., mere rationality review), than in specifying a clear blueprint for what it is. Indeed, the opinion's description of the process is highly problematic. On the one hand, the agency's decision "is entitled to a presumption of regularity."<sup>139</sup> On the other hand, "that presumption is not to shield [the agency's] action from a thorough, probing, in-depth review."<sup>140</sup> The reviewing court is "to engage in a substantial inquiry,"<sup>141</sup> and the "inquiry into the facts is to be searching and careful."<sup>142</sup> But, at the same time, "the ultimate standard of review is a narrow one," and "[t]he court is not empowered to substitute its judgment for that of the agency."<sup>143</sup>

Given such mixed signals from the Supreme Court, it is not surprising that the contemporary practice of arbitrary and capricious review is more accurately conceptualized as a spectrum rather than a unitary standard. At one end of this spectrum is a fairly deferential form of review illustrated by the 1983 *Baltimore Gas & Electric* decision, in which the Supreme Court finally rejected a long and determined challenge to nuclear power plant development emphasizing that technical issues should often be left to agency experts rather than be scrutinized by the courts.<sup>144</sup>

In this more deferential mode of section 706(2)(A) review, the court's role is seen as "limited, albeit important"; the agency's decision may be set aside "only for substantial procedural or substantive reasons as mandated by statute."<sup>145</sup> Agency rules often address issues about which knowledge is limited and uncertainty prevails. Judicial review seeks to recognize such limitations by requiring that the agency's findings be supported by "a body of reputable scientific [or other] thought."<sup>146</sup> The agency's expertise, and the complexity and uncertainty of the regulatory task, are emphasized<sup>147</sup> and the court's "only task is to determine whether the [agency] has considered the

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139. *See id.* at 415 (citing *Pacific States Box*, 296 U.S. at 185).

140. *See id.*

141. *See id.* at 403.

142. *Id.* at 416.

143. *See id.*

144. *See Baltimore Gas & Elec. Co. v. NRDC, Inc.*, 462 U.S. 87 (1983); *see also Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.*, 435 U.S. 519 (1978).

145. *See Baltimore Gas*, 462 U.S. at 97 (quoting *Vermont Yankee*, in part).

146. *See Industrial Union Dept. AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 659 (1980).

147. *See Baltimore Gas*, 462 U.S. at 103.

relevant factors and articulated a rational connection between the facts found and the choice made.”<sup>148</sup> “Minor” ambiguities in what the agency did are harmless<sup>149</sup> while the assessment of whether the administrative outcome is “within the bounds of reasoned decision-making” focuses on the agency’s overall methodology and is willing to net out strengths and weaknesses of particular strands of its decision.<sup>150</sup>

At the other end of the spectrum is the vigorous vetting of “hard look” review. Developed and practiced most fully by the federal courts of appeals, this mode of arbitrary and capricious review was used by the United States Supreme Court in another 1983 decision, *Motor Vehicles Manufacturers Association v. State Farm*, which invalidated the U.S. Department of Transportation’s rescission of its automotive passive restraint rule.<sup>151</sup> “Hard look” review examines whether the “agency has relied on factors which Congress intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”<sup>152</sup>

In theory, hard-look review asks whether the agency took a hard look at the issues; in practice, the court takes a hard look at how the agency worked its way through the regulatory problem.<sup>153</sup> Specifically, for the agency to overcome the challenge that its action was “arbitrary, capricious, or an abuse of discretion,” it must demonstrate a decisional process of diligent data collection and revelation, careful identification of significant facets of the problem and consideration of possible alternative solutions, and lucid explanation of its assumptions, conclusions, and judgments.

The rigorousness of the review evinces a concern that variables be accounted for, that the representativeness of test conditions be ascertained, that the validity of tests be assured and the statistical significance of results determined. Collectively, these concerns have

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148. *See id.* at 105.

149. *See id.* at 108.

150. *See id.* at 105.

151. *See* 463 U.S. 29 (1983).

152. *See id.* at 43.

153. *See* *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851 (D.C. Cir. 1970) (“The function of the court is to assure that the agency has given reasoned consideration to all the material facts and issues. This calls for insistence that the agency articulate with reasonable clarity its reasons for decision, and identify the significance of the crucial facts. . .”).

sometimes been expressed as a need for “reasoned decision-making” and sometimes as a need for adequate “methodology.” However expressed, these more substantive concerns have been coupled with a requirement that assumptions be stated, that process be revealed, that the rejection of alternate theories or abandonment of alternative courses of action be explained and that the rationale for the ultimate decision be set forth in a manner which permits the public to exercise its statutory prerogative of comment and the courts to exercise their statutory responsibility upon review.<sup>154</sup>

Thus, the focus is not on whether the court reviewing the agency rule agrees with the rule or reasons given, but rather on whether there is a reasonable basis for the agency judgment and an indication that it was a product of careful work. For this reason, both the agency process and its stated reason for the rule are critical to surviving “hard look” review. Hard look epitomizes both the legitimating and the ossifying capacity of judicial review.

The combination of *Baltimore Gas* and *State Farm* stands as a warning against facile descriptions, or predictions, about the course of section 706 review—the Supreme Court resolved two highly significant and hotly controverted rulemakings, in the space of just over two weeks, through two modes of review that shared little other than the label “arbitrary and capricious.” Perhaps the most useful way of viewing the complexity of APA review is to recognize it as emblematic of a tension inherent in a body of administrative law that attempts, simultaneously, both to facilitate and to check regulatory government.

### C. *The Limitations of Judicial Review*

Although the reviewing court acts as a check on agency rule-making to ensure that the rule stays within proper bounds, the court is supposed to stay within its own bounds and not substitute its judgment for that of the agency. Policymaking is not a function of judicial review; it is instead the province of the legislative and executive branches. Excessive judicial review then not only intrudes on this province of the other branches, but it can also disrupt sound agency governance and coherent agency regulation, as agency rules often address technical issues about which knowledge is limited and uncertainty prevails.

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154. See *National Lime Ass'n. v. EPA*, 627 F.2d 416, 452-53 (D.C. Cir. 1980).

Judicial review is not a speedy or inexpensive process, and regulated parties and agencies often settle matters because events cannot wait. As noted earlier, the legal system is generally willing to overlook these disadvantages because properly applied judicial review, despite its “limited office,” can be a powerful yet disciplined safeguard for curbing rulemaking excesses. In certain situations, however, the balance of interests weighs differently, and judicial review is *not* available. For example, courts do not normally supervise foreign policy, nor the Federal Reserve Board’s regulation of the nation’s money supply, although both of these governmental functions are vitally important to the welfare of the nation. Similarly, agencies’ choices about which entities to proceed against as enforcement targets,<sup>155</sup> and about how to spend lump-sum appropriations,<sup>156</sup> are largely unreviewable. In all of these areas, courts have elected to forego whatever advantages might flow from the presence of a judicial check, because of doubts about the courts’ competence to evaluate the relevant administrative judgments, or reservations about the practical burdens of judicial review.

