

ARTICLES

ADMINISTRATIVE PROCESS IN AN INFORMATION AGE: THE TRANSFORMATION OF AGENCY ACTION UNDER THE DATA QUALITY ACT

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I. INTRODUCTION

When originally enacted on December 21, 2000, as a two-paragraph rider to a Department of Treasury appropriations bill—without any congressional hearings or explanatory legislative history—the Data Quality Act (“DQA”)¹ appeared innocent and innocuous enough. Ostensibly, it intends to improve the quality, objectivity, utility, and integrity of information that federal agencies disseminate to the public. The DQA requires that agencies ensure the quality of information and data that underlies administrative actions—including proposed new rules and regulations, published studies, and guidance documents.²

Since the end of the nineteenth century, administrative agencies have played an “increasingly important role in the legal regulation of economic and social activity.”³ Agencies promote the public health, safety, and welfare, provide a more workable framework for government action than a cumbersome legal process, bear a technical expertise in specific areas they seek to regulate, and are more conducive to bureaucratic and scientific neutrality than other social institutions.⁴ While agencies often regulate by formal and informal rulemakings, these procedures have become so time consuming and costly that the process has become “ossified.”⁵ In this Internet age, agencies now

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1. 44 U.S.C. § 3516 note, Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 (2001). The Data Quality Act is often referred to as the “Information Quality Act.”

2. *Id.*

3. Richard E. Levy & Sydney A. Shapiro, *Administrative Procedure and the Decline of the Trial*, 51 U. KAN. L. REV. 473, 473 (2003).

4. *Id.* at 476.

5. *Id.* at 489 (citation omitted); see also Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L. J. 1385, 1387 (1992) (contending that “it is much harder for an agency to promulgate a rule now. . . . Agency explanations for rules are far more lengthy and intricate than they were in the 1960s and early 1970s.”).

disseminate information through an expansive electronic network.⁶ The range of this information dissemination is staggering, and includes guidance documents, advisory opinions, scientific reports, and compliance assistance. Despite this rapid expansion, there has existed no legal mechanism for challenging the quality, objectivity, utility, and integrity of the information that agencies disseminate.

Touted as the most significant change to the federal rulemaking process since the enactment of the Administrative Procedure Act ("APA")⁷ in 1946,⁸ the DQA provides an unprecedented channel through which both individual citizens and industries may challenge types of agency action that had long been immune from legal scrutiny. Unlike the typical APA challenge, which centers on whether an agency has abused its discretion or acted in an arbitrary and capricious manner,⁹ the DQA permits affected parties to contest the underlying data and information used to formulate governmental regulations, rather than merely challenging a rule during the rulemaking process or waiting until an agency takes final action to file an expensive lawsuit.¹⁰ The DQA's relatively straightforward administrative mechanism should enable cost-efficient challenges that will permit the agencies to take the first bite at a correction, rather than being compelled to do so through litigation or court order.

Simply stated, the DQA intends to improve the quality of federal rulemaking and the information upon which agencies base their decision-making and actions. By limiting administrative action to circumstances that can be supported by underlying data and information, agencies will in theory only act in limited, necessary, and justified circumstances. By requiring heightened transparency in agency actions, the DQA purports to "counter the ability of particular interest groups to capture the agenda of the agencies."¹¹

However, in the initial years following the DQA's enactment, quite the contrary has occurred. For industry, the DQA represents yet another weapon capable of delaying or derailing agency action. The focus of industry has been anything but altruistic. In 2000, the cost to the national economy of complying with federal rules rose to \$843 billion, or eight percent of the gross domestic product.¹² Following an administration that favors corporate concerns over the common man and fits science to political ideology,¹³ industry has so far used the DQA to challenge the scientific assertions made

6. See generally Paul Noe et al., *Learning to Live with the Data Quality Act*, 33 ENVTL. L. REP. 10224 (2003).

7. 5 U.S.C. §§ 551–559 (2003).

8. See James W. Conrad, Jr., *The Information Quality Act: Antiregulatory Costs of Mythic Proportions?*, 12 KAN J. L. & PUB. POL'Y 521 (2003) (arguing that the DQA is the most significant conceptual advance in administrative law in the last three decades); Maureen Lorenzetti, *Watching Government: Data Quality*, OIL & GAS J., Oct. 7, 2002, at 31.

9. 5 U.S.C. § 706(2)(A) (2003).

10. Stephanie M. Horvath, *Law to Let Businesses Attack Data Underlying Rules*, STUDIES, WALL ST. J., July 5, 2002, at A4.

11. Noe et al., *supra* note 6, at 10225 (arguing that the DQA could have the unintended impact of increasing governmental accountability to the public).

12. *Draft Report to Congress on the Costs and Benefits of Federal Regulations*, 67 Fed. Reg. 15,014, 15,040 n.28 (Mar. 28, 2002).

13. See generally E. Donald Elliott et al., *Science, Agencies and the Courts: Is There a Crowd?*, 31 ENVTL. L. REP. 10125 (2001) (asserting that the role of science is being increasingly marginalized and is playing less of a role in the decision-making process); David Kohn, *Government Bends, Hides Facts, Say Scientists: 60 Leading Researchers, Including Nobelists, Detail Suppression Under Bush*, BALTIMORE SUN, Feb.

by agencies—regardless of whether such assertions are controversial or non-controversial.

More importantly, the DQA is the latest signpost in a purported trend towards transparency in the federal regulatory process. With roots buried deeply in the economic analysis of law movement, the DQA is the latest in a long string of governmental action—including executive orders, statutory authority, and proposed federal legislation—that requires an objective and empirical justification prior to engaging in regulatory action. Because it requires a showing of the precise, quantifiable information that underlies an agency's action, the DQA pushes the American legal system further away from the "Precautionary Principle,"¹⁴ the framework for regulation that is favored in Europe. By disallowing regulation in the face of scientific uncertainty, the DQA pushes the United States further down a path that favors probusiness, laissez faire regulation at the expense of protecting the health, safety, and well-being of the general public.

In its first year since implementation, federal agencies have denied most industry challenges, citing valid existing procedural and information safeguards that pre-date the DQA. The routine denial of these requests may open a floodgate of litigation unintended by the DQA. However, the quick action of agencies to assert the soundness of their information quality procedures raises another, more daunting problem: federal agencies may not be fulfilling their mandates under the DQA, and information in the DQA age has not improved at all.

Part II of this Article briefly discusses the role of agencies in the American system of government as well as constitutional and statutory limitations on administrative action. Part III introduces the basic precepts of economic analysis of law and traces how these precepts have been repeatedly manifested, in increasing frequency, in executive and congressional actions. Part IV details the background of the DQA and discusses key definitions, phrases, and requirements. Part V surveys various DQA concerns and predictions tendered by competing interest groups, from individuals to industry to public interest entities. Part VI considers the premise of the DQA as "Regulatory Daubert," drawing an analogy between enactment of the DQA and the evolution of the law of evidence. Finally, Part VII assesses what has transpired at the Environmental Protection Agency ("EPA") since the DQA's enactment, surveying a number of DQA petitions and lawsuits and how the EPA has disposed of them.

II. THE ROLE OF ADMINISTRATIVE AGENCIES IN THE AMERICAN SYSTEM OF GOVERNMENT

The role of administrative agencies in the American system of government has grown dramatically since 1887, when Congress established the first agency, the

19, 2004, at 1A (reporting that over sixty scientists, including twenty Nobel laureates, have charged the Bush administration of manipulating scientific knowledge that conflicts with political goals).

14. NATIONAL ACADEMY OF SCIENCES, ENSURING THE QUALITY OF DATA DISSEMINATED BY THE FEDERAL GOVERNMENT, Mar. 22, 2002, at 90 [hereinafter "NAS WORKSHOP #2"] (stating that the precautionary principle envisions that in instances when not all information is known, regulators should err on the side of enacting extra protections).

Interstate Commerce Commission, to regulate railroads.¹⁵ Administrative agencies rose to prominence during the New Deal in the 1930s, a period marked by a governmental commitment to “act positively, to itself identify and solve economic and social problems as opposed to leaving these matters to a free market and private solutions.”¹⁶ In the 1960s, the number and scope of federal regulatory agencies greatly expanded, covering, *inter alia*, the regulation of oil prices, energy production, environmental pollution, workplace safety, and consumer protection.¹⁷ In 1999, there existed 143 federal agencies that employed 3.1 million civilians.¹⁸

Administrative agencies play a wide variety of roles in American society. Agencies are “the authorities and operating units of the government except for constitutionally established entities.”¹⁹ Agencies implement various social, economic, and quality of life programs.²⁰ They regulate business, preventing corporations from achieving monopolies over private markets, and emergent industries, helping to set guidelines and a framework for new technology.²¹ They conduct regulatory programs that increase public awareness about potential risks to human health, and then promulgate rules or issue guidance documents that detail how to avoid said risks.

Agencies tailor their regulatory techniques to meet individual problems and circumstances.²² They often require licensure and certification prior to undertaking specific activities, establish standards and guidelines that govern conduct, adjudicate violations and impose penalties, and potentially influence public conduct through a wide variety of informal information dissemination.²³

A comprehensive discussion of the limitations on agency action and rulemaking is more properly the subject of a law school course on administrative law. For purposes of this Article, however, it is important to note that both constitutional principles and statutory authority limit the conduct of agencies. As interpreted by substantial case law, the United States Constitution addresses the degree to which Congress may delegate power and responsibility to executive agencies.²⁴ In addition, agencies may not impermissibly intrude on the province of the legislative and judicial branches of government,²⁵ must adhere to substantive due process clause concerns when conducting

15. STEPHEN BREYER, *REGULATION AND ITS REFORM* 1 (1982).

16. ERNEST GELLHORN & RONALD M. LEVIN, *ADMINISTRATIVE LAW AND PROCESS* 1 (4th ed. 1997) (stating that the economic depression of the 1930s was followed by a proliferation of agencies during the New Deal that aimed to “stabilize the economy, temper the exercise of unregulated markets, and provide some financial security for individuals”).

17. BREYER, *supra* note 15, at 1 (contending that from 1936 to 1977, the number of pages of Federal Regulations in the Federal Register grew from 2,599 to 65,603, and that permanent full-time positions in regulatory agencies grew from 28,000 in 1970 to 81,000 in 1979).

18. Daniel J. Solove, *The Darkest Domain: Deference, Judicial Review, and the Bill of Rights*, 84 IOWA L. REV. 941, 960 (1999).

19. PETER L. STRAUSS ET AL., *GELLHORN AND BYSE’S ADMINISTRATIVE LAW: CASE AND COMMENTS* 8 (2003).

20. ALFRED C. AMAN & WILLIAM T. MAYTON, *ADMINISTRATIVE LAW* 1 (1993).

21. GELLHORN & LEVIN, *supra* note 16, at 1.

22. *Id.* at 2.

23. *Id.*

24. See generally STRAUSS ET AL., *supra* note 19, at 66–83 (discussing the history of the delegation doctrine from the late 1800s to the present).

25. See, e.g., *INS v. Chadha*, 462 U.S. 919 (1983) (holding that a one-house legislative veto was unconstitutional); *Bowsher v. Synar*, 478 U.S. 714 (1986) (holding that a balanced budget statute contained an

adjudications,²⁶ and offer procedural due process when an agency may injure a protected interest through an informal action, benefits determination, or rulemaking.²⁷

The APA provides the general statutory framework for agencies to conduct both formal and informal rulemakings. The APA's more typical, informal "notice and comment" rulemaking involves four steps: (1) publication of the proposed rule in the Federal Register; (2) receipt of written and oral comments from the public; (3) possible modification or alteration of the rule in response to the comments; and (4) publication of the final rule with a statement of purpose.²⁸ In more limited circumstances, agencies may also conduct "formal" rulemaking, a process which generally requires a formal hearing in which parties provide testimony, present evidence taken on the record, and cross-examine adverse witnesses.²⁹

As a threshold matter, the APA governs agency rulemaking procedures. While the APA contains no provisions specifically addressing information quality,³⁰ it does prohibit, in formal rulemakings and adjudications, *ex parte* communications between agency employees and interested persons outside the agency.³¹ The APA prohibits agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,"³² and allows for judicial review of final agency actions.³³ The APA's judicial review provision allows a party to sue an agency for making a policy decision with no rational basis or for exercising a bias in its actions.³⁴ However, it does not provide the specific means, like the DQA, for challenging the information that underlies agency action.

III. HISTORY OF ECONOMIC ANALYSIS/INFORMATION QUALITY

A. General Background

Brought into mainstream legal academia in the 1970s,³⁵ economic analysis of law applies microeconomic theories to the analysis of legal rules and institutions.³⁶

unconstitutional assignment of executive functions to an agent of the legislative branch).

26. See, e.g., *Morgan v. United States*, 304 U.S. 1, 18 (1938) (holding that "the right to a hearing embraces not only the right to present evidence but also a reasonable opportunity to know the claims of the opposing party and to meet them").

27. See, e.g., *Mathews v. Eldridge*, 424 U.S. 319 (1976) (holding that the Due Process Clause of the Fifth Amendment does not require an evidentiary hearing prior to the termination of disability benefits).

28. 5 U.S.C. § 553(b)-(d) (2003). See also Richard A. Greene, *Recent Developments in Federal Regulatory Policy*, 6 J. SMALL & EMERGING BUS. L. 607, 609 (2002).

29. 5 U.S.C. § 556(d)-(e) (2003).

30. See Conrad, *supra* note 8, at 532-33 (arguing that the APA is ill-suited to address the risks posed by information activities and has not provided effective judicial review of free-standing information disseminations).

31. 5 U.S.C. § 557(d) (2003).

32. *Id.* § 706(2)(A).

33. *Id.* § 702.

34. See RICHARD A. POSNER, *ECONOMIC ANALYSIS OF LAW* 642 (6th ed. 2003) (arguing that judicial review under the APA arises from a desire to control agency bias).

35. See generally *id.*

36. *Economic Analysis of Law*, STANDARD ENCYCLOPEDIA OF PHILOSOPHY, available at <http://plato.stanford.edu/entries/legal-econanalysis/> (last visited Apr. 7, 2005) [hereinafter *Economic*].

Economic analysis of law attempts to explain rules as they are, rather than trying to change them solely for the sake of improvement.³⁷ While the movement itself is difficult to briefly and accurately encapsulate, the key principles include: (1) legal rules should be efficient; (2) legal processes generally gravitate to efficient rules; and (3) individuals respond to legal rules economically.³⁸

Economic analysis of law is primarily concerned with “using economic methods as theoretical constructs for analyzing, in economic terms, the rules and laws adopted by a particular society.”³⁹ As Malloy notes, “[B]y subjecting legal doctrine to economic cost and benefit analysis and to concepts of economic efficiency, [economic analysis of law] can allow us to draw certain conclusions about the consequences and alleged social value of particular legal arrangements.”⁴⁰ From a public policy perspective, economic analysis of law focuses both on the effects of legal rules on private individuals and on “political economy,” the interplay between the operation of political institutions, such as courts, legislatures, and executive and administrative agencies.⁴¹

Economic analysis of law is typically associated with a conservative ideology towards government and society. Conservatives use economic analysis of law to support their arguments about the deleterious effects and undue burdens that excessive regulations will bear on small businesses and private citizens. Typical conservative arguments promote the adoption of market-based trading systems and maintain that the free market is best suited to handle regulatory issues on its own, without government intervention. Such intervention is presumptively inappropriate, especially when scientific data is unsound or in the face of informational or scientific uncertainty. Conservatives also advocate for: (1) “sound science” as a precursor for valid risk assessment, (2) the use of cost-benefit analysis to shape environmental programs, and (3) maintaining a minimum quality of data to support regulatory decisions.⁴²

B. Cost-Benefit Analysis: The Principal Tool of Economic Analysis

Since the 1930s, the principal tool of economic analysis used to evaluate public expenditure decisions has been cost-benefit analysis (“CBA”),⁴³ a process that requires

Analysis]. This paper differentiates between economic analysis of law and law and economics, the latter of which is commonly described as a broader, comparative analysis between economic, philosophical, political, and legal institutions. See also ROBIN PAUL MALLOY, *LAW AND ECONOMICS: A COMPARATIVE APPROACH TO THEORY AND PRACTICE* 3 (1990).

37. POSNER, *supra* note 34, at 25.

38. *Economic Analysis*, *supra* note 36.

39. MALLOY, *supra* note 36, at 3.

40. *Id.*

41. *Economic Analysis*, *supra* note 36.

42. Rena I. Steinzor, *Toward Better Bubbles and Future Lives: A Progressive Response to the Conservative Agenda for Reforming Environmental Law*, 32 ENVTL. L. REP. 11421, 11423 (2002). In contrast, a progressive regulatory agenda maintains that, “the public’s health—regardless of class, race, ethnicity, gender, or age—must be protected from the consequences of industrial and agricultural activity.” *Id.* Government, and not private business, is best suited to protect the “birth rights” protected by regulatory structures, including a clean environment and public health. *Id.* Finally, progressives believe in the precautionary principle, which maintains that regulatory action is appropriate—and even necessary—in situations when uncertainty surrounds a risk. *Id.*

43. EDITH STOKEY & RICHARD ZECKHAUSER, *A PRIMER FOR POLICY ANALYSIS* 134 (1978) (arguing that governmental use of CBA arose in the 1930s with the analysis of water resource projects and has increased in

“systematic enumeration of all benefits and all costs, tangible and intangible, whether readily quantifiable or difficult to measure, that will accrue to all members of society if a particular project is adopted.”⁴⁴ CBA is useful for determining whether a proposed course of action is efficient compared to alternative courses of action.⁴⁵

CBA typically incorporates a description of the total outcomes of various projects and provides a rule for choosing among them.⁴⁶ One common procedure for a CBA includes:

- (1) The project or projects to be analyzed are identified.
- (2) All the impacts, both favorable and unfavorable, present and future, on all of society are determined.
- (3) Values, usually in dollars, are assigned to these impacts. Favorable impacts will be registered as benefits, unfavorable ones as costs.
- (4) The net benefit (total benefit minus total cost) is calculated.
- (5) The choice is made.⁴⁷

CBA may be either “monetized,” which reduces each cost and benefit of a regulatory proposal to a dollar figure and then calculates a monetary cost or benefit for the

use since World War II). This paper focuses on cost-benefit analysis. Other tools of economic analysis include regulatory scorecards, *see* Richard W. Parker, *Grading the Government*, 70 U. CHI. L. REV. 1345, 1345 (2003) (stating the regulatory scorecards are “scathing critiques of government . . . which purport to show that the costs of many government regulations vastly outweigh their benefits”), discount rates, *see* POSNER, *supra* note 34, at 398–99 (defining the discount rate as the rate to be used to discount the future benefits to a present value cost that may be compared to a present actual cost), Office of Management & Budget, Circular A-4, Regulatory Analysis, at 31–38 (Sept. 17, 2003), *available at* <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf> (last visited Apr. 5, 2005) [hereinafter OMB Circular A-4] (arguing that agencies should use discount rates when benefits or costs are delayed or otherwise separated in time from each other), and qualified adjusted life years (“QALYs”), *see* James K. Hammitt, *Valuing Health: Quality-Adjusted Life Years or Willingness to Pay?*, 11 RISK IN PERSPECTIVE: HARVARD CENTER FOR RISK ANALYSIS 1 (2003) (defining QALYs as useful for measuring an individual’s future longevity and the quality of the individual’s health during that time).

44. STOKEY & ZECKHAUSER, *supra* note 43, at 134.

45. Fred Anderson et al., *Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, and Judicial Review*, 11 DUKE ENV. L. & POL’Y F. 89, 91–92 (2000) (listing the costs of a regulatory action as the time, labor, material, and capital expended, and the benefits as the gains in utility to the beneficiary population). CBA has been defined as “a method of pure evaluation, conducted without regard to the possible use of its results in a decision; to an input into decision, with the decision maker free to reject the results of the analysis on the basis of other considerations; or to the exclusive method of decision.” POSNER, *supra* note 34, at 397.

46. STOKEY & ZECKHAUSER, *supra* note 43, at 134.

47. *Id.* at 136.

proposal, or “non-monetized,” which relies on intuition and judgment rather than formal commensuration to balance varying costs and benefits.⁴⁸

Critics of economic analysis argue that tools like CBA may contribute to a “paralysis by analysis” of government agencies, in that excessive CBA may drain agency resources and slow down the rulemaking process.⁴⁹ CBA may also engender a potential bias against protective legislation. Finally, not all benefits and costs may be easily “monetized” or translated into numerical terms for purposes of cost-benefit analysis.⁵⁰

It goes without saying that for economic analysis to have any credence, the underlying assumptions and data that comprise the economic calculations must be accurate and reliable. For the economic analysis of law movement to become deeply and permanently entrenched in the American system of government, it must be able to counter claims that CBA and other tools fail to accurately represent real world concerns.

Therein lies the power and the importance of the DQA to the economic analysis of law movement. By requiring the use of only proven and widely accepted data and information, proponents of economic analysis may dismiss criticisms that CBA is ill-suited to work in the real world—all the while quashing potential administrative actions before they even arise.

C. Government Use of Economic Analysis and Data Quality

1. The Rise of OMB and OIRA

Since the Nixon Administration, American presidents, through a centralized mechanism for agency oversight, have vowed to rein in the expanding realm of federal regulations.⁵¹ Created in 1970, the U.S. Office of Management and Budget (“OMB”) prepares the President’s annual budget proposal to Congress, assists in the management of the executive branch, and conducts in-depth regulatory review of significant rules proposed by federal agencies.⁵² OMB reviews the actions of over 100 other agencies, boards, and commissions.⁵³ According to one commentator:

48. Matthew D. Adler, *Risk, Death and Harm: The Normative Foundations of Risk Regulation*, 87 MINN. L. REV. 1293, 1394 (2003). In instances when costs and benefits may not be easily monetized, agencies may employ cost effectiveness analysis. OMB Circular A-4, *supra* note 43, at 11. This tool of economic analysis is “designed to compare a set of regulatory actions with the same primary outcome . . . or multiple outcomes that can be integrated into a single numerical index.” *Id.*

49. David C. Vladeck, *Paralysis by Analysis: How Conservatives Plan to Kill Popular Legislation*, AM. PROSPECT (1995), available at <http://www.prospect.org/web/page.wv?Section+root&name=ViewPrint&articleID=5010> (last visited Apr. 7, 2005).

50. Steinzor, *supra* note 42, 11423 (stating that, for the following reasons, risk assessment based on CBA is an inexact science: “The fatal mistake is to step across the line between asking decisionmakers to weigh those factors and requiring them to achieve the bogus goal of ensuring that benefits, to the dollar, always outweigh costs, with this artificial equation the sum total of what determines the final decision.”).

51. Jim Ostroff, *The Office of Information and Regulatory Affairs is Emerging from Obscurity as a Rule Reviewer, to the Benefit of Small Businesses*, KIPLINGER BUS. FORECASTS, Apr. 1, 2002.

52. See Office of Management & Budget, *OMB in Perspective*, available at http://www.whitehouse.gov/omb/organization/omb_overview_slides.pdf (last visited Apr. 7, 2005) (discussing OMB’s missions and goals).

53. *Id.*

OMB stands at a critical point within the nerve center of the federal government and holds a key position in the communication network that links the President, the rest of the Executive Branch, and the Congress. So positioned, it can exert a significant impact on public policy outcomes through its budgetary, legislative, managerial, and regulation review mandates.⁵⁴

Regulatory reform of OMB's role as reviewer of regulations—with an increasing emphasis on economic analysis and information quality—has been a governmental focus for the past three decades. In 1974, President Gerald Ford issued Executive Order 11,821,⁵⁵ which provided that “[m]ajor proposals . . . for the promulgation of regulations or rules by any executive branch agency must be accompanied by a statement which certifies that the inflationary impact of the proposal has been evaluated.”⁵⁶ In 1978, President Jimmy Carter issued Executive Order 12,044, entitled “Improving Government Regulations,” which adopted a number of the principles of economic analysis.⁵⁷ It directed federal agencies to ensure that: (1) the need for and purposes of a proposed regulation were clearly established; (2) meaningful alternatives were considered and analyzed before a final regulation was issued; and (3) regulatory analysis was conducted on significant regulations having major economic consequences to the national economy.⁵⁸

Regulatory reform of OMB's role and responsibilities continued into the 1980s, when environmentalists called for reform of the agency.⁵⁹ Established in 1980 under the Paperwork Reduction Act,⁶⁰ the Office of Information and Regulatory Affairs (“OIRA”), a division of OMB, carries the lead role in executive oversight. OIRA is a little-known, behind-the-scenes agency that wields considerable regulatory power. OIRA acts as an administrative gatekeeper, with the power to review and block certain regulations. Staffed by career civil servants, OIRA develops and oversees the implementation of government-wide policies in the areas of information technology and policy, privacy, and statistical policy.⁶¹

In 1981, President Ronald Reagan issued Executive Order 12,291,⁶² which required that most regulations issued by federal agencies satisfy a CBA, and that the agencies must submit a Regulatory Impact Analysis of “major rules” which would have an

54. *Id.* (quoting SHELLEY LYNNE TOMKIN, *INSIDE OMB: POLITICS AND PROCESS IN THE PRESIDENTIAL BUDGET OFFICE* xi (1998)).

55. Exec. Order No. 11,821, 39 Fed. Reg. 41,501 (Nov. 27, 1974).

56. *Id.* (providing that the OMB Director must consider the following factors in the evaluation of proposed agency action: the cost impact on consumers, businesses, markets, or government entities; the effect on productivity of wage earners, businesses, or government; the effect on government; and the effect on supplies of important products or services). Two years later, President Ford retitled Executive Order 11,821 to become “Economic Impact Statements.” Exec. Order No. 11,949, 42 Fed. Reg. 1017 (Dec. 31, 1976).

57. Exec. Order No. 12,044, 43 Fed. Reg. 12,661 (Mar. 23, 1978).

58. *Id.*

59. Ostroff, *supra* note 51 (citing a 1984 article in the *Virginia Journal of Natural Resources*, in which the author, now an attorney for the Natural Resources Defense Council, asserted that “if regulatory review is to increase bureaucratic accountability and provide more reasoned decision making, the courts and Congress must act” to change OMB's methods of operation).

60. 44 U.S.C. §§ 3501–3520 (2000).

61. See Office of Information and Regulatory Affairs, *OIRA Q&A's*, at http://www.whitehouse.gov/omb/inforeg/qa_2-25-02.pdf (last visited Apr. 7, 2005).

62. Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1981).

annual impact of \$100 million or more on the national economy.⁶³ Under Executive Order 12,291, federal agencies had to provide OMB with a description of the potential costs and benefits of a rule, including those that may not be quantified in monetary terms.⁶⁴ They were also required to provide a description of alternatives to the proposed rulemaking and include legal explanations of why such alternatives were not taken.⁶⁵ In keeping with the conservative trend towards economic analysis, Executive Order 12,291 required that agencies identify market failures prior to considering regulatory action.⁶⁶

In 1985, President Reagan issued Executive Order 12,498,⁶⁷ which required agencies to submit to OMB a statement of their regulatory policies, goals, and objectives for each year,⁶⁸ and to ensure that such plans were consistent with the goals of the agency and of the Administration, including the Administration's regulatory principles.⁶⁹

In September 1993, President Bill Clinton issued Executive Order 12,866,⁷⁰ "Regulatory Planning and Review," which revoked both Executive Order 12,291 and 12,498, but retained many elements of economic analysis. In particular Executive Order 12,866 requires that:

Federal agencies should promulgate only such regulations as are required by law . . . or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health or safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.⁷¹

For "significant" regulatory actions,⁷² Executive Order 12,866 requires that agencies submit to OIRA an assessment of the potential costs and benefits of the regulatory action⁷³ and an assessment of potentially effective and reasonable alternatives to the proposed regulation.⁷⁴ OIRA typically has ninety calendar days to review submitted rules and to ensure that they are consistent with applicable law, and the President's priorities, and do not conflict with the actions of other agencies.⁷⁵

63. *Id.* § 3(c)(2).

64. *Id.* § 3(d)(1)–(3).

65. *Id.* § 3(d)(4).

66. Susan E. Dudley, *Bush's Rejuvenated OIRA*, 24 REGULATION 5 (2001), available at <http://www.regulationmagazine.org/pubs/regulation/regv24n4/mercatusreports.pdf> (last visited Mar. 21, 2005).

67. Exec. Order No. 12,498, 50 Fed. Reg. 1,036 (Jan. 4, 1985).

68. *Id.* § 1(a).

69. *Id.* § 3(a).

70. Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

71. *Id.* § 1(a).

72. *Id.* § 3(f)(1)–(3) (defining significant regulatory actions as those that have an annual effect on the economy of \$100 million or more or that create a serious inconsistency or otherwise interfere with an action taken or planned by another agency).

73. *Id.* § 6(a)(3)(B)(ii).

74. *Id.* § 6(a)(3)(C)(iii).

75. *Id.* § 6(b)(2)(B).

Executive Order 12,866 also addresses transparency in the regulatory process and information quality. For example, the order imposes strict public disclosure requirements of communications between OIRA employees and outside parties made during a regulatory review.⁷⁶ In addition, Executive Order 12,866 requires that agencies, after OIRA completes its review, (1) identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced, and (2) identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.⁷⁷

Under President Clinton, OIRA's role was considerably more dormant, with regulatory review giving a wide berth to agency discretion. However, under President George W. Bush, OIRA has regained a quiet power, asserting a role similar to that under the Nixon and Reagan Administrations. This has coincided with President Bush's appointment of John Graham to head OIRA, a nomination that received relatively little media coverage or political controversy—but one which has borne far-reaching effects on federal regulatory policy.