These enclaves of governmental action are, of course, remote from the context of major rulemaking activity. Judicial review of significant environmental, health, or safety regulations has always been readily available. Even in that context, however, some *aspects* of the agency’s decision-making process are normally exempt from judicial scrutiny. A court will not, for example, “review” whether an agency spent too much on a major rulemaking proceeding, or whether it deployed its rulemaking staff in an inefficient manner.

In this connection, it is important to bear in mind that judicial review is only one of a number of control mechanisms that government uses to rein in the bureaucracy. Presidents exert influence over rulemaking in numerous ways, such as through their choices of the agency’s top leadership, through budget requests, and through intangible exercises of the power of persuasion to promote the objectives of “the Administration.” Executive oversight of significant rulemaking proceedings has in recent years been formalized in the OIRA review process.<sup>157</sup>

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155. See, e.g., *Heckler v. Chaney*, 470 U.S. 821 (1985) (holding that there is a presumption of unreviewability of an agency’s decision not to undertake enforcement action).

156. See, e.g., *Lincoln v. Vigil*, 508 U.S. 182 (1993) (holding that an agency’s program decision was not subject to judicial review under the APA).

157. See Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 3 (1995).

Congress, for its part, also has at its disposal a wide variety of tools for reviewing and reacting against rulemaking initiatives, ranging from informal devices such as correspondence and committee oversight hearings to more formal actions such as bills for periodic reauthorization of agency mandates, appropriations, and budget measures. Pursuant to the recently enacted Congressional Review Act,<sup>158</sup> Congress has an opportunity to review every major rule before it goes into effect.<sup>159</sup>

Given the presence of political oversight, it should not be surprising that some of the analytical steps that agencies are required to take as they reach a complex decision have been shielded from judicial scrutiny, largely because of a belief that these phases of the decision-making process are better suited to enforcement by the political branches. Particularly relevant to the subject matter of this report is the example of Executive Order 12866 and its predecessor.<sup>160</sup> The Clinton order prescribes extensive guidelines for cost-benefit analysis of significant rules, but goes on to admonish: “This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States . . . .”<sup>161</sup> Almost identical language appeared in the Reagan order.<sup>162</sup> Courts have consistently respected these admonitions, declining to allow any private enforcement of these presidential directives.<sup>163</sup> Presumably the executive order’s requirements would have been drafted very differently had the authors anticipated judicial enforcement of those requirements.

Legal requirements that are intended to structure deliberations as between the agencies and Congress have also been deemed judicially unreviewable. Congress frequently directs an agency to submit a report or make a finding for transmission to the legislative branch on a subject within the agency’s purview.<sup>164</sup> Private interests have occasionally sought APA review of these agency pronouncements, con-

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158. See Congressional Review Act of Agency Rulemaking, 5 U.S.C. §§ 801-808 (1994).

159. See *id.* § 801.

160. See Exec. Order No. 12866, 3 C.F.R. 638, 649 (1993), *reprinted in* 5 U.S.C. § 601 history (Supp. 1993); the predecessor Order was Exec. Order No. 12291.

161. See *id.*

162. See Exec. Order No. 12291, 3 C.F.R. 128, 133-34 (1981), *reprinted in* 5 U.S.C. § 601 history (1988).

163. See, e.g., *Michigan v. Thomas*, 805 F.2d 176, 187 (6th Cir. 1986).

164. See, e.g., *Guerrero v. Clinton*, 157 F.3d 1190, 1191 (9th Cir. 1998).

tending that they are incomplete or inaccurate.<sup>165</sup> Naturally, they rely on the *Abbott Labs* presumption of reviewability, but to no avail—the courts have treated the reporting requirements as unsuitable for judicial enforcement.<sup>166</sup>

The general point is that, as society continues to invent new tools for keeping administrators within acceptable bounds, the question of whether, on balance, judicial review is an appropriate means for implementing a given mechanism is fundamentally a prudential matter. The APA model of review works well within its own sphere, but it may or may not be well suited for application in fresh contexts. The presumption of reviewability is a starting point, but it is not dispositive.

## V. S. 981: ANALYSIS AND COMMENTARY

### A. *Judicial Review of Regulatory Analysis*

While judicial review is often controversial, neither the proponents nor the opponents of agency rules would do away with it entirely. Accordingly, judicial review must be treated with care in any legislation requiring risk assessment and cost-benefit analysis. S. 981 exemplifies the tendency of such legislative initiatives to impose multiple analytical requirements (e.g., various “best practices” of risk assessment and cost-benefit analysis)<sup>167</sup> as well as multiple institutional requirements (e.g., independent peer reviews of agency risk assessments and cost-benefit analyses).<sup>168</sup> Mandating such measures through legislation will invite stakeholders with interests in agency actions to challenge agency compliance with these criteria by instigating judicial review. As a result, the legislative approach taken toward judicial review of agency analyses will influence the nature and extent of subsequent litigation involving agencies and stakeholders.

Previous proposals of the 104<sup>th</sup> Congress generally followed the ordinary rules for judicial enforcement of congressional requirements on agencies.<sup>169</sup> Compliance with analytical and institutional requirements would be subject to judicial review in connection with review

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165. *See, e.g.*, *Guerrero v. Clinton*, 157 F.3d 1190 (9th Cir. 1998); *Taylor Bay Protective Ass'n v. EPA*, 884 F.2d 1073, 1080-81 (8th Cir. 1989); *NRDC v. Hodel*, 865 F.2d 228, 316-19 (D.C. Cir. 1988).

166. *See id.*

167. *See* Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 623(b)(2)(1998).

168. *See id.* §§ 624-25.

169. *See* Comprehensive Regulatory Reform Act of 1995, S. 343, 104th Cong. (1995).

of compliance with other provisions of law for final agency actions. In order to avoid unnecessary remands of agency rules, the legal doctrines of harmless error and relevance would apply to agency compliance with analytical requirements. However, courts would have been authorized to remand a rule in whole or in part, stay the effectiveness of a rule, or compel compliance with law as a response to violation of these provisions. The Clinton Administration raised concerns that this legislative approach could lead to extensive and unduly burdensome litigation against agencies.<sup>170</sup>

Two conceptually distinct approaches may avoid the potential administrative paralysis which judicial review of regulatory analysis requirements might otherwise create. One approach is to maintain judicial review as currently available under the APA, but legislate only the minimum critical set of analytical and procedural requirements that would be subject to judicial review independent of a challenge to the final rule. This approach presents a challenge to the relevant scientific communities by requiring them to recommend a limited number of requirements that will assure agency analyses of diverse issues meet an acceptable level of quality and transparency—a level that is itself difficult to define. The second approach is to maintain a larger number of analytic and procedural requirements but restrict or eliminate the opportunity for judicial review of each of these specific requirements except insofar as they are relevant to review of a final rule under current law. This approach poses a challenge to members of the legal community because it requires them to acquiesce in special changes to the established regime of judicial review under the APA that has generally proven to be workable.