Graham founded and directed the Harvard Center for Risk Analysis, which was launched with a mission of promoting reasoned public responses to health, safety, and environmental hazards by taking a broad view of public health.⁷⁸ A controversial but avowed devotee of cost-benefit analysis,⁷⁹ Graham strongly believes in methods of empirically evaluating regulatory efficacy.⁸⁰ He also adheres to the concept of quality-adjusted life years ("QALYs") saved, an approach that objectively values the quality of life experienced by the individual who is exposed to the risk.⁸¹

Once empowered at OIRA, Graham announced a "science-based" overhaul of the federal regulatory process.⁸² In September 2001, Graham announced that OIRA would work with the agencies to again enforce Executive Order 12,866.⁸³ OMB would employ "a host of requirements and guidelines," including peer review, risk assessments, and risk impact analyses, to review proposed federal regulations.⁸⁴

76. Exec. Order No. 12,866 § 6(b)(4)(A)–(D).

77. *Id.* § 6(a)(3)(E)(ii)–(iii).

78. Ellen Nakashima, *For Bush's Regulatory Czar, The Equation is Persuasion; Graham Wields Cost-Benefit Analysis For, Against Rules*, WASH. POST, May 10, 2002, at A35. See also Riskworld, at www.riskworld.com (last visited Apr. 24, 2005).

79. *Id.* (describing Graham's approach as "regulations czar" as being deeply grounded in the balancing of costs and benefits, and risks and rewards).

80. See Randall Lutter, *The Role of Economic Analysis in Regulatory Reform*, 22 REGULATION 38, 40 (1999), available at www.cato.org/pubs/regulation/regv22n2/econanalysis.pdf (last visited Mar. 21, 2005) (contending that "[b]enefit cost analysis can help to inform Congress and the public about the economic merits and effects of congressional mandates and agencies' actions").

81. See Steinzor, *supra* note 42, at 11423 (arguing that QALYs "empower bureaucrats to engage in an elaborate, pseudo-scientific triage of various sub-populations").

82. Ellen Nakashima, *Chief Plans Overhaul of Regulatory Process, Report: "Science-Based" Approach Sought*, WASH. POST, March 20, 2002, at A31.

83. Memorandum from John D. Graham, OIRA Administrator, to President's Management Council (Sept. 20, 2001), available at http://www.whitehouse.gov/omb/inforeg/oira_review-process.html (last visited Jan. 30, 2005).

84. OMB to Use "Science-Based" Guidelines in Rule Review, AM. POL. NETWORK: AM. HEALTH LINE, Sept. 26, 2001, at 5.

Graham stated that OIRA would reject proposed regulations that “lack an adequate cost benefit analysis and reasonable alternatives.”⁸⁵

The results have been significant. In Graham’s first two years as OIRA Director, OIRA used Executive Order 12,866 to return sixteen rules to agencies for reconsideration, compared to nine rules returned during the first eight years of the executive order.⁸⁶ In September 2003, OMB released “Circular A-4,”⁸⁷ which is designed to define good regulatory analysis for standardizing the manner in which the costs and benefits of federal regulatory actions are measured and reported.⁸⁸ A comprehensive document, summarizing many of the precepts of economic analysis, OMB’s Circular requires that economic analyses be transparent with reproducible results.⁸⁹ In addition, agencies “should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates.”⁹⁰

While Graham contends that OMB is operating at an “unprecedented level of transparency,”⁹¹ critics deride him as being “an industry ally who has a long record of crusading against health, safety and environmental standards.”⁹² Graham’s critics have alleged that his approach is anything but scientific. Far from increasing transparency and information quality, they claim that Graham’s increased use of the “return letter,” the administration’s method of informing an agency that its work or regulation does not pass muster, is simply another tool of economic analysis by which a potential agency may be quashed.⁹³

As a strict adherent of the conservative principles of economic analysis of law, Graham is expected to strictly enforce the DQA by requiring that regulations be based on quality data and accepted science, and not on specially ordered research that reaches alternative conclusions.⁹⁴ For its part, the DQA could serve to augment the considerable power that resides within OIRA.⁹⁵

85. *Id.*

86. Dudley, *supra* note 66, at 5.

87. OMB Circular A-4, *supra* note 43, at 1.

88. *See id.*

89. *Id.* at 17.

90. *Id.*

91. Marty Coyne, *Players Dispute Effectiveness of White House Transparency on Rules*, GREENWIRE, Oct. 30, 2003, available at http://www.eenews.net/Greenwire/searcharchive/test_search-display.cgi?q=players+dispute&file=%2FGreenwire%2Fsearcharchive%2FNewsline%2F2003%2FOct30%2F10300302.htm (last visited Apr. 7, 2005).

92. Phineas Fiske, *White House Should Give This Nomination a Push*, NEWSDAY, June 20, 2001, at A28.

93. Nakashima, *supra* note 78, at A35 (contending that by comparison, the Clinton Administration sent no return letters during its final three years).

94. Ostroff, *supra* note 51.

95. James T. O'Reilly, *Administrative Law Discussion Forum: The 411 on 515: How OIRA's Expanded Information Rules in 2002 Will Impact Rulemaking and Agency Publicity Actions*, 54 ADMIN. L. REV. 835, 837 (2002).

2. Enacted Statutes Addressing Data Quality

a. *The Regulatory Flexibility Act*

In 1980, Congress passed the Regulatory Flexibility Act (“RFA”),⁹⁶ which requires that agencies consider the effect of regulation on small business entities.⁹⁷ For agency rulemakings subject to notice and comment under APA § 553, the RFA requires that the agencies conduct a Regulatory Flexibility (“Reg-Flex”) Analysis.⁹⁸ The components of a Reg-Flex Analysis include a description of why the action is being taken,⁹⁹ an explanation of the legal basis and objective of the rule,¹⁰⁰ and consideration of alternatives to the rule.¹⁰¹ In 1996, Congress amended the RFA with the Small Business Regulatory Enforcement Fairness Act (“SBREFA”).¹⁰² SBREFA provided new tools to ensure that agencies properly review the impact of proposed rules on small entities.¹⁰³

b. *The Unfunded Mandates Reform Act*

Under the Unfunded Mandates Reform Act,¹⁰⁴ agencies must prepare a written statement of the benefits and costs prior to issuing a proposed or final rule that may result in an aggregate annual expenditure by a state or local government, or by the private sector, of \$100 million or more.¹⁰⁵

c. *The Paperwork Reduction Act*

In order to address data quality and ensure that agencies act solely upon good information, Congress enacted the Paperwork Reduction Act (“PRA”),¹⁰⁶ which directed that OIRA “provide direction and oversee . . . agency dissemination of public access to information.”¹⁰⁷ OIRA was directed to develop and implement policies, principles, and guidelines for the dissemination of public information by a federal agency, “regardless of the form or format in which such information is

96. 5 U.S.C. §§ 601–611 (2003).

97. *Id.* § 602.

98. *Id.* § 603(a)–(b).

99. *Id.* § 603(b)(1).

100. *Id.* § 603(b)(2).

101. *Id.* § 603(c).

102. 5 U.S.C. § 611 (2003).

103. Greene, *supra* note 28, at 611. As part of SBREFA, the Congressional Review Act, 5 U.S.C. §§ 801 et seq. (1996), allows Congress sixty days to review and reject new proposed federal regulations. *Id.* § 801(a)(3)(A). Should any member of Congress object to the regulation, he or she may introduce a “Resolution of Disapproval,” which then comes up for a majority vote before both houses of Congress. *Id.* § 801(a)(3)(B). If the president then signs the resolution, the proposed regulation is thwarted. *Id.*

104. 2 U.S.C. §§ 1501–1571 (2000).

105. *Id.* § 1532(a).

106. 44 U.S.C. §§ 3501–3549 (2000).

107. *Id.* § 3504(a)(1)(B)(ii).

disseminated.”¹⁰⁸ In addition, the PRA requires that each federal agency manage its information resources to “improve the integrity, quality, and utility of information to all users within and outside the agency, including capabilities for ensuring dissemination of public information.”¹⁰⁹ With respect to information dissemination, each agency must:

(1) ensure that the public has timely and equitable access to the agency’s public information, including ensuring such access through—

(A) encouraging a diversity of public and private sources for information based on government public information; . . .

(B) providing timely and equitable access to the underlying data (in whole or in part); and

(C) agency dissemination of public information in an efficient, effective, and economical manner.¹¹⁰

Finally, the PRA requires that agencies, to the maximum extent practicable, use information technology to improve data quality.¹¹¹

3. Congressional Legislation Addressing Data Quality

For the past few decades, Congress, like the Executive Branch, has expressed a sustained and growing interest in regulatory reform addressing elements of economic analysis of law—in particular, with legislation addressing tools to improve the regulatory process. In recent years, Congress has shown a growing emphasis on data and information quality, culminating with the enactment of the DQA in the 106th Congress and continuing under the Republican-controlled 108th Congress.

a. 103rd Congress

The 103rd Congress addressed a number of proposals focusing on regulatory reform and transparency in government. For example, the House Science Committee considered the Risk Assessment Improvement Act, which addressed aspects of federal risk assessment.¹¹² The Safe Drinking Water Act Amendments of 1994¹¹³ contained provisions for CBA and transparency in agency rulemaking.¹¹⁴ Finally, the Risk Communication Act of 1993¹¹⁵ required EPA’s risk communication to be based on

108. *Id.* § 3504(d)(1).

109. *Id.* § 3506(b)(1)(C).

110. *Id.* § 3506(d)(1)(A)–(C).

111. 44 U.S.C. § 3506(c)(3)(J) (2000).

112. H.R. 4306, 103d Cong. (1994).

113. S. 2019, 103d Cong. (1994).

114. *Id.* § 15 (stating that “the [EPA] Administrator shall also estimate the private and public costs and benefits associated with selected major Federal actions chosen by the Administrator that have the most significant impact on human health or the environment”).

115. H.R. 2910, 103d Cong. (1993).

sound science and transparent assumptions. All three of these measures failed to become law.

b. 104th Congress

During the 104th Congress, there was a concerted effort to establish data quality, peer review, and best available evidence procedures on a comprehensive basis across federal regulatory agencies.¹¹⁶ The Republican "Contract for America" in 1994 sparked a renewed interest in economic analysis of law, and marked the transformation of America into a "cost-benefit state" where "its performance will be assessed . . . by comparing the costs of government action with its benefits."¹¹⁷ For instance, the House Governmental Affairs Committee scheduled a series of six hearings addressing various issues of regulatory reform.¹¹⁸ One of the hearings specifically addressed the issue of CBA.¹¹⁹

The House passed the Risk Assessment and Cost-Benefit Act of 1995,¹²⁰ which covered a broad range of risk-related ideas, including CBA for major rules, and would have applied to all federal agencies that implemented regulatory programs designed to protect public health, safety, and environmental laws. The House also passed the Paperwork Elimination Act of 1996,¹²¹ which proposed to amend the Paperwork Reduction Act by incorporating alternative information technologies to improve data quality.¹²²

In addition, the Senate considered the Comprehensive Regulatory Reform Act of 1995 ("CRRR").¹²³ Senator Orrin Hatch introduced Amendment 1554 to the CRRR, which stated that when an agency publishes a notice of proposed rulemaking for a major rule, "the agency shall issue and place in the rulemaking file an initial cost-benefit analysis, and shall include a summary of such analysis in the notice of proposed rulemaking."¹²⁴

Senator Hatch's amendment also included a subchapter of risk assessments that addressed data quality concerns.¹²⁵ In performing risk assessments, each agency was directed to (1) use only "the best reasonably available scientific data and scientific understanding," (2) select data "based on a reasoned analysis of the quality and

116. Noe et al., *supra* note 6, at 10232 (reporting that the issues were debated extensively and passed through the House in a reconciliation bill, but that extensive language did not get through the Senate).

117. Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 9 (1998) (citing Cass R. Sunstein, *Legislative Foreword: Congress, Constitutional Moments, and the Cost-Benefit State*, 48 STAN L. REV. 247, 249 (1996)). McGarity argues that CBA may eventually be used by powerful interest groups to "undermine the regulatory walls that Congress has erected to protect human health and the environment." *Id.* at 12.

118. Press Release, House Governmental Affairs Committee, Continuation of Regulatory Reform Hearings (Feb. 13, 1995) (stating that the Committee considered at least seven regulatory reform bills).

119. *Id.*

120. H.R. 1022, 104th Cong. (1995).

121. H.R. 2715, 104th Cong. (1996).

122. *Id.* § 5(c). Similar bills were considered, but not enacted, in subsequent legislative sessions. See Paperwork Elimination Act of 1997, H.R. 852, 105th Cong. (1997); Paperwork Elimination Act of 1999, H.R. 439, 106th Cong. (1999); Paperwork Elimination Act of 2001, H.R. 749, 107th Cong. (2001).

123. S. 343, 104th Cong. (1995).

124. 145 CONG. REC. S10,017 (daily ed. July 14, 1995) (statement of Sen. Hatch).

125. *Id.* at S10,020.

relevance of the data,” and (3) “consider whether the data were published in the peer-reviewed scientific literature, or developed in accordance with . . . other appropriate protocols to ensure data quality.”¹²⁶

In 1995, the Senate also considered the Regulatory Procedures Reform Act.¹²⁷ The Act would have required that federal agencies conduct a CBA before publishing a “major rule.”¹²⁸ In evaluating and comparing costs and benefits, “the agency shall not rely on cost, benefit, or risk assessment information that is not accompanied by data, analysis, or other supporting materials that would enable the agency and other persons interested in the rulemaking to assess the accuracy, reliability, and uncertainty factors applicable to such information.”¹²⁹ Finally, for the purposes of risk assessments, agencies would have to “consider whether the data were developed in accordance with good scientific practice or other protocols to ensure data quality.”¹³⁰

c. 105th Congress

The trend towards transparency continued into the 105th Congress, which addressed data quality and economic analysis in the Less Pollution Through Technology Act of 1997,¹³¹ in which Congress directed EPA to design and implement a “performance-based measurement system . . . to encourage the development of new environmental monitoring technologies.”¹³² Congress failed to enact the Regulatory Improvement Act of 1997,¹³³ which would have required that agencies conduct risk assessments based on “scientific and economic analysis.”¹³⁴ In addition, the Small Business Programs Reauthorization and Amendments Acts of 1997¹³⁵ addressed economic analysis and data quality in a Small Business Administration (“SBA”) loan monitoring system.¹³⁶ The SBA Administrator must “determine data quality standards and control systems for ensuring information accuracy”¹³⁷ and “analyze the benefits and costs of alternatives and use to demonstrate the advantage of the final project.”¹³⁸

126. *Id.*

127. S. 1001, 104th Cong. (1995).

128. *Id.* § 621(4)(A) (The Regulatory Procedures Reform Act defines a “major rule” as “a rule or a group of closely related rules that the agency proposing the rule . . . reasonably determines is likely to have a gross annual effect on the economy of \$100,000,000 or more in reasonably quantifiable direct and indirect costs.”).

129. *Id.* § 622(e)(2)(A). For major rules, agencies would issue and place in the rulemaking file an initial cost-benefit analysis and then provide, pursuant to APA § 553, the public with an opportunity to comment. *Id.* § 622(c)(1)(A)–(B). When publishing a final major rule, the agency shall also file a final CBA, and a summary of the analysis in the rule’s statement of basis and purpose. *Id.* § 622(d)(1).

130. *Id.* § 634(b)(3).

131. H.R. 3065, 105th Cong. (1997).

132. *Id.*

133. S. 981, 105th Cong. (1997).

134. *Id.* § 2.

135. H.R. 2261, 105th Cong. (1997).

136. *Id.* § 204.

137. *Id.* § 204(a)(4).

138. *Id.* § 204(a)(6).

d. 106th Congress

The 106th Congress passed the DQA as part of a Treasury appropriations bill.¹³⁹ In addition, the House Subcommittee on Oversight, Investigations, and Emergency Management held a hearing entitled “Program Data Quality.”¹⁴⁰ The House also considered the Regulatory Improvement Act of 2000,¹⁴¹ which addressed CBA of major rules and stated that “[t]he public has the right to know about . . . the quality of scientific and economic analysis used to support decisions. Such knowledge will promote the quality, integrity, responsiveness, and acceptability of agency actions.”¹⁴² The Second Generation of Environmental Improvement Act of 1999¹⁴³ required the EPA Administrator to submit to Congress and publish in the Federal Register a plan for all of the EPA’s information activities.¹⁴⁴ The Act required the EPA to, *inter alia*, “establish procedures to assure data quality . . . and accuracy, including the detection and correction of errors both prior to and following public dissemination.”¹⁴⁵

Finally, the Federal Information Policy Act of 2000¹⁴⁶ addressed information quality in the federal government by establishing a Federal Chief Information Officer and an Office of Information Policy in the Executive Office of the President.¹⁴⁷ The Act required that, in its collection of information, the federal government must use information technology to “improve data quality, agency efficiency and responsiveness to the public.”¹⁴⁸

e. 107th Congress

Despite the revolution that John Graham has continued at OMB, Congress continues to address governmental transparency and information quality. For instance, the Department of Environmental Protection Act¹⁴⁹ proposed to rename the EPA, elevate it to a Cabinet-level agency,¹⁵⁰ and create a Bureau of Environmental Statistics “to provide . . . such environmental quality and related public health and economic information, and such evaluation and analyses of such information . . . to meet adequately and fully the needs of the Department.”¹⁵¹ Much like language contained in the DQA, the Director of the new agency was charged with “ensuring that data and measures referred to . . . are accurate, reliable, relevant, and in a form that permits

139. 44 U.S.C. § 3516 note, Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 (2001); see *infra* Part IV.

140. *Program Data Quality: Hearing Before the Comm. on Transportation and Infrastructure: Subcomm. on Oversight, Investigations, and Emergency Management*, 106th Cong. (2000).

141. H.R. 3311, 106th Cong. (1999).

142. *Id.* § 2(6).

143. H.R. 3448, 106th Cong. (1999).

144. *Id.* § 103(a).

145. *Id.* § 103(b)(3).

146. H.R. 5024, 106th Cong. (2000).

147. *Id.* § 2(b)(1).

148. *Id.* § 3606(c)(3)(C)(vii).

149. H.R. 2694, 107th Cong. (2001).

150. *Id.* § 101(a)(1).

151. *Id.* § 111(a).

systematic analysis.”¹⁵² The Director also had to make “readily accessible or, to the extent practicable, disseminating all publicly available data . . . in a timely manner and using dissemination methods that will maximize the utility of such publicly available information to the public.”¹⁵³

In addition, the Paperwork Elimination Acts of 1999 and 2001 proposed to amend the Paperwork Reduction Act by, among other things, encouraging the use of “alternative information technologies, that provide for electronic submission, maintenance, or disclosure of information, to reduce the burden and improve data quality, agency efficiency, and responsiveness to the public.”¹⁵⁴

f. 108th Congress

With Republicans controlling both houses, the 108th Congress has focused considerable attention on regulatory reform. In March 2003, Congress conducted a hearing that surveyed the merits of establishing an independent peer review entity for agency actions.¹⁵⁵ The Bush Administration has expressed support for H.R. 2138, a bill that would elevate EPA to Cabinet-level status and create a Bureau of Environmental Statistics that would provide for independent and expert monitoring and reporting of environmental conditions.¹⁵⁶

At least two proposed bills specifically reference the requirements of the Data Quality Act.¹⁵⁷ In addition, the Senate Appropriations Committee expressed the “belief that data endorsed by the Federal Government should be of the highest quality and that the public have the opportunity to review the data disseminated . . . for its accuracy and have available to it a streamlined procedure for correcting inaccuracies.”¹⁵⁸

152. *Id.* § 111(c)(1)(C).

153. *Id.* § 111(c)(1)(F).

154. H.R. 439, 106th Cong. § 4(c) (1999); H.R. 541, 107th Cong. § 4(c) (2001); H.R. 749, 107th Cong. § 4(c) (2001).

155. *See Independent Peer Review of Products that Support Agency Decision-Making: Hearing Before the Subcomm. on Water Resources and Environment of the House Comm. on Transportation and Infrastructure*, 108th Cong. (2003).

156. *Elevation of the Environmental Protection Agency to Department Level Status: Hearing on H.R. 37 and H.R. 2138 Before the Subcomm. on Energy Policy, Natural Resources and Regulatory Affairs of the House Comm. on Government Reform*, 108th Cong. 196, 202 (2003) (testimony of Marianne Lamont Horinko, Acting Administrator, U.S. Environmental Protection Agency) (contending that an independent Bureau of Environmental Statistics “will advance [EPA’s] ability to achieve our shared goal of protecting human health and the environment. Development of statistical measures will . . . fill identified gaps and create information needed to allow the remainder of the Agency to measure progress against environmental results.”).

157. The Clear Skies Act of 2003, S. 1844, 108th Cong. § 407(j)(2)(D) (2003) (“The Administrator shall make a determination based on the study and other information satisfying the criteria of the Data Quality Act whether to establish emissions limitations”); The Safe, Accountable, Flexible, and Efficient Transportation Equity Act of 2004, S. 1072, 108th Cong. § 4250 (2003) (“[T]he Inspector General for the Department of Transportation shall audit the compliance reviews . . . and submit a report . . . on . . . whether the public access information in the Safety Status Measurement System meets the agency’s requirements under the Data Quality Act.”).

158. S. REP. NO. 108-1046, at 136 (2004).

IV. THE DATA QUALITY ACT—BACKGROUND AND DESCRIPTION

A. General Background

The Data Quality Act (“DQA”) was originally enacted in December 2000 as a little-noticed rider to a Treasury appropriations bill introduced by Representative Jo Anne Emerson of Missouri.¹⁵⁹ Signed into law by President Bill Clinton, the DQA provides:

In General—The Director of the Office of Management and Budget shall, by not later than September 30, 2001, and with public and Federal agency involvement, issue guidelines under sections 3504(d)(1) and 3516 of Title 44, United States Code, that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies in fulfillment of the purposes and provisions of Chapter 35 of Title 44, United States Code, commonly referred to as the Paperwork Reduction Act.

Content of Guidelines—The guidelines under subsection (a) shall—

(1) apply to the sharing of Federal agencies of, and access to, information disseminated by Federal agencies; and

(2) require that each Federal agency to which the guidelines apply—

(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guideline issued under subsection (a); and

(C) report periodically to the Director—

(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and;

159. Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 (2001); *Background on Data Quality Guidelines*, OMB Watch, May 28, 2002, available at <http://www.ombwatch.org/article/articleview/773/1/1> (last viewed Mar. 21, 2005).

(ii) how such complaints were handled by the agency.¹⁶⁰

The DQA requires agencies to (1) ensure and maximize the quality, objectivity, utility, and integrity of information that they disseminate, (2) establish an administrative process that allows affected persons to seek and obtain correction of that information, and (3) report yearly to the OMB concerning the receipt and resolution of complaints. In plainer language, the DQA affords affected individuals with the opportunity to file a request for correction ("RFC") and, if necessary, a petition for reconsideration if the scientific, technical, statistical, or financial information in question does not meet DQA standards.¹⁶¹

By May 1, 2002, each agency covered by the Paperwork Reduction Act¹⁶² was required to publish information quality guidelines and to allow for a period of public comment. By July 1, 2002, these agencies were required to draft reports, revised to reflect public comments, and submit them to OMB for review.¹⁶³ Finally, by October 1, 2002, each covered agency published information quality guidelines in their final form.¹⁶⁴

The DQA was enacted without congressional hearings and very limited legislative history.¹⁶⁵ Because of this utter lack of guidance, there is no way to discern the breadth or impact intended by Congress. However, on February 22, 2002, as mandated by the DQA, OMB published *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* ("OMB Guidelines")¹⁶⁶ to guide agencies concerning the implementation of the DQA. Here follows a brief summary of some of the key language contained in the DQA, as interpreted by OMB.

B. Dissemination

The DQA applies to any information that an agency "disseminates" to the public for the first time after October 1, 2002,¹⁶⁷ but it fails to expressly define what constitutes dissemination. According to OMB's Guidelines, dissemination includes any "agency initiated or sponsored distribution of information to the public."¹⁶⁸ OMB defines "information" to include "any communication or representation of knowledge

160. Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515.

161. Frederick R. Anderson, *The Practice: Administrative Law: Data Quality Act*, NAT'L L. J., Oct. 14, 2002, available at http://www.thecre.com/pdf/20040621_data_quality_act.pdf (last visited Mar. 31, 2005).

162. 44 U.S.C. §§ 3501-3520 (2000).

163. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002).

164. *Id.* at 8453.

165. The Conference Report for the DQA provided the following brief language: "The Committee includes a new provision requiring the OMB to develop guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by federal agencies." H.R. CONF. REP. NO. 106-756 83 (2000).

166. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8452.

167. *Id.* at 8459.

168. *Id.* at 8460.

such as facts and data, in any medium of form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.”¹⁶⁹ Information may be “influential,” covering the scientific, financial, or statistical information upon which an agency relies,¹⁷⁰ regardless of whether such information was generated by the government itself or a private third party.

What gives the DQA its bite is its wide range of potential applicability.¹⁷¹ The DQA applies not only to the information that an agency includes in a proposed rulemaking, but also to information that it releases via informal actions. In this information age, sparked by the Internet revolution, the wide range of potential informal dissemination is staggering.¹⁷² Outside of the traditional administrative rulemaking context, agencies disseminate information in published studies, guidance documents, or reports.¹⁷³ These publications invariably include the dissemination of information, thus opening the door to a DQA challenge. The DQA could apply to a seemingly limitless number of instances.¹⁷⁴

In the administrative rulemaking context, information quality is at a premium. According to one commentator:

Information is thus a prerequisite for participation in the rulemaking processes. . . . Participants must have some capacity to develop information upon which to base comments. . . . The possession or lack of information . . . effectively circumscribes the set of parties ‘eligible’ to participate in the development of rules.”¹⁷⁵

However, procedural protections provided by the APA would force an agency to consider DQA concerns that arise from the notice and comment process. Because of these pre-existing APA protections, the DQA will most likely impact the informal, non-rulemaking context, in which agencies will be forced to specifically address DQA concerns.

169. *Id.*

170. *Id.*

171. Noe et al., *supra* note 6, at 10226 (describing the DQA enactment as an “October Revolution” that “potentially packs quite a wallop, because of the implications of information today. Information is power.”).

172. Conrad, *supra* note 8, at 527 (arguing that a dramatic change in government information dissemination has resulted from the advent of the lawsuit, the ubiquity of computers, and the rising importance of agency websites).

173. *Id.* (asserting that “[v]irtually all new documents released publicly by federal agencies, and many historic documents, are now available on [agency] websites”).

174. The OMB specifies that the DQA will not apply to information requested under Freedom of Information Act requests, or the distribution of an agency’s correspondence with individuals, press releases, archival records, public filings, subpoenas, or adjudicative processes. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).

175. Steven Croley, *Making Rules: An Introduction*, 93 MICH. L. REV. 1511, 1519–20 (1995) (reviewing CORNELIUS M. KERWIN, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY (1994)) (reporting the results of a survey of interest groups participating in the rulemaking, in that 83.4 % of the surveyed groups suggest that they “almost always” raise issues concerning the quality of information supporting a proposed rule).

C. Quality, Objectivity, Utility, and Integrity

The DQA also requires that agencies ensure the quality, objectivity, utility, and integrity of disseminated information.¹⁷⁶ Again, the statute in itself fails to define these terms. OMB defines “quality” as an encompassing term that is comprised of “utility, objectivity, and integrity.”¹⁷⁷ “Utility” is defined as the “usefulness of the information to its intended users.”¹⁷⁸ OMB defines “integrity” as referring to the security of information, how agencies are required to protect information from unauthorized access or revision and ensure that the information is not compromised through corruption or falsification.¹⁷⁹

Perhaps most significant is the DQA’s “objectivity” requirement.¹⁸⁰ OMB has defined this term as having dual contexts—both in terms of “presentation” and of “substance.”¹⁸¹ When information is “accurate, clear, complete, and unbiased,” it is presented in an objective manner.¹⁸² Substantive objectivity focuses on “ensuring accurate, reliable, and unbiased information.”¹⁸³ It requires that scientific, statistical, and financial information be generated or developed according to sound scientific and research methods.¹⁸⁴

Industry will undoubtedly use the objectivity definition to submit specific DQA challenges, arguing that information is inaccurate, incomplete, or not subject to sound research methods. For example, in June 2002, the EPA proposed effluent limitation guidelines for the construction and development industry.¹⁸⁵ Several trade organizations¹⁸⁶ submitted comments challenging the economic assumptions underlying the proposed rules. The organizations commented that for apartment properties, the EPA “failed to properly assess the cost associated with current compliance activities and is underestimating the costs of the new rule.”¹⁸⁷

Though not specifically addressed, this situation appeared to be the perfect situation for submitting an RFC raising the DQA’s objectivity requirements. For instance, the EPA assumed that multi-family construction occurs in the same manner and duration as in single-family housing and that each project phase—land acquisition,

176. 44 U.S.C. § 3516 note, Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515 (2001).

177. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8459.

178. *Id.*

179. *Id.* at 8460.

180. *Id.* at 8459–60.

181. *Id.*

182. *Id.* at 8459.

183. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8459.