The drafters of S. 981, in collaboration with the Clinton Administration, elected the second course for addressing concerns about unproductive litigation.<sup>171</sup> The compromise appears to be a workable one, although its language (particularly that of section 627) needs further clarity so as not to unravel the dominant approach to judicial review of agency activities that has evolved under the APA and which section 623 arguably seeks to preserve. As indicated, in its current form, section 627 permits significant disagreement regarding the extent to which judicial review would be limited or altered from that which is currently available under the APA.<sup>172</sup> Thus, if an agency's

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170. See Cass R. Sunstein, *Congress, Constitutional Moments, and the Cost-Benefit State*, 48 *STAN. L. REV.* 247, 278 (1996).

171. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 627 (1998).

172. See *id.*

inadequate regulatory analysis would have been grounds for judicial reversal under existing law (i.e., the APA or an agency's authorizing statute), it seems to be the intent of S. 981's authors to preserve such opportunity for judicial scrutiny under section 623. Despite this objective, when sections 623 and 627 are read in conjunction, it is not at all clear that the language employed secures the intended result.<sup>173</sup>

Moreover, a drawback of the current compromise is that it is likely to stimulate additional litigation on the distinction between an agency's "failure to perform" the required analysis or review and the "adequacy" of an agency's compliance with such required analysis or review.<sup>174</sup> How is a court to distinguish inadequate compliance from failure to perform? What may seem to be a clear conceptual distinction might prove to be murky when specific technical reports or reviews that were performed by agencies are challenged and scrutinized. In Table 2 we have described three hypothetical cases that might be difficult to resolve under the terms of the modified version of S. 981.

**Table 2:**  
**Potential Litigation Issues Concerning**  
**the Distinction between "Failure to Perform" under S. 981**  
**and "Inadequate Compliance" with the Requirements of S. 981**

***Case #1***

An agency's regulatory analysis includes an extensive analysis of a rule's costs but includes no analysis of the rule's benefits, except for several qualitative statements about how the rule might reduce pollution. Has the agency "failed to perform" a cost-benefit analysis?

***Case #2***

An agency's health risk assessment includes an extensive analysis of the potential hazards of a new technology, but does not address whether human exposure to the technology under real-world conditions would be likely to cause adverse health effects. Has the agency "failed to perform" a risk assessment? Would § 627(e) preclude review of this "inadequate" assessment?

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173. *See id.* §§ 623, 627.

174. *See id.*

**Case #3**

An agency decides, on grounds of equity, to promulgate a rule whose benefits do not justify its costs. The agency's cost-benefit determination considered only one "flexible alternative" to the final rule. Petitioners argue that one or two other flexible alternatives should have been considered, especially since commentators in the record proposed them. Did the agency "fail to perform" the cost-benefit determination when it did not consider more than one flexible alternative? Or was this simply a case of inadequate compliance that does not justify judicial reversal under S. 981?

Some Workshop participants would therefore prefer that the sponsors of S. 981 and the Administration reconsider the limitations on judicial review that have been negotiated. These limitations are a departure from the current APA judicial review that Congress has not deemed to be necessary in other legislative contexts.<sup>175</sup> According to this view, current APA judicial review has proven to be workable, will offer some predictability to agencies and stakeholders, and is not clearly inapplicable to the analytical and institutional requirements included in S. 981. If there are too many requirements in S. 981 to permit APA-style review (without creating dysfunctional litigation), then the proper drafting solution may be to limit the number of requirements to those that are critical to the quality and transparency of an analysis or review. In this regard, it is interesting that the analytical requirements in the recent amendments to the Safe Drinking Water Act are more concise than the requirements in S. 981.<sup>176</sup> Having made this suggestion, these same Workshop participants emphasize that the compromise struck in response to Administration concerns—while not ideal or preferable—is certainly a reasonable one that could ultimately be worked out by agencies and courts.

On the other hand, there are some Workshop participants who prefer the compromise negotiated with the Administration and are skeptical about the alternative approach just described. The argument that APA judicial review has proven to be workable may not be applicable to the lengthy and technically challenging provisions of S. 981, provisions that are certainly more specialized than the procedural requirements for rulemaking in APA section 553. Thus, in these participants' view, even if the specifications in S. 981 were dras-

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175. See Safe Drinking Water Act Amendments of 1994, H.R. 3992, 103rd Cong. § 6(c)(5) (1994) (APA review was applied to the risk assessment and cost-benefit requirements included in the recent amendments to the Safe Drinking Water Act).

176. See *id.*; cf. Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 627 (1998).

tically edited down, wide-open reviewability of such specifications would open up the prospect of a substantial increase in litigation, sometimes before judges who may lack the expertise to apply the criteria reliably. Furthermore, these participants would argue such a curtailment of the S. 981 requirements would tend to defeat the sponsors' goal of codifying in statutory form a relatively complete summary of the "best practices" followed by sophisticated practitioners of cost-benefit analysis and risk assessment.

Finally, these participants, who prefer the Clinton Administration compromise, would suggest that the problem of distinguishing between "failure to perform" and "adequacy of performance" under the S. 981 model may well prove less daunting than the above discussion would seem to indicate. They reason as follows: As rulemaking agencies learn to adapt to a S. 981 world, the most common complaint about these agencies' cost-benefit analyses and risk assessments will be that such studies are superficial, or that they are slanted in the direction the agency prefers—not that they contain the sort of conspicuous omissions that would give rise to a strong contention that the agency "failed to perform" the required analysis. An agency is unlikely to leave such glaring gaps in its stated justification for a major rule, because it invites reversal under the existing hard look standard if it ignores significant comments or has "entirely failed to consider an important aspect of the problem."<sup>177</sup> Of course, a given reviewing court might prove to be quite deferential, in the manner of *Baltimore Gas*, but the agency has strong incentives not to gamble on that eventuality.<sup>178</sup> In practice, the "failure to perform" clause of section 627(d) is most likely to come into play where an agency claims to be *exempt* from S. 981 requirements and thus does not even purport to have observed them.<sup>179</sup> Thus, in the view of these Workshop participants, the S. 981 approach to judicial review does not pose major problems of manageability.

#### B. *Applicability of Risk Assessment Principles to "Free Standing" Risk Assessments under S. 981*

Agencies are increasingly looking for ways to accomplish regulatory goals through informational approaches that do not entail a major rulemaking. One possible approach is the publication of an offi-

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177. See *Motor Vehicles Mfrs. Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 43 (1983).

178. See *Baltimore Gas & Elec. Co. v. NRDC, Inc.*, 462 U.S. 87, 103 (1983)

179. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 627(d) (1998).

cial risk assessment report, in which an agency may conclude that a risk is significant, insignificant, or cannot yet be evaluated given available data. Informational approaches are useful because they can make the public aware of significant risks and thereby stimulate protective decision-making, they can reassure the public that alleged hazards do not represent a significant risk, or they can stimulate the scientific community to generate missing data that are required to complete a risk assessment.

Agency risk assessments can have important ramifications outside of a federal rulemaking context. Information from federal agency risk assessments is widely used in society by journalists and reporters, consumers and producers in the marketplace, other federal agencies, state and local regulatory officials, international agencies, foreign governments, and by litigants in liability lawsuits.<sup>180</sup> We use the phrase “free-standing” risk assessments to refer to final, official risk determinations by agencies that are not published as part of a major rulemaking.