184. *Id.* (stating that “if data and analytical results have been subjected to formal, independent peer review,” one can presume acceptable objectivity).

185. Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category, 67 Fed. Reg. 42,644 (June 24, 2002).

186. The trade organizations included the National Multi Housing Council (“NMHC”), the National Apartment Association (“NAA”), and the Associated General Contractors of America.

187. NMHC/NAA ELG Comments, Attachment 3—The Effect of EPA’s Proposed Rule on the Multi-Family Housing Industry 89, Dec. 23, 2002, available at <http://www.nmhc.org/Content/ServeFile.cfm?FileID=3317> (last visited Apr. 7, 2005).

development, and construction—takes twelve months.¹⁸⁸ The organizations introduced evidence that contradicted these assumptions, suggesting that the multifamily project phase was between 6.5 and 9.5 years.¹⁸⁹ Under the substantive objectivity prong of the DQA, the organizations could have requested that the EPA make corrections to or redact inaccurate and unreliable information that was not properly tailored to fit the multifamily housing industry. They could have also asserted that the EPA's assumptions were biased, as the proposed rule's economic analysis maintains that the information derived from single family housing focus groups set up by the National Association of Home Builders.¹⁹⁰ In terms of presentation objectivity, the organizations could have argued that the information underlying the rule was incomplete.¹⁹¹

While the aforementioned organizations could have filed a DQA challenge, its ultimate chance of success was questionable. Because the DQA challenge would have arisen in an informal rulemaking, the EPA could have easily dismissed any DQA issues by generally suggesting in its response to comments that it considered DQA implications of the proposed rule.¹⁹² What is certain is that regulated industry will seemingly raise the DQA issue each and every time that it believes the rule or action is not objective—and that agencies will be forced to address these challenges.

D. Influential Information

For DQA purposes, the OMB requires that agencies employ heightened scrutiny before adopting "influential information."¹⁹³ The OMB defines influential information

188. *Id.*

189. *Id.* The organizations also asserted that, contrary to the EPA's assumptions, multifamily property developers do not operate under a system of cross-subsidization, but rather more typically as a self-funded enterprise, usually as an independent limited liability partnership or limited liability company. On April 1, 2004, the EPA opted against imposing ELGs for the construction and development industry, instead relying on a range of existing programs, regulations, and initiatives at the federal, state, and local level for the control of storm water runoff from construction sites. See Environmental Protection Agency, *Fact Sheet: Final Action—Selection of a Non-Regulatory Option* (Mar. 2004), available at <http://www.epa.gov/guide/construction/final-action-fs.htm> (last visited Apr. 30, 2004). In its withdrawal of the proposed rule, EPA stated that the NMHC and the NAA:

commented on certain issues with our methodology. They also provided data to replace assumptions EPA had made on the duration of projects, timing of expenditures, and financial independence of a firm's individual projects from other projects. We reviewed the information and found that it contained valid assumptions for the modeling. Thus, we now consider . . . multifamily projects to be independent (not cross-subsidized by other projects) and have set the duration . . . of multifamily projects to nine years.

Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category, 69 Fed. Reg. 22,476, 22,476 (Apr. 26, 2004).

190. NMHC/NAA ELG Comments, *supra* note 187, at 90.

191. The NAHB surveyed its membership to create an Erosion and Sediment Control/Stormwater Management Ordinance Summary. This chart revealed the duplicative nature of the EPA's proposed rule, in that at least 41 states had already passed ordinances dealing with sediment and erosion control and storm water runoff for residential construction and development. In addition, the NMHC and the NAA surveyed their membership and learned that on a typical, 300-unit garden apartment community, with 18 units per acre, compliance costs would amount to \$1,350 per acre—far in excess of the EPA's estimate of \$59 per acre. *Id.* at 90–91.

192. See *supra* Part IV.B.

193. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8457 (Feb. 22, 2002).

as having a “clear and substantial impact on important public policies or important private sector decisions.”¹⁹⁴ For purposes of the DQA, an agency must provide a “high degree of transparency” for influential information.¹⁹⁵ This may be achieved by the “reproducibility” of information by qualified third parties.¹⁹⁶ The OMB also requires that agencies engaging in health, safety, and environmental risk analyses must “adopt or adapt” the demanding quality standards contained in the Safe Drinking Water Act.¹⁹⁷ These include applying the “best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices” and “data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).”¹⁹⁸

To mount DQA challenges, industry will likely address the definition of “influential information,” which includes any regulatory decision affecting the public health and welfare and decisions affecting the environment.¹⁹⁹ This expansive definition will enable industry to make DQA challenges on the myriad issues to which they are fundamentally opposed. As a hypothetical example, the United States Center for Disease Control’s Advisory Committee on Childhood Lead Poisoning Prevention recently considered lowering the permissible threshold level (“intervention level”) for childhood exposure to lead from 10 µg/dL to 5 µg/dL.²⁰⁰ A study by the National Institute of Environmental Health Sciences suggested that “children who have blood lead concentrations lower than 10 micrograms per deciliter suffer intellectual impairment from the exposure . . . [and] that the amount of impairment attributed to lead was most pronounced at lower levels.”²⁰¹

Because such a change would have significant ramifications across society as well as heightened compliance costs, regulated industry will challenge such a rule as a matter of course. Regardless of what information is disseminated, industry groups will argue that the CDC has failed to satisfy the DQA’s objectivity prong by neglecting to consider relevant studies that conclude that “there is still substantial uncertainty with respect to health outcomes of childhood lead exposure resulting in [blood lead levels] below 10 µg/dL.”²⁰² Regardless of the ultimate outcomes, the mere fact that industry can submit

194. *Id.* at 8460 (maintaining that for influential data, agencies must “include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties”).

195. *Id.*

196. *Id.*

197. *Id.* (citing 42 U.S.C. § 300g-1(b)(3)(A)–(B)).

198. 42 U.S.C. § 300g-1(b)(3)(A)–(B) (2003) (listing additional requirements, including: “(i) each population addressed by any estimate of public health effects; (ii) the expected risk or central estimate of risk for the specific populations; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.” *Id.* § 300g-1(b)(3)(B)(i)–(iv)).

199. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8460 (Feb. 22, 2002).

200. Susan M. Bernard, *Should the Centers for Disease Control and Prevention’s Childhood Lead Poisoning Intervention Level Be Lowered?*, 93 AM. J. OF PUB. HEALTH 1253, 1253 (2003).

201. *Lead Deemed Harmful Even at Very Low Blood Concentrations*, 16 ASBESTOS & LEAD ABATEMENT REP. 6 (2003).

202. Bernard, *supra* note 200, at 1255 (concluding that “[s]etting lead cleanup and abatement targets to

these challenges under the DQA could significantly hinder the actions of federal agencies.

E. Pre-Dissemination Review

OMB Guidelines require that information disseminated by federal agencies after October 1, 2002, must undergo internal pre-dissemination review before it is released to the public.²⁰³ Specifically, OMB Guidelines require that “[t]his process shall enable the agency to substantiate the quality of information it has disseminated through documentation or other means appropriate to the information.”²⁰⁴

While this process is intended to “enable the agency to substantiate the quality of information it has disseminated,”²⁰⁵ in practice it may have a negligible beneficial effect. To avoid a DQA request, an agency would just have to expressly state, in the published response to comments in a rulemaking, or within a guidance document, that the information had in fact been subjected to pre-dissemination review. It would seem difficult for an affected party to prevail on a challenge centering on the sufficiency of the review. Only if an agency admits to not having performed the review, an unlikely scenario, would an affected party be able to temporarily forestall agency action until a review is completed.²⁰⁶

F. Administrative Complaint Process

Under the DQA, agencies are expected to maintain “administrative mechanisms” that permit “affected persons to seek and obtain . . . timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines.”²⁰⁷ These mechanisms should be “flexible, appropriate to the nature and timeliness of the disseminated information” and “incorporated into agency information resources management and administrative practices.”²⁰⁸ In addition, agencies must establish “appropriate” time periods to respond to administrative complaints,²⁰⁹ and to provide an “administrative appeal process to review the agency’s initial decision and specify appropriate time limits in which to resolve such requests for reconsideration.”²¹⁰

achieve postabatement exposure of no more than 10 µg/dL does not adequately protect children’s health and may in some cases be contrary to federal environmental health laws and policies”).

203. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8459.

204. *Id.*

205. *Id.*

206. Alternatively, pre-dissemination review could serve to significantly improve information quality, by correcting errors at the end of the regulatory process—a process that would subsequently reduce potential DQA challenges.

207. *Id.* Agencies are not required to establish new procedures for information that is utilized in the rulemaking process; if the process is insufficient to meet this objective an agency should reform the existing process rather than create duplicative processes. *Id.*

208. *Id.*

209. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8459.

210. *Id.* The administrative challenge mechanism applies to information disseminated after the same date, regardless of when it was first disseminated.

The DQA's potential power lies in the administrative mechanism. A recent RFC to the EPA highlights the possible type of challenge that the DQA could permit. On March 10, 2004, a host of business and real estate trade organizations, led by the National Multi Housing Council, filed an RFC challenging information contained in an EPA policy entitled "Applicability of Safe Drinking Water Act to Submetered Properties."²¹¹ The petitioning organizations took issue with a single assertion in the EPA's policy.²¹² The requestors contended that the EPA's assertion violated the DQA's requirements of pre-dissemination review, as well as its objectivity and utility prongs.²¹³ Most significantly, the parties tendered a specific request for correction to the EPA. They implored the EPA to (1) disclose the process that the statement at issue underwent as part of the internal agency pre-dissemination review, (2) conduct a comprehensive literature review of the established studies, (3) correct the statement in the revised policy, and (4) reissue its revised policy with corrected information.²¹⁴

Under the APA's provisions for notice and comment rulemaking, the APA obligates an agency to respond to data quality concerns raised in comments.²¹⁵ However, because of agencies increasing use and reliance on information dissemination outside of the rulemaking context,²¹⁶ agencies will be forced to address these RFCs in a timely and specific manner. In a perfect world, where agencies could spend unlimited time and resources in addressing these RFCs, information quality would improve by necessity and circumstance. If the agency fails to correct these alleged information problems, the requestors could then petition for a reconsideration, the denial of which could constitute "final" agency action, thereby opening the door to litigation against the agency.

V. INTEREST GROUP RESPONSE TO THE DQA

A. Industry and Business Groups: Decidedly in Favor of the DQA

To supporters, the DQA is "an innocuous call for federal agencies to improve the accuracy of their data."²¹⁷ In addition to being harmless, they argue that the Act is a necessary foundation for "improvement in the overall quality of information which the

211. 68 Fed. Reg. 74,233 (Dec. 23, 2003).

212. See NMHC/NAA Request for Correction, Mar. 10, 2004, available at <http://www.epa.gov/quality/informationguidelines/documents/04017.pdf> (last visited Mar. 21, 2005) [hereinafter NMHC/NAA RFC]. The requestors took issue with the EPA's statement that the "EPA believes that RUBS[Ratio Utility Billing Systems] or other allocation billing systems . . . do not encourage water conservation." 68 Fed. Reg. 74,235 is erroneous in light of the conclusions found in the open literature on this topic. *Id.* at 2.

213. *Id.*

214. *Id.* at 9.

215. 5 U.S.C. § 553(b) (2004).

216. See *supra* Part III.B.

217. Bryant Urstadt, *One-Act Farce*, HARPER'S MAGAZINE, June 1, 2003, at 52; NATIONAL ACADEMY OF SCIENCES, ENSURING THE QUALITY OF DATA DISSEMINATED BY THE FEDERAL GOVERNMENT, Mar. 21, 2002, at 25 [hereinafter "NAS WORKSHOP #1"] (reporting that the OMB believes that the DQA will move agencies in a direction of heightened transparency regarding underlying assumptions, so that reviewers may specifically trace the reasoning behind agency action).

federal government disseminates to the public.”²¹⁸ It has also rectified a glaring omission of the APA and prior administrative legal framework: the inability to provide clear accountability for government use of information to accomplish policy goals.²¹⁹ The DQA could also benefit agency credibility by enhancing transparency through the required reproducibility of scientific studies and improved fact checking.²²⁰

Predictably, industry and pro-business groups have applauded the loudest over the enactment of the DQA.²²¹ The DQA is commonly regarded as the brainchild of Jim Tozzi,²²² an industry lobbyist with the Center for Regulatory Effectiveness, a pro-business think-tank located in Washington, D.C.²²³ One explanation for the law’s enactment was that corporate interests wanted to counter indiscriminate “data dumps” of information into federal Internet sites.²²⁴ Whatever the reasons underlying its enactment, the DQA, according to Tozzi, is “turning out to be a lot more significant than we thought it would be. . . . It sets standards for which you can now judge whatever the government issues.”²²⁵

DQA supporters argue that ensuring the quality of information at the time of dissemination—rather than years down the road, after businesses have spent billions of dollars complying with flawed regulations—is the precise justification for the DQA. Supporters have pointed to a number of instances in which agencies have used flawed data—and in which the DQA could have provided a measure of relief. In 2002, an EPA study utilized to establish Clean Air Act standards for the regulation of industry was found to contain a software error.²²⁶ The program exaggerated the reported effects of

218. Center for Regulatory Effectiveness, *Generic Comments to All Federal Agencies Related to Data Quality Guidelines*, at www.thecre.com/pdf/20020531_cre-generic.pdf (last visited May. 4, 2005).

219. Conrad, *supra* note 8, at 526.

220. O’Reilly, *supra* note 95, at 848. One could argue that while the DQA may be the latest step in the economic analysis of law movement, it also fits into a pattern of laws that actually address transparency in government legislation. See, e.g., The Freedom of Information Act, 5 U.S.C. § 552 (2000); Levy & Shapiro, *supra* note 3, at 506 (citing the Sunshine Act, 5 U.S.C. § 552(b) (2000) (requiring that any agency headed by a multi-member commission meet in public) and the Federal Advisory Committee Act, *id.* at App. §§ 1–16 (2000) (requiring federal advisory committees to meet in open session)).

221. The United States Chamber of Commerce has put together a Data Quality Working Group. The Working Group is comprised of a broad coalition of industry and pro-business interests, including the American Chemistry Council, Dow Chemicals, the National Multi Housing Council, National Association of Realtors, National Federation of Independent Business, the American Trucking Association, Fannie Mae, ExxonMobil, the Heritage Foundation, the Edison Electrical Institute, and various law firms. The Working Group met regularly in the period immediately following enactment of the DQA, and in the period in which the individual agencies promulgated their own information quality guidelines. The Working Group continues to meet to discuss potential legislative updates to the DQA and litigation concerns, and to review pending and completed DQA challenges.

222. Tozzi worked at the OMB from 1972 to 1983 and served as deputy director of the OMB’s Office of Information and Regulatory Affairs. Pat Phibbs, *Lawsuit Charges White House Climate Report Fails to Meet Federal Information Standards*, BUREAU OF NAT’L AFFAIRS DAILY ENV’T REPORT, Aug. 13, 2003, at A-5.

223. See Sidney Shapiro, *An Overview of the Data Quality Act* (forthcoming) (on file with author). Interest in the DQA piqued in 1999 when Ropes & Gray, a law firm, published a white paper arguing that “there were insufficient protections for those who might be adversely affected when agencies produced information on the web and in reports.” Noe et al., *supra* note 6, at 10229. In 2001, the American Bar Association’s House of Delegates recommended that agencies provide procedural protections for individuals concerning information contained on such media. *Id.*

224. Anderson, *supra* note 161.

225. Horvath, *supra* note 10, at A4.

226. *Id.*

air pollution on human health by an estimated twenty-three percent.²²⁷ According to the United States Chamber of Commerce, the EPA's program was two years old when the error was discovered; the DQA could have provided the channel for faster relief.²²⁸ Explained William Kovacs, Vice President of Environment and Technology at the Chamber of Commerce: "The data-quality issue is so basic. . . . You've got to use good data and make sure the assumptions they use are correct."²²⁹

In addition, heightened information transparency can yield significant benefits for both regulated entities and industry. For instance, certain information, like the EPA's Toxic Release Inventory Program disclosure, does not impose additional regulations, or exact any enforceable obligations or preventative action, on regulated industry.²³⁰ Rather, the information is necessary for maintaining a healthy environment—and maintaining accurate and current information is a key component to the program's success. Finally, there is no reason to assume that the DQA will not find support in parties who are traditionally opposed to industry and business interests. For example, pro-environmental groups, like the Sierra Club, could use the DQA to challenge industry-sponsored science. And, if the purpose of the DQA is truly to foster transparency in disseminated government information, then individual citizens and public interest groups, when they encounter what they perceive to be incorrect information, could submit the same DQA challenge as industry—with the same potential range of results.

B. "Paralysis by Analysis": Critics Believe that the DQA Will Further Ossify the Administrative Process

Critics fear that the DQA has rendered an already precarious legal framework for regulating industry conduct even more unstable. Prior to the DQA's enactment, no specific legal mechanism existed for challenging the information underlying agency action.²³¹ The APA's standards of review—arbitrary and capricious and abuse of discretion—address the political decision-making merits of a decision. As its title suggests, the APA focuses on procedural issues as opposed to substantive ones.

There is a widespread fear that the DQA could represent an "over-correction" to the aforementioned legal void. In the context of non-binding agency guidance (e.g., a scientific study posted on an agency's web site), the DQA could become a "tool of industry."²³² Industry could conceivably challenge any and all regulatory action. Industry's innumerable actions will lead to agencies removing information from public reports or their web sites and will discourage accuracy debates.²³³

227. *Id.*

228. *Id.*

229. *Id.*

230. Letter from Thomas McGarity, President, Center for Progressive Regulation 4 (May 31, 2002), available at <http://www.progressiveregulation.org/commentary/dataQuality.pdf> (last viewed Mar. 21, 2005) (stating that the EPA's Toxic Release Inventory only requires that facilities report information and that further steps are up to industry).

231. See *supra* Parts I–II.

232. Noe et al., *supra* note 6, at 10227.

233. *Id.* at 10229.

This phenomenon could exacerbate what has been deemed to be the “ossification” of administrative processes.²³⁴ Critics also argue that the law creates “reams of extra paperwork” and hurdles that will complicate the federal rulemaking process.²³⁵ The DQA imposes new review procedures to information before agencies will accept the information.²³⁶ While ostensibly intended to improve data, the DQA will, in reality, through endless contention and challenges, actually suppress data.²³⁷ If DQA challenges “provide the opportunity for diversion of agency effort and cost inflation, . . . it is . . . possible that the resulting administrative procedure will make [agency] programs . . . less timely and cost effective.”²³⁸ In the words of Frank O'Donnell, executive director of Clean Air Trust, the DQA is designed to “throw sand into the gears of regulatory machinery.”²³⁹ This phenomenon has been described as “paralysis by analysis”²⁴⁰ or “death by data quality.”²⁴¹ Refraining from regulatory action until data quality improves to an acceptable level could result in substantial public harm.²⁴²

Herein lays a significant conflict within the DQA: the tension between an affected party's access to markets that might be impaired by an airing of information quality concerns versus the public's interest in having a government capable of responding quickly to concerns.²⁴³ For the individual, increased transparency has been described as one of the “necessary preconditions to a properly functioning market.”²⁴⁴ However, for industry, transparency may be at a lesser premium, as many times it is industry itself that is funding the science. The DQA could be used by industry to challenge the science that it does not fund. Agencies would counter industry's challenges with information generated by the agency itself or from outside sources who paid for the studies. Such a situation would parallel the “battle of the experts” phenomenon that characterizes typical American litigation.

In addition, there exists a fundamental paradox between the way that scientists and regulators operate.²⁴⁵ “Congress has required agencies to regulate on the basis of

234. Thomas O. McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525, 533–34 (arguing that it is extremely difficult for an agency to promulgate a rule, because of the sheer volume of information that must be gathered, technical and economic analyses, the absence of key information on relevant questions, the need to draw inferences from existing data, large uncertainties, and the professional judgment of staff that is attempting to achieve outcome-oriented regulatory policy).

235. Urstadt, *supra* note 217, at 52.

236. Anderson, *supra* note 161.

237. Urstadt, *supra* note 217, at 52.

238. STRAUSS ET AL., *supra* note 19, at 280.

239. Lorenzetti, *supra* note 8, at 31.

240. Vladeck, *supra* note 49.

241. Letter from Thomas McGarity, *supra* note 230, at 5.

242. *Id.* at 4 (“The danger is that data quality will become a goal in and of itself, rather than a way of ensuring the most effective regulation possible under the circumstances. This danger is real.”). See also Roger C. Cramton, *A Comment on Trial-Type Hearings in Nuclear Power Plant Siting*, 58 VA. L. REV. 585, 591–92 (1972) (arguing that the potential benefits of administrative procedure—including fairness and accuracy—should be balanced against the “efficient disposition of agency business”); Celia Campbell-Mohn & John S. Applegate, *Learning from NEPA: Guidelines for Responsible Risk Regulation*, 28 HARV. ENVTL. L. REV. 93, 121–23 (1999).

243. NAS WORKSHOP #1, *supra* note 217, at 18 (arguing that the federal government does not have a history of expeditious reaction to perceived environmental, health, and safety problems).

244. Letter from Thomas McGarity, *supra* note 230, at 4.

245. See generally Shapiro, *supra* note 223, at 9.

incomplete information, rather than wait for more scientific studies while a hazard goes unabated.”²⁴⁶ In contrast, scientists typically will refrain from drawing a conclusion when they have failed to achieve “perfect knowledge.”²⁴⁷ Science can be an evolutionary process, in which results and conclusions are often ambiguous or subject to equally plausible interpretations.²⁴⁸ According to Robert O’Keefe of the Health Effects Institute, “[M]uch of the data we are trying to make perfect will never be perfect given . . . that this is an evolving art. Yet we need to make decisions based on that imperfect data.”²⁴⁹ Finally, detractors argue that for data to be objective under the DQA, independent scientists must agree on its validity.²⁵⁰ This may lead to “limitless” opportunities to lodge complaints about objectivity.²⁵¹

VI. DRAWING THE *DAUBERT* ANALOGY

In many ways, enactment of the DQA is a significant signpost in the history of agency action. The DQA’s potential impact is so significant that it has been deemed “Regulatory *Daubert*,”²⁵² a reference to the significant 1993 United States Supreme Court decision²⁵³ that drastically impacted the rules governing the admission of scientific evidence in federal court proceedings. Just as *Daubert* and its progeny altered the evidentiary landscape, the DQA threatens to radically change the ability of agencies to regulate. To better judge the merits of this comparison, it is necessary to review how *Daubert* has impacted the evolving history of evidentiary law.

A. A Brief History of Evidentiary Law

Prior to the enactment of the Federal Rules of Evidence, *Frye v. United States*²⁵⁴ governed admissibility of novel scientific evidence. *Frye* centered on a trial court’s refusal to admit evidence based on the forerunner of the modern lie detector test.²⁵⁵ The Court of Appeals for the District of Columbia held that:

[W]hile courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is

246. *Id.* See also Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 89 (1988) (arguing that the goal of governing is different from the goal of science).

247. See, e.g., NAS WORKSHOP #1, *supra* note 217, at 15; Lucinda M. Finley, *Guarding the Gate to the Courthouse: How Trial Judges are Using Their Evidentiary Screening Role to Remake Tort Causation Rules*, 49 DEPAUL L. REV. 335, 361 (stating that in medical practice, physicians do not wait for conclusive studies prior to making diagnoses with a reasonable degree of medical certainty).

248. NAS WORKSHOP #1, *supra* note 217, at 15.

249. NAS WORKSHOP #2, *supra* note 14, at 20.

250. Anderson, *supra* note 161.

251. *Id.*

252. Elliott et al., *supra* note 13, at 10129.

253. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

254. 293 F. 1013 (D.C. Cir. 1923).

255. David E. Bernstein, *Frye, Frye, Frye Again: The Past, Present, and Future of the General Acceptance Test*, 41 JURIMETRICS J. 385, 388 (2001).

made must be sufficiently established to have gained *general acceptance* in the particular field in which it belongs.²⁵⁶

Under *Frye*, if an expert's opinion is based upon a scientific theory or technique, the theory and technique must be one that is generally accepted in the relevant scientific community.²⁵⁷ To qualify as being generally accepted in the relevant scientific community, *Frye* required a showing of wide acceptance, generally by either peer review or publication, that the theory or evidence and was capable of being reliably reproduced.²⁵⁸

While *Frye* gradually spread throughout the early part of the 20th century,²⁵⁹ by the 1950s, criticism of *Frye*'s general acceptance test became more apparent.²⁶⁰ The *Frye* standard was commonly regarded as making the court a "conservative" gatekeeper to distinguish between legitimate science and "junk science."²⁶¹ The criticisms include that: (1) the general acceptance test was too restrictive on emerging science; (2) the *Frye* holding was overly vague in failing to define "general acceptance"; and (3) confusion among the judges led to contradictory rulings in varying jurisdictions.²⁶²

In 1975, the Federal Rules of Evidence ("FRE") went into effect.²⁶³ FRE 702 states that any qualified expert who possesses "scientific, technical, or other specialized knowledge [that] will assist the trier of fact to understand the evidence or to determine a fact in issue" may testify at trial.²⁶⁴ Under FRE 702, the expert's testimony must be based on "sufficient facts or data," and must be the "product of reliable principles and methods."²⁶⁵ Also, if the facts or data in a particular case are of a type "reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence in order for the opinion or inference to be admitted."²⁶⁶ Finally, under the FRE, the judge remains the gatekeeper of questions of evidentiary admissibility.²⁶⁷

256. *Frye*, 293 F. at 1014 (emphasis added).

257. See Finley, *supra* note 247, at 340 (contending that under *Frye*, a scientific opinion must be "generally accepted" within the scientific community in order to be admissible).

258. *Id.*

259. Bernstein, *supra* note 255, at 388–89 (arguing that *Frye* may not have been as slow to spread as some scholars suggest, in large part because (1) some courts accepted the *Frye* holding without expressly citing it, (2) *Frye* only applied to novel scientific techniques, and there were few novel techniques that the court did not readily accept, and (3) most state court opinions are unpublished).

260. *Id.* at 389 (citing Professor Charles McCormick's treatise on evidence, which argued that the general acceptance test "is a proper condition upon the court's taking judicial notice of scientific facts, but not a criterion for the admissibility of scientific evidence").

261. *Id.*

262. *Id.* at 390.

263. See generally FED. R. EVID. (1975) (amended 2000).

264. FED. R. EVID. 702.

265. *Id.*

266. FED. R. EVID. 703.

267. FED. R. EVID. 104(a) ("Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court . . .").

B. Daubert Background

Daubert arose out of a dissatisfaction with *Frye*'s general acceptance test and the Federal Rules of Evidence.²⁶⁸ *Daubert* involved the admissibility of expert testimony linking the use of Benedectin, an anti-nausea drug, with birth defects.²⁶⁹ The United States Supreme Court held that the FRE should guide the courts, with judges acting as evidentiary gatekeepers.²⁷⁰ As such a gatekeeper, a trial judge must ensure that the proffered scientific evidence is both relevant and reliable.²⁷¹ The judge must make determinations about whether "the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue."²⁷²

To help a trial judge make the Rule 702 determination, the Supreme Court provided the following non-exclusive list of factors: (1) whether the theory or technique can be and has been tested;²⁷³ (2) whether the theory or technique has been subjected to peer review and publication;²⁷⁴ (3) the known or potential rate of error;²⁷⁵ (4) the existence and maintenance of standards controlling the technique's operation;²⁷⁶ and (5) whether the theory or technique has been generally accepted by the scientific community.²⁷⁷

While *Daubert* was enacted to liberalize evidentiary rules, in reality it has had the exact opposite effect.²⁷⁸ In traditional Anglo-Saxon jurisprudence, scientific questions are resolved in litigation through the use of "expert" witnesses, who provide opinion testimony.²⁷⁹ However, the FRE turned out to "provide[] limited guidance, and courts . . . tended to interpret them as allowing virtually any opinion testimony from a witness who qualified as an expert."²⁸⁰ Unlike fact witnesses, experts could be paid for their

268. Bernstein, *supra* note 255, at 390 (contending that during the 1980s, a number of influential commentators began to focus on the reliability of expert testimony, and suggested lists of factors that courts could examine to determine reliability).

269. *Daubert*, 509 U.S. at 582–85.

270. *Id.* at 589.

271. See Andrew R. Stolfi, Note, *Why Illinois Should Abandon Frye's General Acceptance Standard for the Admission of Novel Scientific Evidence*, 78 CHI.-KENT L. REV. 861, 866–67 (2003).

272. *Daubert*, 509 U.S. at 592. The holding in *Daubert* has been extended by several subsequent cases. In *General Electric Co. v. Joiner*, the Supreme Court held that a court of appeals may not apply "a particularly stringent standard of review" when considering a trial court's ruling on the admissibility of scientific evidence. 78 F.3d 524, 529 (11th Cir. 1997), *rev'd*, 522 U.S. 136 (1997). In addition, a district court may scrutinize the reliability of an expert's reasoning process and conclusions in addition to the general methodology. Bernstein, *supra* note 255, at 386. In *Kuhmo Tire Co. v. Carmichael*, the Supreme Court extended the *Daubert* holding to non-scientific expert testimony and held that a trial judge may use the *Daubert* technical criteria as a guide, and not a mandatory requirement. 526 U.S. 137, 141 (1999).

273. *Daubert*, 509 U.S. at 593.

274. *Id.*

275. *Id.* at 594.