The authors of S. 981 recognized that, where free-standing risk assessments published by agencies may have the effect of major rules,<sup>181</sup> they should typically be grounded in sound scientific principles. An agency may choose to publish a free-standing risk assessment for a variety of reasons:

- the agency may lack rulemaking authority or the resources required to perform a rulemaking;
- the risk may be judged to be too localized or insignificant to justify a rulemaking;
- the risk may not be effectively controlled without international agreements;
- the risk may be regulated under delegated state programs; or
- the risk is not addressed best through a rulemaking..

It is therefore reasonable to expect federal agencies to publish important risk assessments that are not a part of a federal rulemaking process. Despite the importance of free-standing risk assessments, a close reading of S. 981 reveals that the bill does not provide new procedures or special judicial protection to those citizens whose interests are harmed or may be harmed in the future by a free-standing risk as-

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180. See *The Regulatory Improvement Act of 1997: Hearing on S. 981 Before the Committee on Governmental Affairs*, 105<sup>th</sup> Congress, 41-43 (1997) (statement of John D. Graham, Director and Professor, Harvard Center for Risk Analysis).

181. See *Regulatory Improvement Act of 1998*, S. 981, 105th Cong., § 624 (a)(1)(A)(ii) (1998).

assessment that is not based on sound principles of risk assessment.

Section 624(a)(1)(A)(ii) of S. 981 authorizes the Director of OMB to apply the “principles for risk assessment” in section 624 to “any risk assessment that is not the basis of a rulemaking that the Director reasonably anticipates is likely to have an annual effect on the economy of \$100 million or more in reasonably quantifiable costs and that the Director determines shall be subject to the requirements of this section.”<sup>182</sup> Since the free-standing risk assessment is not a regulatory action, it may be difficult or impossible to gauge its monetary impact. It should also be noted that section 627(c) forecloses any judicial review of the Director’s judgment as to what constitutes a “major rule,” but the bill does not explicitly preclude judicial review of a Director’s decision to apply (or not to apply) the principles of section 624 to a free-standing risk assessment.<sup>183</sup> Thus it appears, based on the structure of sections 624 and 627, that the authors of S. 981 may have meant to allow such review by the courts.<sup>184</sup> If not, section 627(c) should specifically refer to the Director’s determination in section 624(a)(1)(A)(ii).<sup>185</sup> Moreover, section 627(d) appears to preclude review of a free-standing risk assessment that is not part of a rulemaking—it limits review of “any risk assessment” to review as part of a final rule.<sup>186</sup> And section 627(a)(2) limits review to the terms of section 627.<sup>187</sup> Thus, judicial review of free-standing risk assessments, although currently available in some cases<sup>188</sup> may (whether intentionally or inadvertently) be prevented by S. 981.

It is not always appropriate to use the courts as a check on abuse of executive branch discretion. Congress, through oversight activity, can identify agency abuses, and where appropriate, use powers of persuasion, appropriation, and/or authorization to rectify an abuse. Yet Congress lacks the requisite sustained focus and technical resources to be a completely dependable and effective force for quality in risk assessment. The OMB Director can, in certain circumstances, be a useful check on agency powers that are exercised without sufficient regard for science and economics. OMB staff have a particu-

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182. See Regulatory Improvement Act of 1999, S. 746, 106th Cong. § 624(a)(1)(A)(ii) (1999) (The 1998 version of the Regulatory Improvement Act, S. 981, contains similar language).

183. See *id.* § 627(c).

184. See *id.* §§ 624(a)(1)(A)(ii), 627(c).

185. See *id.*

186. See *id.* § 627(d).

187. See *id.* § 627(a)(2).

188. See, e.g., *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 4 F. Supp. 2d 435 (M.D. N.C. 1998).

larly strong background in economics and have accumulated a wealth of experience reviewing regulatory analyses submitted by agencies under the authority of presidential executive orders.

Yet some Workshop participants question the wisdom of giving the OMB Director complete control over whether a free-standing risk assessment is subject to the “principles for risk assessment” in section 624.<sup>189</sup> Perhaps more importantly, they are also concerned about precluding judicial review of whether a free-standing risk assessment complies with section 624’s principles for sound risk assessment practice.<sup>190</sup> In the final analysis, these participants note, the agency head and the Director are political officials in the Executive Office of the President who, like most agency heads, serve at the pleasure of the President of the United States. It is not difficult to imagine circumstances in which political pressures may induce an agency head, the OMB Director, and even Congress and the White House to seek (or permit) publication of an official risk assessment report, even though that report is not grounded in the principles of sound risk assessment.

For example, it has been suggested that the British government, under pressure from the agricultural sector of the economy, issued a poorly grounded statement that bovine spongiform encephalopathies (BSE) did not represent a risk to the beef supply of Britain and Europe.<sup>191</sup> Alternatively, in a rush to respond to public fears about the potential risks of a new or unpopular technology (e.g., future biotechnology products), officials in the White House and Congress may see political value in a risk assessment report that exaggerates the risk of the biotechnology. In the view of some Workshop participants, it is precisely such circumstances that call for the judicial branch of government to offer checks and balances to the analytical system outlined in S. 981. Judicial review of a very similar set of risk assessments—the environmental impact statements required of federal agencies under NEPA<sup>192</sup>—has a long and respectable pedigree. It is not clear why risk assessment should be reviewable under NEPA but not reviewable under S. 981.<sup>193</sup>

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189. See Regulatory Improvement Act of 1999, S. 746, 106th Cong. § 624(a)(1)(A)(ii) (1999). (The 1998 version of the Regulatory Improvement Act, S. 981, contains similar language).

190. See *id.* § 627(d).

191. See John Darnton, *London Adamant as European Nations Ban British Beef*, N.Y. TIMES, March 26, 1996.

192. See National Environmental Policy Act, 42 U.S.C. § 4332(c)(i) (1994).

193. See *id.*

Moreover, these participants would suggest that some opportunity for judicial review of whether free-standing risk assessments under S. 981 have complied with key risk assessment principles would be an appropriate use of the power of judicial review in modern administrative government. It is of course inappropriate for a reviewing court to substitute its technical judgment for the judgment of the expert administrative agency; federal courts are generally inclined to defer to agency judgments on scientific and technical matters, unless the agency's technical judgements are clearly erroneous or are outside a "zone of reasonableness."<sup>194</sup> Reluctance to extend judicial review to agency risk-determinations may be rooted, at least in part, in the fact that the analytical requirements in section 624 are perhaps more numerous and prescriptive than is necessary and appropriate.<sup>195</sup>

Although there may be value in limited judicial review of free-standing agency risk determinations, the proponents of such review are also sensitive to concerns that agencies responsible for protecting health, safety, and the environment should not be subject to multiple, interlocutory challenges. If an agency's risk assessment is clearly part of a well-defined rulemaking process, then courts should be expected to consolidate challenges to the risk assessment with any other challenges to the final rule at the end of the rulemaking process. If a court has already heard and resolved challenges to a final agency risk assessment, it would not typically be appropriate for a court to rehear these risk assessment challenges in a subsequent rulemaking by the agency—a rulemaking that was presumably not anticipated to occur when the agency's risk assessment was published. In cases where an agency has proposed a risk assessment and intends to issue a final risk assessment, judicial review would normally be appropriate at the stage of the final risk assessment (assuming a major rulemaking is not also in progress, in which case publication of the final rule would be the appropriate time for legal challenges). Courts can handle these choices through doctrines of "the law of the case" and "ripeness"<sup>196</sup> without need for torturing the language of S. 981.