276. *Id.*

277. *Id.* at 594–95.

278. See Finley, *supra* note 247, at 335 (arguing that after *Daubert*, federal judges have substantially raised "the threshold of scientific proof plaintiffs need to get their expert causation testimony admitted").

279. Cliff Hutchinson & Robert Powell, *A New Plague—Mold Litigation: How Junk Science and Hysteria Built an Industry*, U.S. CHAMBER OF COMMERCE'S INST. FOR LEGAL REFORM & THE CTR. FOR LEGAL POL'Y AT THE MANHATTAN INST. 19 (2003), available at <http://www.uschamber.com/press/releases/2003/july/03-126.htm> (last viewed Mar. 21, 2005) (emphasis omitted).

280. *Id.*

testimony—a financial reality that resulted in a thriving industry of “‘hired gun’ testifiers who were willing to testify to whatever opinion was needed.”²⁸¹

Perhaps the most significant fallout is how *Daubert* has been linked to “junk science,” a phenomenon commonly defined as “pseudo-scientific theories with no true scientific basis, concocted . . . to support a position in court.”²⁸² Junk science typically promotes information that has the sole purpose of promoting an individual’s ideology.²⁸³

Much to the benefit of deep-pocketed defendants and to the chagrin of plaintiffs, judges rigidly apply *Daubert* principles. In cases ranging from mass toxic torts to occupational exposures to individual suits, filing a *Daubert* challenge to any and all causation has become strategically necessary and routine.²⁸⁴ In many cases, judges have transformed their gatekeeper duty into one of a “junior scientist” charged with analyzing and scrutinizing all expert evidence in an attempt to keep flawed science out of the courtroom.²⁸⁵ As a result, trial courts routinely strike “relevant and instructive testimony of well-known and respected experts in their fields of expertise, even when the evidence is methodologically sound and meets the two-pronged *Daubert* test of relevance and reliability.”²⁸⁶ In addition, opposing parties will call experts to testify in support of the scientific validity of a particular methodology, as opposed to causation issues.²⁸⁷ Because of this trend, opposing parties “may find themselves out of luck if they do not proffer testimony to support the methodology underlying the testimony of the main causation witness/expert.”²⁸⁸ In the quest to keep junk science out of the courthouse, *Daubert* has denied many deserving plaintiffs of their day in court.

C. How the DQA May Have a Similar Impact to *Daubert*

A recent administrative law trend has been the extension of *Daubert* principles to the regulatory arena—creating what has been deemed “Regulatory *Daubert*,” whereby agency decisions in administrative actions must be grounded on reliable, sound science

281. *Id.* Hutchinson and Powell cite the following: Michael H. Graham, *Expert Witness Testimony and the Federal Rules of Evidence: Insuring Adequate Assurance of Trustworthiness*, 1986 U. ILL. L. REV. 43, 45 (“Today practicing lawyers can locate quickly and easily an expert to advocate nearly anything the lawyers desire.”); Sharon Begley, *Ban on “Junk Science” Also Keeps Jurors From Sound Evidence*, WALL ST. J., June 27, 2003, at B1 (quoting the former editor of the *New England Journal of Medicine* as stating that prior to *Daubert*, “[i]t was pitiful how people with few credentials, who made a career out of courtroom testimony, were hired to be expert witnesses”).

282. Hutchinson & Powell, *supra* note 279, at 20 (citing PETER W. HUBER, *GALILEO’S REVENGE: JUNK SCIENCE IN THE COURTHOUSE* (1991)). See also Finley, *supra* note 247, at 338 (defining “junk science” as expert opinions not being well founded in scientific methodology or being based on significant departures from the mainstream of scientific opinion).

283. *Elevation of the Environmental Protection Agency to Department Level Status: Hearing on H.R. 37 and H.R. 2138 Before the Subcomm. on Energy Policy, Natural Resources and Regulatory Affairs of the House Comm. on Government Reform*, 108th Cong. 3 (2003) (attachment 1 to the statement of Dr. A. Alan Moghissi, President, Institute for Regulatory Science), available at <http://reform.house.gov/UploadedFiles/9-9-03%20Moghissi%20Testimony.pdf> (last viewed Mar. 21, 2005).

284. TEE L. GUIDOTTI & SUSAN G. ROSE, *SCIENCE ON THE WITNESS STAND: EVALUATING SCIENTIFIC EVIDENCE IN LAW, ADJUDICATION AND POLICY* 82 (2001).

285. *Id.*

286. *Id.*

287. *Id.* at 86–87.

288. *Id.* at 87.

to withstand judicial scrutiny.²⁸⁹ While federal case law has yet to specifically extend *Daubert* principles to review agency actions, it seems logical that if an agency based an action solely on unreliable information, a reviewing court could have adequate authority to vacate and remand the rule.²⁹⁰

By importing *Daubert*-type principles into judicial review under the Administrative Procedure Act, we can better define the principles of judicial review, make them more consistent, and better advise the Agency, the public, and Congress of the standards the EPA, as well as the Supreme Court, should apply in the review of agency science.²⁹¹

The idea behind Regulatory *Daubert* is to raise the bar for accepting agency action to allow it only upon a showing of reliable and relevant data or information. Regulatory *Daubert* could promote "the full disclosure of all of the Agency's underlying principles, assumptions, and facts and obligate the Agency to come completely clean on the foundation for its scientific decision."²⁹² Given such appropriate, full disclosure, an agency would be entitled to policy deference on the information foundation underlying its decision.²⁹³

Under such a model, the DQA could parallel a trend that is occurring in an increasing number of cases, in both the state and federal court systems, that now require "the presence of some sort of studies with statistically significant findings before allowing medical causation evidence and/or testimony to go to the jury."²⁹⁴ The requirement of underlying statistics before admitting a scientific methodology will, perhaps unfairly, classify novel or emergent science as junk science. Even though a potential plaintiff could get a cutting-edge, non-conventional diagnosis from his physician, said diagnosis would be inadmissible in a court of law.

This trend is yet another similarity between *Daubert* and the DQA's requirements. If one of the public policies behind the DQA is indeed transparency, industry will no doubt argue that an agency should refrain from engaging in a rulemaking or other activity until it can justify its actions with substantial and complete underlying information. While it is too early to tell for sure if the DQA will mirror *Daubert*'s restrictive application, it appears at least possible that the DQA could have a chilling effect on agency actions that are based on emergent science or not fully proven science.

289. Paul S. Miller & Bert W. Rein, "Gatekeeping" Agency Reliance on Scientific and Technical Materials After *Daubert*: Ensuring Relevance and Reliability in the Administrative Process, 17 *TOURO L. REV.* 297, 305-06 (2000). The federal government has also evidenced a willingness to further this trend. For instance, the Science, Technology, and Law program of the National Academies of Science was created because the "[Supreme] Court's *Daubert* decision has had ramifications across the entire field of civil litigation, in criminal litigation, and obviously in the regulatory arena." NAS WORKSHOP #1, *supra* note 217, at 3.

290. See Miller & Rein, *supra* note 289, at 315 (stating that *Daubert* principles of relevance and reliability are "clearly compatible" with APA standards of review). In addition, the DQA would seemingly not violate the "principle of deference to administrative interpretation" laid out in the U.S. Supreme Court's seminal decision, *Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984). *Id.* at 318. The *Chevron* holding limits such deference only to legal interpretations reflecting policy or political judgments and not to strictly information concerns. *Id.* at 318-19.

291. Elliott et al., *supra* note 13, at 10129 (citation omitted).

292. *Id.* at 10130.

293. *Id.*

294. GUIDOTTI & ROSE, *supra* note 284, at 89 (citing *Berry v. CSX Transp., Inc.*, 709 So. 2d 552, 570 (Fla. App. 1998); *Kelly v. American Heyer-Schulte Corp.*, 957 F. Supp. 843 (W.D. Tex. 1997), *dismissed by Kelly v. American Heyer-Schulte Corp.*, 139 F.3d 899 (5th Cir. 1998)).

One of the open questions involving the DQA is the degree to which reviewing courts will intervene in DQA challenges. The DQA does not specifically address the issue, which has been subject to considerable debate among legal scholars.²⁹⁵ Some contend that the DQA embodies a “win at the agency” strategy that presupposes extensive DQA litigation.²⁹⁶ Such a strategy would include submitting an RFC to the agency that identifies a claimed deficiency and a statement of requested agency action that would correct the problem.²⁹⁷

It seems more likely, however, that the courts will likely get involved in DQA challenges and denials. To fully achieve its purported potential as a “good government” statute, the DQA may require judicial enforcement.²⁹⁸ Typically, the availability of judicial review for DQA RFCs will be for the courts, not the agencies, to decide.²⁹⁹ In addition, there is a strong presumption under the APA in favor of judicial review.³⁰⁰ As one commentator suggests, “[c]ourts have engaged in judicial oversight of other good-government statutes such as the Freedom of Information Act because they seek to change entrenched bureaucratic behavior. . . . Courts decide for themselves what the statutory plan requires them to do.”³⁰¹ In addition, by promulgating a scientific report or a guidance document on its web site, an agency has arguably engaged in “final” agency action, which could trigger general review provisions under the APA.³⁰²

To date, there have been only a handful of lawsuits filed over DQA concerns. On August 6, 2003, the Competitive Enterprise Institute (“CEI”), a free-market advocacy group, filed suit in federal court,³⁰³ alleging that the White House Office of Science and

295. See Shapiro, *supra* note 223, at 14–15 (contending that the issues involving eventual DQA court action include standing and ripeness and other procedural issues, as well as whether Congress intended to preclude judicial review and whether the dissemination of information is a “final” agency action, the prerequisite for review under the APA); NAS WORKSHOP #1, *supra* note 217, at 73 (arguing that Congress could have intended to preclude judicial review under the DQA, except in cases of a clear abuse of discretion, and that courts will not likely step in to adjudicate the right and wrong of controversial, non-settled science); *id.* at 115 (arguing that because the DQA creates mandatory duties, it “imposes procedures that are the kind that courts historically have policed”).

296. Noe et al., *supra* note 6, at 10230 (reporting the comments of Jim Tozzi, who suggested that a “win in court” approach would clog the system).

297. *Id.* at 10231.

298. *Id.* at 10228 (arguing that courts tend to review typical good government statutes, like the Federal Advisory Committee Act, the Freedom of Information Act, and NEPA, and that a strong judicial presumption of the availability of judicial review exists in the absence of a congressional indication of a preclusion of judicial review); NAS WORKSHOP #1, *supra* note 217, at 22–23 (arguing that “it will probably take a few critical court decisions before we know how this law and the associated guideline will be interpreted by judges”).

299. Conrad, *supra* note 8, at 539.

300. *Id.* (arguing “that the fundamental purpose of enacting the [DQA] was to establish statutorily an administrative decision-making process precisely so that affected persons would have some final agency action from which to appeal”).

301. Shapiro, *supra* note 223, at 15.

302. *Id.* (stating that final agency actions occur when “rights or obligations have been determined” from which “legal obligations will flow,” or when “an agency’s failure to correct information has some independent impact on public policy or private sector decisions, i.e. has some ‘real-world’ impact”); see also O’Reilly, *supra* note 95, at 841 (arguing that although judicial review is not expressly provided under the DQA, it is likely to be inferred, once the challenger has exhausted the DQA’s administrative remedies). Incidentally, simply securing judicial review under the APA does not guarantee success. Rather, courts typically grant broad discretion over agencies’ choices of procedures and decline to impose significant constitutional and statutory constraints on these decisions. See Levy & Shapiro, *supra* note 3, at 473.

303. Competitive Enter. Inst. v. Bush, D.D.C. No. 03-1670, Aug. 6, 2003.

Technology Policy violated DQA standards when it distributed a report on climate change to President Bush and the Congress.³⁰⁴ In January 2002, CEI allegedly requested that the White House Science Office cease dissemination of *Climate Change Impacts on the United States: The Potential Consequences of Climate Variability and Change*, because the document allegedly “removed information that would let readers know the uncertainty with which it characterized certain historical climate information.”³⁰⁵

The White House Science Office rejected CEI’s petition in 2003, and failed to respond to CEI’s subsequent appeal.³⁰⁶ CEI argued that failure to respond constituted a rejection of its appeal, and said rejection amounted to final agency action.³⁰⁷ In November 2003, CEI dropped its DQA lawsuit, after the White House publicly acknowledged that the document had not been subjected to DQA guidelines.³⁰⁸

On December 9, 2003, the Public Employees for Environmental Responsibility (“PEER”) filed suit against the United States Army Corps of Engineers, alleging that the Corps failed to respond to a DQA RFC.³⁰⁹ Filed in the United States District Court of the District of Columbia, PEER’s lawsuit contends that information contained in a monthly status report on the Mississippi River failed to comply with DQA standards for objectivity, utility, and integrity of information.³¹⁰ In addition, the U.S. Chamber and the Salt Institute recently filed a lawsuit claiming that the U.S. Department of Health and Human Services violated the DQA by withholding information from a federally funded study about the blood pressure effects of dietary salt.³¹¹ As of submission of this dissertation, these cases remains active.

VII. SURVEY OF DQA CHALLENGES TO EPA

Now that over two years have passed since its enactment, a cursory review of the DQA’s impact on federal agencies is appropriate. This section focuses on the DQA’s impact on the U.S. Environmental Protection Agency (“EPA”), and how the EPA has handled DQA challenges. As a threshold concern, it should be noted that the EPA, like OMB and OIRA, has entered the regulatory reform arena, embracing principles of economic analysis of law. EPA Administrator Mike Leavitt’s approach to environmental protection is encapsulated in the “Enlibra Principles,” which he co-authored with former Oregon Governor John Kitzhaber. One of the principles, entitled “Recognition of Benefits and Costs,” contends that “[e]nvironmental decisions should

304. Phibbs, *supra* note 222, at A-5.

305. *Id.* (stating that removal of the information in question created “an unsupportable and inaccurate portrayal of data recreating past climate”).

306. *Id.*

307. *Id.*

308. Darren Samuelsohn, *CEI, White House Resolve Suit with New Disclaimer Over Data Quality*, GREENWIRE, November 7, 2003, available at http://www.eenews.net/Greenwire/searcharchive/test_search-display.cgi?q=samuelsohn&file=%2FGreenwire%2Fsearcharchive%2FNewsline%2F2003%2FNov7%2F11070307.htm (last visited Apr. 7, 2005).

309. *Second Lawsuit Filed Under the DQA*, OMB Watch, Dec. 15, 2003 (on file with author).