On the other hand, some of the other Workshop participants disagree with the foregoing recommendations. They believe that if courts are to refrain from reviewing the Director's designation of a

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194. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 627(d) (1998) (judicial review for cost-benefit analysis only available on the "arbitrary, capricious, [or] an abuse of discretion" standard).

195. See *id.* § 624.

196. See *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 727-28 (1998).

particular rule as “major” (or his failure to make that designation), the same should be true when the Director designates a free-standing risk assessment as appropriate for S. 981 analysis (or fails to make that designation). Indeed, they note, S. 981 expressly precludes judicial review of OIRA’s rulemaking oversight functions taken as a whole.<sup>197</sup> The bill parallels current law in this respect; notwithstanding *Abbott*, courts do not engage in direct review of OIRA oversight today.<sup>198</sup> Presumably this judicial self-restraint rests on the notions that OIRA review is an integral part of the President’s oversight responsibilities, and that the actual regulatory authority rests with the agency, which of course is subject to traditional APA review. The bill’s preclusion of review of OIRA’s actions may or may not be wise, but these participants see no basis for carving out a special exception for free-standing risk assessments. Surely, these participants assert, there is no reason to believe that free-standing risk assessments tend to be *more* threatening to private interests than are substantive rules, which have the force of law. Yet it is important to recognize that agency powers to assess risks are not currently subject to the same degree of administrative and judicial review that is applicable to major rules. Thus, people who are harmed by agency risk assessments have less recourse than those who might be harmed by a rule. If judicial review of free-standing risk assessments is judged to be inappropriate or ineffective, it may be worthwhile to buttress OIRA’s review capabilities in this area.

Despite their disagreement on some issues, the Workshop participants as a whole note that some legal protection against agency use of unsound risk assessment practices may already exist under the general provisions of the Administrative Procedure Act.<sup>199</sup> There are a few rare instances where the federal courts have been persuaded that an agency risk assessment amounts to “final agency action,” making some review by the judiciary appropriate. One such case involving the EPA’s risk assessment of environmental tobacco smoke is currently being heard in a federal appeals court.<sup>200</sup> Our reading is that

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197. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 624 (1998).

198. See *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140-41 (1967).

199. See Administrative Procedure Act, 5 U.S.C. § 706(2) (1994).

200. See *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 4 F.Supp. 2d 435 (M.D. N.C. 1998). Elsewhere, however, appellate courts have held that administrative pronouncements that are intended as educational undertakings, and are not intended to alter any legal rights, are not reviewable agency actions. See *Industrial Safety Equip. Ass’n v. EPA*, 37 F.2d 1115, 117-22 (D.C. Cir. 1988); *American Trucking Ass’n Inc. v. U.S.*, 755 F.2d 1292, 1296-97 (7th Cir. 1985).

the authors of S. 981 did not really intend to reduce such protections as may exist under the APA, but the negotiated language is ambiguous at best and could foreclose such judicial review. Thus, we would encourage such review of risk assessment to be clearly allowed in future legislation of this sort.

### C. *Substitution Risks*

In section 623, S. 981 requires a regulatory agency to identify and evaluate “substitution risks” that could result from a major rule when “scientific information” on such risks is “reasonably available” to the agency.<sup>201</sup> “Substitution risk” is defined to be “a reasonably identifiable significant increased risk to health, safety, and the environment expected to result from a regulatory option and [which] does not include risks attributable to the effect of an option on the income of individuals.”<sup>202</sup> This provision reflects concern in the scholarly literature that even well-intentioned regulations often have adverse effects on health, safety, and the environment that could have been prevented through better analysis and creative design of regulatory programs.<sup>203</sup>

Would an agency’s failure to consider such substitution risks be reviewable in court under S. 981? The answer to this question is not entirely clear. In section 623, a “regulatory analysis” includes three components: a cost-benefit analysis, a risk assessment (if required), and an evaluation of substitution risks.<sup>204</sup> Yet the term “substitution risk” is not mentioned in the judicial review section of the bill (section 627), where explicit mention is made of cost-benefit analysis, cost-benefit determination, risk assessment, and peer review.<sup>205</sup> The ambiguity about whether substitution risk is subject to judicial review is an invitation for confusion and possibly unnecessary litigation. We recommend that an agency’s failure to evaluate substitution risks be subject to judicial review under section 627 in a fashion similar to judicial review of an agency’s failure to perform a risk assessment.

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201. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 623 (b)(1)(B)(ii)(2)(C) (1998).

202. See *id.* § 621(11).

203. See e.g. Jonathan Baert Wiener, *Protecting the Global Environment*, in RISK VERSUS RISK 103 (John D. Graham & Jonathan Baert Wiener eds. 1995).

204. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 623 (b)(1)(B)(ii)(2)(A)-(C) (1998).

205. See *id.* § 627(d).

The language in S. 981 also places numerous restrictions on when “risks” induced by regulation are to be considered in a regulatory analysis. The definition of the term itself excludes such risks that are not “reasonably identifiable,” “significant,” and “expected to result” from a regulation.<sup>206</sup> If the risks result from impacts on the incomes of individuals, they are also excluded.<sup>207</sup> Even if each of these exclusions is inapplicable, such risks must be identified and evaluated only when “scientific information” about them is “reasonably available to the agency.”<sup>208</sup> It is not clear what an “evaluation” of such risks would entail. These numerous restrictions on consideration of substitution risks are presumably intended to protect the agency against speculative, poorly grounded claims, but they may also trigger a variety of complicated legal arguments.

Several scholars have proposed a more straightforward approach to legislation about substitution risk.<sup>209</sup> They suggest that the agency be required to demonstrate, to the extent feasible or reasonable, that any countervailing risks created by a rule be justified or outweighed by the reductions in risk expected to result from the regulation—in short, this approach seeks evidence that the regulation will do more good than harm. Instead of placing arbitrary restrictions on the risks to be considered, this approach emphasizes the substitution risks that are large or compelling compared to the risks to be reduced by the regulation. The “to the extent feasible” or “reasonable” proviso is intended to prevent excessive investment by agencies in analysis of countervailing risks. This net-risk test, which has already been employed by several courts,<sup>210</sup> could be considered a part of the “arbitrary and capricious” test that judges normally apply under the APA. It is also part of the definitions of “costs” and “benefits” under section 621 of S. 981. We believe that this approach is worthy of consideration as an alternative to the language in S. 981.

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206. See S. REP. NO. 105-188, at 46 (1998).

207. See *id.*

208. See *id.*

209. See, e.g., Jonathan Baert Wiener, *Managing the Iatrogenic Risk of Risk Management*, 9 RISK: HEALTH SAFETY AND THE ENVIRONMENT 39 (1998); Cass R. Sunstein, *Congress, Constitutional Moments, and the Cost Benefit State*, 48 STAN. L. REV. 247, 288-98 (1996); CASS R. SUNSTEIN, *FREE MARKETS AND SOCIAL JUSTICE*, 298-317 (1997); Edward W. Warren and Gary E. Marchant, *More Good than Harm: a first principle for environmental agencies and reviewing courts.*, 20 ECOLOGY L.Q. 379 (1993). Note, however, that Professor Sunstein does not seek to override any contrary directions from Congress that may be contained in specific regulatory statutes.

210. See, e.g., *Competitive Enterprise Inst. v. NHTSA*, 956 F.2d 321, 324-27 (D.C. Cir. 1992); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1220-27 (5th Cir. 1991).

#### D. *The Role of Peer Review in The Regulatory Process*

S. 981 embodies the general consensus that agency risk assessment and cost-benefit analyses benefit from scientific peer review. Nonetheless, this expert scrutiny should not become a straitjacket for agency decisionmakers, and courts must appreciate the limitations of peer review when asked to review agency regulations that are subject to a risk assessment requirement. Peer review is best understood as a supplement to, rather than a substitute for, existing forms of external scrutiny. It cannot replace notice-and-comment rulemaking procedures or the possibility of judicial review of a regulation. Instead, by offering agency officials a *preview* of likely objections, independent scientific experts can help them anticipate and hopefully minimize weaknesses in a risk assessment or other predicate for a regulation, thereby sharpening subsequent reviews by interested private parties and officials in the three branches of government.

At the outset, legislators should clarify what form(s) of peer review they have in mind. Section 625(b)(1)(A) fails to do so.<sup>211</sup> Commentators generally have endorsed the use of scientific advisory committees or panels by federal administrative agencies.<sup>212</sup> In contrast, some observers have criticized agencies' reliance on editorial peer review as a way of certifying the reliability of information appearing in published scientific articles.<sup>213</sup> Although flexibility allows an agency to calibrate the scope and intensity of peer review in the risk assessment process (as section 625(d) appropriately encourages), misunderstandings may arise about which among the many different forms of scientific peer review were intended by Congress.<sup>214</sup>

Assuming that peer review of agency risk assessments typically will entail eliciting input from some sort of committee of independent experts, one may glean valuable insights about the use of this mecha-

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211. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 625(b)(1)(A) (1998).

212. See Recommendations and Statements of the Administrative Conference Regarding Administrative Practice and Procedure, 50 Fed. Reg. 52,893, 52,896 (1985) (to be codified at 1 C.F.R. pt. 305 & 310); See generally JOHN D. GRAHAM, HARNESSING SCIENCE FOR ENVIRONMENTAL REGULATION (1991); SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS (1990); Thomas S. Burack, Note, *Of Reliable Science: Scientific Peer Review, Federal Regulatory Agencies, and the Courts*, 7 VA. J. NAT. RESOURCES L. 27 (1987); see also General Accounting Office, *Regulatory Reform—Agencies Could Improve Development, Documentation, and Clarity of Economic Analyses*, RCED 98-142, Ch. 2:2.2 (1998).

213. See generally Lars Noah, *Sanctifying Scientific Peer Review: Publication as a Proxy for Regulatory Decisionmaking*, 59 U. PITT. L. REV. 677, 693-711 (1998).

214. See Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 625(d)(1999). (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this provision).

nism from agencies such as the EPA and the FDA, both of which have made extensive use of peer review panels in the last few decades. Although generally regarded as successful, such scientific advisory committees or panels may have only limited utility if their input is not sought until fairly late in an agency's decision-making process. If conducted early in an agency's risk assessment as called for by section 625(g),<sup>215</sup> panel peer review can provide valuable expertise and diverse perspectives, and it can focus attention on data inadequacies in time for corrections.

The CPSC's experience with its chronic hazard advisory panels provides a different cautionary lesson. Legislative overspecification of procedures for peer review, including demands for open meetings and interest group representation (as opposed to disciplinary balance in the composition of the panel), may make the process unduly cumbersome. Section 625(e) exempts required peer reviews from the Federal Advisory Committee Act.<sup>216</sup> Nevertheless, section 625(1)(A)'s requirement that peer review mechanisms be "broadly representative" may inappropriately lead to demands for representation by various stakeholders rather than a diversity of scientific and other technical disciplines.<sup>217</sup> If understood as a structured form of brainstorming by a group of technical experts from different backgrounds, peer review cannot function as effectively if the process becomes overly proceduralized.

For all of its potential advantages, panel peer review has certain significant limitations. No matter how thorough their consideration, independent experts cannot certify the accuracy of an agency's scientific judgments. Some commentators have analogized peer review to an independent audit of a business by an accounting firm, but without the benefit of anything comparable to generally accepted accounting principles (GAAP).<sup>218</sup> This limitation may have particular resonance in the risk assessment field, which some observers have described as a "trans-scientific" exercise, inevitably requiring policy or value judgments.<sup>219</sup> In this sense, peer review seems more apt for the scientific

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215. *See id.* at § 625(g). (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this provision).

216. *See* Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 625(e)(1999) (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this provision).

217. *See id.* at § 625(b)(1)(A).

218. *See* KENNETH R. FOSTER & PETER W. HUBER, *JUDGING SCIENCE: SCIENTIFIC EVIDENCE AND THE FEDERAL COURTS* 180 (1997).

219. *See* Thomas. O. McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 *GEO.*

inputs for a risk assessment (e.g., weight-of-the-evidence evaluations of bioassay results), as done in the Safe Drinking Water Act Amendments of 1996.<sup>220</sup> In addition, independent experts could offer valuable assistance in formulating generic risk assessment guidelines. With regard to specific risk assessments for particular rulemaking initiatives, however, some peer reviewers predictably will disagree about how best to interpret ambiguous research or resolve uncertainties. For that reason, agencies should not feel hamstrung by failures to convince their peer review panels. Just as an editor of a scientific journal retains the prerogative to ignore comments from a referee, agency officials must not cede their power to pursue rulemaking to independent and unaccountable peer reviewers.

Moreover, panel peer review cannot serve as a substitute for notice-and-comment rulemaking procedures with respect to an agency's risk assessment. In a sense, the public comment period represents a continuation of the peer review process. Just as editorial peer review provides only a first cut on the reliability of new research submitted for publication, followed by a less structured but ultimately more important opportunity for post-publication peer review, panel reviews of draft risk assessments cannot provide a definitive seal of approval (or disapproval) of any risk assessment. Instead, like editors can help authors improve a manuscript before publication, panel peer review may help the agency better anticipate adverse public comments. Conversely, the notice-and-comment process does not make prior independent peer review redundant and an unnecessary source of additional delay. Truly disinterested experts do not typically go to the effort of filing comments unless an advocate has hired them for that purpose, and peer review is best understood as a collaborative process where scientists from different disciplines are able to hash out disagreements. This extra effort invested early in the process is likely to provide a net benefit by reducing the prospect of challenges to a regulation that later may trigger time-consuming and resource-draining litigation.