310. *Id.*

311. Pat Phibbs, *Chamber, Institute File Data Quality Suit Seeking Release of Salt Study Information*, BUREAU OF NAT’L AFFAIRS DAILY ENV’T REPORT, Apr. 1, 2004, at A-41.

be guided by an assessment of the true costs and true benefits of different options, including life-cycle costs. . . . Options should consider all social, legal, economic, and political factors, while ensuring that neither quantitative nor qualitative factors dominate.”³¹²

In October 2002, the EPA published its *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (“EPA Guidelines”).³¹³ As required by the OMB, the EPA’s Guidelines contain the Agency’s policy and procedural guidance for ensuring information quality, outline the administrative mechanisms for pre-dissemination review of information products, and enable affected persons to seek and obtain corrections of information that allegedly does not comport with DQA standards.³¹⁴

The EPA’s Guidelines closely track those put out by the OMB. Both include goals that “[d]isseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity . . . [and] [a]dministrative mechanisms for correction should be flexible, [and] appropriate to the nature and timeliness of the disseminated information.”³¹⁵ The EPA employs the OMB’s definitions for many of the DQA’s key words and phrases, including “quality, objectivity, integrity, and utility,”³¹⁶ “information,”³¹⁷ and “influential information.”³¹⁸ In addition, the EPA’s Guidelines survey the Agency’s existing information management systems.³¹⁹

The EPA’s Guidelines also specify the administrative mechanisms by which an affected person or party may request a correction of allegedly erroneous information.³²⁰ The EPA expressly lists the information that should be included in a request for correction,³²¹ endeavors to respond to such requests within 90 days,³²² and asserts that

312. Environmental Protection Agency, *Mike Leavitt on Environmental Stewardship*, available at <http://www.epa.gov/adminweb/leavitt/enlibra.htm> (last visited on Apr. 7, 2005). The EPA also recently formed a work group to address problematic issues inherent in cost-benefit analysis—namely, that certain risks pose difficulties for economists to place a value on the benefits on their reduction or eradication. The Agency recently announced the preliminary results from a case study that involved a work group that brought risk and economic analysts together with the goal of developing risk assessment in a way that made it easier for economists to place dollar values on the benefits of reducing exposure to chemicals and pollutants. See Pat Pibbs, *Policies, Guidance on Many Scientific Issues Under Development*, EPA Staff Tell Advisers, BUREAU OF NAT’L AFFAIRS DAILY ENV’T REPORT, Dec. 15, 2003, at A-10.

313. Environmental Protection Agency, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (October 15, 2002), available at <http://www.epa.gov/fedrgstr/EPA-GENERAL/2002/October/Day-15/g26176.htm> (last visited Apr. 7, 2005) [hereinafter “EPA Guidelines”].

314. EPA Guidelines § 1.

315. *Id.*; 67 Fed. Reg. 8452, 8458–59 (Feb. 22, 2002).

316. EPA Guidelines § 5.1; 67 Fed. Reg. at 8459.

317. EPA Guidelines § 5.3; 67 Fed. Reg. at 8460.

318. EPA Guidelines § 5.3; 67 Fed. Reg. at 8455.

319. EPA Guidelines §§ 4–4.9 (listing these systems to include: a quality system, a peer review policy, an action development process, an integrated error correction process, an information resources management manual, a risk characterization policy and handbook, and program-specific policies).

320. *Id.* § 8 et seq.

321. EPA Guidelines § 8.2 (listing the following information as being necessary for a request for correction: name and contact information for the individual or organization submitting a complaint; a description of the information the person believes does not comply with EPA or OMB Guidelines, including specific citations to the information and to applicable sections of the EPA or OMB Guidelines; an explanation of how the information does not comply with EPA or OMB Guidelines; recommendations of corrective action; and an explanation of how the alleged error affects or how a correction would benefit the requestor).

it will determine the appropriate corrective action.³²³ To help ensure transparency of its information quality process, the EPA has launched a web site to enable the public to view all DQA petitions, the EPA's acknowledgement and response letters, and other DQA-related correspondence.³²⁴

Prior to October 1, 2002, the date on which the DQA requirements went into effect, much scholarly controversy centered on whether the DQA would have any practical impact on agency function. For instance, agencies will universally assert that they have data quality and error-correction procedures in place that pre-date the DQA's enactment. For example, over an eighteen-month period prior to the DQA, the EPA contends that it received 1,000 notifications and submissions that have come in via the agency's error correction notification process.³²⁵ The EPA determined that 300 of these were valid, resulting in 120 that required data being corrected.³²⁶

In practice, challenges under the DQA are not playing out in the rulemaking context, as was predicted by many scholarly pundits and legal commentators. Instead, industry is using the DQA in Requests for Corrections ("RFCs") and to counter other informal administrative processes. Between enactment of the DQA and October 2003, the EPA received 13 RFCs and two petitions for reconsideration.³²⁷ As of publication of this article, the EPA has not granted a single RFC. The EPA has instead come up with novel ways of dismissing these claims. The EPA has determined that several of the requests do not fall under the DQA for procedural reasons. On several instances, the EPA has asserted that it is not the appropriate agency to consider requests for correction.³²⁸ The EPA has also asserted that RFCs under the DQA are inappropriate where other administrative actions could conceivably remedy the alleged problem.³²⁹

The EPA has based several decisions on whether a dissemination of information was implicated. For example, the EPA deemed a DQA request incomplete because it failed to include a reference to a specific piece of information by the EPA.³³⁰ In addition, the EPA's Office of Air and Radiation challenged two EPA documents,

322. *Id.* § 8.4.

323. *Id.* (stating that for appropriate corrective action, the Agency will consider, among other things, the nature and timeliness of the information involved and the significance of the error on the use of the information and the magnitude of the error).

324. See Environmental Protection Agency, *EPA's Information Quality Guidelines (IQG)*, at <http://www.epa.gov/quality/informationguidelines/> (last visited on Mar. 31, 2005).

325. NAS WORKSHOP #1, *supra* note 217, at 151.

326. *Id.*

327. ENVIRONMENTAL PROTECTION AGENCY, INFORMATION QUALITY FY03 ANNUAL REPORT, U.S. ENVIRONMENTAL PROTECTION AGENCY (2004), available at http://www.epa.gov/quality/informationguidelines/documents/EPA_IQG_FY03_Annual_Report.pdf (last visited on Mar. 30, 2005) [hereinafter "EPA INFORMATION QUALITY REPORT"]. As of publication of the report, EPA had yet to respond to two of the requests for correction.

328. *Id.* § 3.7 (reporting that EPA is "not the appropriate agency to consider requests for correction relative to Climate Action Report 2002," and that request from the Competitive Enterprise Institute was forwarded to the State Department).

329. *Id.* § 3.4 (contending that a DQA request concerning an EPA assertion about the endocrine effects of atrazine on frogs would be treated as a comment in the notice and comment period for the Environmental Risk Assessment for atrazine); *Id.* § 3.14 (Letter from Susan B. Hazen, Principal Deputy Assistant Administrator, U.S. EPA, to Dino Privitera, Morgan, Lewis & Bockius (Nov. 24, 2003) (reporting that EPA intended to update and revise the guidance for preventing asbestos disease among auto mechanics, and that the petitioner's DQA complaints would be considered in the aforementioned notice and comment period)).

330. *Id.* § 3.12 (involving a request that EPA adopt a uniform advisory level for percholate).

alleging that there were format problems due to conversion issues between versions of WordPerfect software.³³¹ The EPA decided that the DQA did not apply, as the request centered on formatting concerns and not a dissemination of information.³³² In December 2002, the United States Chamber of Commerce submitted a DQA request, alleging that the minutes of a Scientific Advisory Board meeting were inaccurate.³³³ The EPA claimed that documents, like the minutes, generated under the Federal Advisory Committee Act were not considered information dissemination under the DQA.³³⁴ And in a challenge regarding the carcinogenicity of percholate, the EPA ruled that meetings with EPA officials were “general meetings” and “there were no official statements regarding the Agency’s position on percholate and any potential impacts on human health . . . we would consider such discussions to be informal communications that the EPA did not disseminate to the public beyond their original context.”³³⁵

Simple disagreements with agency policy decisions have not persuaded the EPA to take corrective action, either. In a response to an RFC submitted by BMW Manufacturing Corporation (“BMW”), the EPA essentially stood by its decision to list BMW as being in significant non-compliance with the Resource Conservation and Recovery Act.³³⁶ The EPA implies that BMW’s RFC failed to satisfy DQA requirements because it involved a disagreement with the EPA’s decision or actions and did not demonstrate a problem with data quality.³³⁷

Finally, any impact the DQA has effected on agency action has been marginal at best. In October 2002, the Chemical Products Corporation (“CPC”) challenged information concerning the reference dose for barium in the EPA’s integrated risk information system (“IRIS”).³³⁸ The EPA briefly and tersely responded that the “petitioner offered an alternative assessment of the relevant science but failed to demonstrate that the EPA’s assessment is not consistent with EPA Guidelines regarding objectivity and reproducibility.”³³⁹ In March 2003, CPC submitted a petition for reconsideration of the EPA’s decision.³⁴⁰ Because it considered the information in CPC’s petition to be “substantially different” from the initial RFC, the EPA treated the petition as an original RFC. In light of CPC’s second RFC, the EPA has stated that the toxicological review and IRIS summary for barium will be revised to include a more explicit and transparent analysis of data.³⁴¹ According to the EPA, “[i]f the expanded analysis does not support the statement currently contained for barium, EPA will reassess the IRIS barium and compounds substance file.”³⁴²

331. *Id.* § 3.0.

332. *Id.*

333. Letter from William L. Kovacs, Vice President, Chamber of Commerce, to United States Environmental Protection Agency (Dec. 17, 2002), *available at* <http://www.epa.gov/quality/informationguidelines/documents/4301.pdf> (last viewed Mar. 31, 2005).

334. EPA INFORMATION QUALITY REPORT § 3.5.

335. *Id.* § 3.9.

336. *Id.* § 3.6.

337. See *BMW Challenges Compliance Listings*, OMB Watch May 21, 2003, *available at* www.ombwatch.org/article/articleprint/1536-1/252 (last viewed Mar. 31, 2005).

338. EPA INFORMATION QUALITY REPORT § 3.3.

339. *Id.*

340. *Id.* § 3.10.

341. *Id.*

342. *Id.* EPA also plans to conduct an external peer review of the revision, and anticipates completion by

CPC's request for correction and subsequent petition for reconsideration may forecast the DQA's potential impact. Far from bringing a tidal wave of litigation, flooding the courts, and shutting down agency action, the DQA will operate on a more microscopic level. Affected individuals will be able to challenge the data and information that underlies agency action, but they will have a tough road to hoe. Industry will possess yet another weapon by which to challenge an agency, but the weapon will work more like a tranquilizer than a nuclear bomb. The rare DQA victory will comprise of an agency begrudgingly conceding a minor point or piece of information.³⁴³ Far from a titanic shift in the process of agency action and conduct, these subtle victories will be the hallmark of life in the DQA age. And in keeping with so many of its predecessors in the economic analysis of law movement, the DQA will have a marginal impact in achieving its stated goal: that of improving information quality and administrative transparency.

VIII. CONCLUSION

In the initial years since its enactment, the Data Quality Act has proved to be an intriguing new development of administrative law. It is the latest in a long string of federal statutory authority and legislation that addresses elements of economic analysis of law. The DQA purports to guarantee the quality, objectivity, integrity, and accuracy of the data that underlies the information that the federal government disseminates to the general public. It has not created a firestorm of litigation or completely bogged down the federal government. It does, however, stand as a significant signpost in the economic analysis of law movement—a movement that relies on the accuracy and transparency of information to render cost-benefit analyses of agency action.

While the DQA is an important step in the economic analysis of law movement, it is certainly not the final one. Transparency in the federal administrative system continues to remain a hot plate issue for Congress. In September 2003, the OMB requested public comments on a proposal to issue new guidance to “realize the benefits of meaningful peer review of the most important science disseminated by the Federal Government regarding regulatory topics.”³⁴⁴ The OMB's proposal also would require each agency that receives a non-frivolous DQA Request for Correction to promptly post the challenge on its website or forward a copy to the OIRA.³⁴⁵ In October 2003, the

June 2004. See *Data Quality Challenge on Barium*, OMB Watch, Dec. 23, 2002, available at www.ombwatch.org/article/articleprint/1231/-1/158/ (last viewed Mar. 31, 2005).

343. In the Chamber's RFC over atrazine, while disputing the petitioners' claims that EPA's risk assessment asserted that atrazine “causes endocrine effects,” the Agency made “minor editorial changes” in its revised assessment to prevent further ambiguity about its position.

344. Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023 (Sept. 15, 2003). Under OMB's proposal, federal agencies would have to require peer review of “significant regulatory information,” which is “scientific or technical information that (i) qualifies as ‘influential’ under OMB's information quality guidelines and (ii) is relevant to regulatory policies.” *Id.* at 54,026 (articulating that peer review is necessary for “significant regulatory information” upon which an agency bases its support for a major regulatory action, or which could have a clear and substantial impact on import public policies or private sector decisions with a possible impact of \$100 million in any year).

345. *Id.* (stating that the posting and reporting requirement will assist OMB in discharging its DQA requirement of monitoring the quality of publicly disseminated information).

General Accounting Office (“GAO”) issued a report³⁴⁶ concluding that the OIRA, while more open than under previous administrations, continues to struggle to comply with the executive orders signed by Presidents Reagan and Clinton.³⁴⁷

Finally, Congress has recently delivered the following statement to the OIRA: “Agencies are shielding significant, influential data and related documents . . . from the requirements of the Federal Data Quality Act.”³⁴⁸ Congress has directed the OIRA to submit a report to the House and Senate Committees on Appropriations on how information quality guidelines to agencies may be updated to improve the transparency of agency science.³⁴⁹ Only the passage of time will tell whether an amendment is needed to spur faster and more effective DQA compliance from federal agencies, or whether the DQA’s two paragraphs, standing alone, rectify a glaring absence of the APA, and adequately address data quality concerns.

346. RULEMAKING: OMB’S ROLE IN REVIEWS OF AGENCIES’ DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS, GAO-03-929 (Oct. 2003).

347. Coyne, *supra* note 91. The GAO report suggested that the OIRA has persuaded the EPA and other federal agencies to make major changes to rules in the early stages of drafting rules. According to the report, 14 of 17 rules submitted by the EPA to the OIRA were significantly changed at the OIRA’s suggestion, and another proposed rule was returned to the EPA. *Id.* In response to the GAO report, Senators Dick Durbin and Joe Lieberman requested that the White House disclose more information about the process by which federal agencies change major rules based on input and revisions from the executive branch. See Press Release, Senate Committee on Governmental Affairs, Lieberman, Durbin Press OIRA on Openness, Accountability (Nov. 7, 2003), available at http://www.senate.gov/~gov_affairs/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=563&Affiliation=R (last visited Apr. 8, 2005) (alleging inadequate disclosure of information about the OIRA’s communications with outside parties, a failure to disclose e-mail, faxes, and documents exchanged between agency regulators and the OIRA staff, and the lack of explanation for why a rule is withdrawn from review).

348. S. REP. NO. 108-146 (2004).

349. *Id.*