A better compromise would make the peer review panel's report part of the record (as provided by section 625(b)(2)(B),<sup>221</sup> but also instruct courts not to assign it any special weight unless considerations

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L.J. 729, 733 (1979); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1613 (1995).

220. See National Drinking Water Regulations, 42 U.S.C. § 300g-1(b)(3)(A)(i), (B)(v) (1994).

221. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 625(b)(2)(B) (1998).

of expertise and credentials justify such weight. A critical peer review should not necessarily derail the agency when defending a regulation in court, and a favorable peer review should not provide an impenetrable shield against objections pressed by individuals who were not able to present their concerns directly to the peer review panel.

Thus, apart from its contribution to the quality of agency decision-making, independent peer review may affect the course of judicial review in a variety of ways. At one extreme, legislation could invite reviewing courts to enforce strict compliance with new procedural hurdles, such as insisting on what may often be largely duplicative peer reviews of an agency's draft and final risk assessments—something that sections 623(b)(3)<sup>222</sup> and (g)<sup>223</sup> strive to avoid. This may not appreciably improve agency decision-making and could certainly worsen the ossification of rulemaking. Under a more moderate scenario, legislation would strive to minimize the risk of undue judicial scrutiny of compliance with procedural mandates, but courts may come to view these procedural hurdles as codifying a substantive standard for non-arbitrary agency decision-making. If this happens, courts again would engage in “hard look” review for agency decision-making at “the frontiers of science,” a decidedly less deferential stance than courts have announced for such cases.<sup>224</sup> Finally, one can imagine that courts would neither review for compliance with new procedural requirements (leaving that task for other branches) nor adopt a more rigorous stance when engaging in substantive review, but instead undertake substantive review under existing APA standards with the benefit of more complete information and elucidation. Peer review by a panel of scientific experts can help agencies generate and refine such information; it cannot substitute even partially for continued but deferential public and judicial scrutiny of health and safety regulations.

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222. *See id.* § 623(b)(3).

223. *See* Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 625(g) (1999) (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this provision).

224. *See* *Baltimore Gas & Elec. Co. v. NRDC, Inc.*, 462 U.S. 87, 103 (1983) (stressing that, when an agency is making predictions “at the frontiers of science,” “a reviewing court must generally be at its most deferential”); *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1495, 1503 (D.C. Cir. 1986); *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976); *see also*, Patricia M. Wald, *Environmental Postcards from the Edge: The Year That Was and the Year That Might Be*, 26 ENVL. L. REP. 10182, 10188 (1996) (warning that a risk assessment mandate might lead courts to adopt a “checklist mentality”).

### E. *Effect of S. 981 on Existing Statutes*

A central question in the debates over the regulatory reform legislation in the last several Congresses has been whether such legislation would supersede or effectively amend the criteria for regulatory decision-making that prevail under pre-existing statutes. For example, Executive Orders 12991 (Reagan) and 12866 (Clinton) and the Unfunded Mandates Reform Act of 1995, while requiring cost-benefit analyses and decision criteria for the issuance of new federal regulations, expressly limit such requirements "to the extent permitted by law" or "unless otherwise prohibited by law."<sup>225</sup> By contrast, the Bliley bill that passed the House in the 104<sup>th</sup> Congress provided that, "notwithstanding any other provision of federal law," its cost-benefit requirements would "supplement and, to the extent there is a conflict, supersede the decision criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated."<sup>226</sup>

Thus, for example, if the Clean Air Act or Occupational Safety and Health Act called for pollution control standards to be set without regard to cost,<sup>227</sup> the new Bliley bill would nevertheless supersede that criterion with a new cost-benefit decision rule. Advocates of such a provision urged that it would bring consistency and rationality to the hodgepodge of decision criteria that obtain under current statutes and ensure that all federal regulations do more good than harm.<sup>228</sup> Critics worried that such a provision would sweep across too many pre-existing statutes without detailed attention to the context of each, possibly requiring cost-benefit decision criteria even when those criteria would be inadvisable for the particular topic of the rulemaking.

The drafters of S. 981 sought to avoid this debate by compromising on more modest language. S. 981 does not provide that its cost-benefit criteria supersede the criteria in force under existing statutes. Section 623(d)(2) expressly states that an agency may issue a

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225. See Exec. Order No. 12291, 3 C.F.R. 128, 133-134 (1981), *reprinted in* 5 U.S.C. § 601 note (Supp. 1988); Exec. Order No. 12866, 3 C.F.R. 638, 641 (1993), *reprinted in* 5 U.S.C. § 601 note (Supp. 1993); Unfunded Mandates Reform Act 2 USC § 1501 and 5 USC § 801 (1994).

226. See Risk Assessment and Cost-Benefit Act of 1995, H.R. 1022, 104th Cong., § 202(b)(1) (1995).

227. See *Lead Industries Ass'n v. EPA*, 647 F.2d 1130, 1148-50 (D.C. Cir. year), *cert. denied*, 449 U.S. 1042 (1980) (finding costs not relevant to air quality standards set under CAA section 109); *American Textile Mfr. Inst. v. Donovan*, 452 U.S. 490, 506-13 (1981) (disallowing cost-benefit analysis under OSHA § 6(b)(5)).

228. See *Reform of Risk Regulation: Achieving More Protection at Less Cost*, 1 Human and Ecological Risk Assessment Journal 183, 193-96 (1995).

regulation even when the agency determines that the rule's benefits do not justify its costs, or that the rule is not the most cost-effective or net beneficial alternative.<sup>229</sup> The same section provides that in such a situation the agency can issue the rule as long as the agency "explain[s] the reasons for selecting the rule notwithstanding such determination"—and that this explanation shall "identify any statutory provision that required the agency to select such rule."<sup>230</sup> The implication is that a prohibition on the use of cost-benefit decision criteria in a pre-existing statute would not be overridden by the cost-benefit determination in S. 981. Furthermore, section 622(b), as modified, provides that "[n]othing in this subchapter shall be construed to alter or modify—(1) the substantive standards applicable to rulemaking under other statutes. . . ."<sup>231</sup> This "savings clause" gives further credence to the view that S. 981 would not supersede or amend the criteria for regulatory decisions under existing statutes.

Still, a creative litigant might be able to persuade some courts that S. 981 does, at least in part, alter the analysis and even the decision criteria employed by agencies. First, such a litigant would point to the word "substantive" in section 622(b)(1).<sup>232</sup> The inclusion of this word suggests that S. 981 could be read to alter the "non-substantive" standards applicable to rulemaking under other statutes. That is, S. 981 could be read to alter the "procedural" aspects of rulemaking under other statutes. If the requirements in section 623(b) (to analyze the costs and benefits, to perform a risk assessment in accordance with section 624, and to evaluate substitution risks) or the requirement in section 625 (to conduct peer review) can be characterized as "procedural" requirements, then these requirements may be binding on agencies under S. 981 notwithstanding any prohibitions on such activities in pre-existing statutes.<sup>233</sup> Indeed, the Senate Governmental Affairs Committee Report on S. 981 says the requirements of sections 623 and 624 are "procedural" in nature.<sup>234</sup> Moreover, the requirement of NEPA that agencies must analyze the environmental impacts of their major actions, without requiring any change in the ultimate agency decision—which is the clear counterpart to the new analysis

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229. See Regulatory Improvement Act of 1998, S. 981, 105th Cong., § 623 (d)(2) (1998).

230. *Id.* at § 623(d)(2)(A).

231. *Id.* at § 622(b).

232. See Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 622(b)(1) (1999) (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this provision).

233. See *id.* at §§ 623-625.

234. See S. Rep. No. 105-188, at V (Report of Sen. Gov't Affairs Committee, "The Regulatory Improvement Act of 1998—Part V. Section by Section Analysis.")

requirements in S. 981—has long been held to be “essentially procedural” by the Supreme Court.<sup>235</sup>

For example, if section 109 of the Clean Air Act<sup>236</sup> is read to prohibit the EPA from any consideration of cost in setting its ambient air quality standards, and if this prohibition on consideration of cost is characterized as “procedural” rather than “substantive,” then the requirement to analyze costs and benefits in section 623(b) of S. 981 would effectively override the prohibition in CAA section 109.<sup>237</sup> The EPA would still be free to adopt an ambient air quality standard for which the costs outweigh the benefits, if it furnished an explanation as provided in section 623(d) of S. 981.<sup>238</sup> But EPA would now be obliged to analyze the costs and benefits in the first place. Because the “failure to perform” such analyses can support judicial remand or invalidation under section 627(e) of S. 981<sup>239</sup>—just as a failure to perform an EIS could be grounds for a court to issue an injunction under NEPA<sup>240</sup>—the “procedural” requirements of S. 981, like those in NEPA, could have a significant impact on agency practice.

If the drafters of S. 981 did not mean to leave open this route for altering existing statutes, it is unclear why they inserted the word “substantive” in section 622(b)(1).<sup>241</sup> At the least, this word will invite litigation to resolve which pre-existing regulatory strictures inconsistent with S. 981 are “substantive” and which are not. On the other hand, if section 622 is rewritten to “save” all pre-existing statutory provision, then section 623(b) may be rendered ineffectual just where it could have most influence, and S. 981 may have little to no real impact on agency practice.<sup>242</sup>

Second, even if S. 981 were not read to alter the prior “procedural” requirements of existing statutes, litigants could argue that S. 981 supplies new standards for rulemaking where the existing statute lacks such standards. The argument would be that statutes which neither prohibit nor require cost-benefit analysis, but leave the choice to

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235. *See* *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349-54 (1989); *Strycker's Bay Neighborhood Council v. Karlen*, 444 U.S. 223, 223-31 (1980); *Vermont Yankee Power Corp. v. NRDC*, 435 U.S. 519, 558 (1978).

236. *See* Clean Air Act 42 U.S.C. §§ 7401, 7409 (1994).

237. *See* Regulatory Improvement Act of 1998, S. 981, 105th Cong., §623(b) (1998).

238. *See id.* at § 623(d) (confirming the “procedural” nature of the cost-benefit analysis).

239. *See id.* at § 623(e).

240. *See* *Amoco Production Co. v. Village of Gambell*, 480 U.S. 531, 540-45 (1987).

241. *See* Regulatory Improvement Act of 1999, S. 746, 106th Cong., § 622(b)(1) (1999). (The 1998 version of the Regulatory Improvement Act, S. 981, does not contain this provision).

242. *See id.*

use cost-benefit analysis (or other risk analyses) open—that is, in the discretion of the agency—would now be superseded and modified by the requirement in S. 981 to conduct such analysis. For example, section 3(8) of the OSHA Act<sup>243</sup> has been held to allow but not require cost-benefit analysis.<sup>244</sup> Section 623 of S. 981 could thus be read to require cost-benefit analysis, a risk assessment, and an evaluation of substitution risks under such a pre-existing statutory provision, because this new requirement would not “alter or modify . . . the substantive standards applicable to rulemaking under” OSHA Act section 3(8).<sup>245</sup> OSHA would still be free to adopt a regulation for which the costs outweigh the benefits, if it furnished an explanation as provided in section 623(d) of S. 981, but only after analyzing the costs and benefits, risks, and substitution risks as provided under section 623(b).<sup>246</sup>

Thus, S. 981, while stopping short of the cost-benefit “supermandate” provided in the Bliley bill, may nevertheless alter some of the analytic parameters of pre-existing statutes. It may require more regulatory analysis where prior statutes prohibited or remained silent on such analysis.

An alternative approach would be a “superauthorization,” in which Congress would authorize agencies to conduct cost-benefit analysis, risk assessment, analysis of substitution risks, and selection of more cost-effective regulatory instruments, notwithstanding inconsistent restrictions in other statutes.<sup>247</sup> But such a superauthorization would not require agencies to employ such analytic or regulatory methods; it would give agencies the discretion to employ these techniques where the agencies see fit. This approach would avoid the criticism of a “supermandate” that such a requirement could force the use of analytic methods (such as cost-benefit analysis or the analysis of substitution risks) even where those methods are inadvisable. Instead, it would leave the decision on the advisability of analytic methods to the agencies. But it would capture much of the advantage of introducing better analytic and regulatory methods in situations where current statutes would obstruct such improvements. Moreo-

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243. See Occupational Safety and Health Administration Act (OSHA), 29 U.S.C. §§ 651-78 (1994).

244. See *International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991).

245. See OSHA, 29 U.S.C. 652 § 8 (1994).

246. See *id.* §§ 623(b), (d).

247. See *Regulatory Reform: Hearings Before the Senate Committee on Governmental Affairs*, 104th Cong., 194-96 (1995) (Testimony of Jonathan B. Wiener, Law Professor, Duke University School of Law).

ver, a superauthorization would put the question of the degree and form of analytic and regulatory innovation in the hands of the executive branch, which is better equipped to make such technical choices than are the legislative and judicial branches. We believe that this “superauthorization” approach is worthy of consideration as a superior alternative to the language in S. 981.

## VI. CONCLUSION

Toward the end of the 105th Congress, proponents of regulatory improvement in the U.S. Senate reached agreement with the Clinton Administration on legislative language concerning the use of risk assessment and cost-benefit analysis by federal regulatory agencies. An important feature of the agreement was specific language concerning the appropriate role of judicial review of agency compliance with analytical requirements. Although no vote was taken in the Senate on this matter, it is likely that the same issues will be confronted by future Congresses when comprehensive or agency-specific legislation is considered that includes analytical requirements.

This Report has described and analyzed how the authors of S. 981 and the Clinton Administration resolved significant differences of opinion about how the judicial review issue should be handled. We have also recommended for consideration an alternative approach that would impose fewer analytical requirements, yet subject those requirements to the established norms of judicial review under the APA. On specific issues concerning risk assessment, substitution risk, and peer review, this Report has discussed weaknesses or ambiguities in the negotiated language and alternative approaches to legislation that are worthy of consideration. Overall, we feel that the negotiated language is a workable effort to balance the need for expeditious administrative action with the need for judicial intervention in cases where agencies fail to perform their mandated analytical responsibilities.