

REGULATORY REFORM: IS IT STILL A PIPE DREAM?

A LOOK AT THE 104TH CONGRESS

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EXECUTIVE SUMMARY

The need for regulatory reform has been recognized for decades. Recent White House efforts on this front have varied dramatically, from President Reagan's controversial, and ultimately ineffectual, attempts to control environmental and safety regulations, to President Clinton's virtual abandonment of regulatory review.

With the 104th Congress, regulatory reform has moved to center stage. It was a major element in the Republican's *Contract With America*, and the House of Representatives' enactment of H.R. 1022 suggested the possibility that real reform might finally be achieved. The House bill attempts to replace the wildly unrealistic risk assessments found in such programs as Superfund with science-based "best estimates." It recognizes the principle that regulations should "do no harm" through a Supermandate provision, under which cost-benefit requirements are imposed on existing law. Most importantly, it allows courts to review whether agencies have in fact complied with these provisions.

By comparison, Senate bill S. 343, which has been significantly weakened during floor debate, takes a far less forceful approach. It lacks any "best estimate" provision, and its cost-benefit requirements can only supplement, rather than override, existing law. The judicial review provision of S. 343 is so weak that an agency's refusal to do any cost-benefit analyses at all may well pass muster in court. S. 343's most promising provision is its replacement of the Delaney Clause with a "negligible risk" standard.

Unless S. 343 is substantially strengthened in conference, its enactment may well be worse than no regulatory reform legislation at all.

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INTRODUCTION

After more than 25 years of explosive growth in federal regulations, growth fueled by both hyperactive Congresses and an ever-expanding federal bureaucracy, the 104th Congress is considering legislation to curb overregulation. To date, the House of Representatives has passed its version of a regulatory reform bill (H.R. 1022) and the Senate is currently debating its version (S. 343). Notwithstanding these efforts, the basic question is still open—will “real” regulatory reform be achieved?

The purpose of this paper is to provide an analysis of the likely impacts of the key provisions of the regulatory reform efforts of the 104th Congress. This paper is the first in a series of analyses to be published until a regulatory reform bill is either enacted or regulatory reform is declared dead in the 104th Congress. It is hoped that honest and realistic appraisals of the regulatory reform efforts will assist the Congress in enacting effective regulatory reform, and the public in understanding what the Congress is doing and why.

The problems of a burgeoning federal regulatory process were first recognized during the New Deal era.

HISTORICAL PERSPECTIVE ON THE REGULATORY PROCESS

The problems of a burgeoning federal regulatory process were first recognized during the New Deal era. In 1939, President Franklin D. Roosevelt asked the Attorney General to appoint a distinguished committee to study existing the regulatory process and to formulate recommendations. The Attorney General’s Committee on Administrative Procedure, chaired by Dean Acheson, produced a series of monographs on agency functions that were submitted in 1941 to the President and Congress. These materials, plus hearings before the Senate Committee on the Judiciary in 1941, led to the Administrative Procedure Act¹ (APA)

being signed into law by President Truman on June 11, 1946.² According to Attorney General Tom C. Clark in 1947,³

The [APA] sets a pattern designed to achieve relative uniformity in the administrative machinery of the Federal Government. It effectuates needed reforms in the administrative process and at the same time preserves the effectiveness of the laws which are enforced by the administrative agencies of the Government.

According to the 1947 *Attorney General's Manual on the Administrative Procedures Act*, the basic purposes of the APA are (1) to require agencies to keep the public currently informed of their organization, procedures and rules, (2) to provide for public participation in the rulemaking process, (3) to prescribe uniform standards for the conduct of formal rulemaking and adjudicatory proceedings which are required by statute to be made on the record after the opportunity for an agency hearing, and (4) to restate the law of judicial review.⁴

As regulations increased, the chief concern shifted to the actual content of regulations, rather than the means by which they were adopted.

Thus, at the time of this first effort at regulatory reform, the goal was to open up the regulatory process itself to the public. However, as the number and scope of regulations increased over the ensuing 30 years, regulatory reform became viewed as necessary for *substantive* rather than *procedural* reasons — that is, the chief concern shifted to the actual content of regulations, rather than the means by which they were adopted. Notwithstanding this widely-held view, it is only within the last several months that the regulatory reform issue has been openly debated in this context.

During the 1960s and 1970s, the federal government sought to remedy newly perceived health, safety and environmental problems by enacting a flood of legislation to be implemented by federal agencies, most notably the Environmental Protection Agency (EPA). In a short time, “informal” rulemaking supplanted the APA’s formal processes as the preferred means of formulating major governmental policies.⁵ By the mid 1970s, the increasing use of informal rulemaking to resolve complex, high-stakes issues led to new statutes and court decisions that placed additional procedural hurdles before agencies seeking to promulgate new regulations. The late 1970s and the 1980s saw increased presidential involvement in the development of regulatory policies.⁶ Even though often procedural in nature, it is through these efforts that regulatory reform began to take on a more substantive character.

Presidential involvement in regulatory reform started in 1971 with the Nixon Administration’s Quality of Life Review, was continued by President Ford’s Executive Order No. 11821, and was subsequently followed by President Carter’s Executive Order No. 12044.⁷ However, it was President Reagan’s Executive Order No. 12291,⁸ issued in 1981, that most significantly intensified Presidential involvement in the regulatory process.

Executive Order No. 12291 established a process whereby proposed regulations with an annual effect on the economy of \$100 million or more would be reviewed by the White House Office of Management and Budget (OMB). The review would examine the potential costs, potential benefits, and net benefits of proposed regulations, as well as any less costly but comparably effective alternatives to the proposed regulations.⁹

The purpose of this review was to ensure that:¹⁰ (1) administrative decisions were based on adequate information concerning the need for, and consequences of, proposed government action; (2) regulatory action was not undertaken unless the potential benefits to society resulting from the regulation outweighed the potential costs; (3) regulatory objectives maximized the net benefits to society; (4) among alternative approaches to any given regulatory objective, the alternative involving the least cost to society was chosen; and (5) agencies set priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future. In essence, Executive Order No. 12291 provided OMB with Presidential authority to control the fate of regulations on a *substantive* basis through cost-benefit analysis.¹¹

President Reagan later reinforced the regulatory review process established by Executive Order No. 12291 with Executive Order No. 12498.¹² In a more specific vein, Executive Order No. 12498 also required that regulations seeking to reduce health or safety risks should be based upon scientific risk assessment procedures and should address risks that are “real and significant” rather than “remote and hypothetical.”¹³

OMB’s implementation of the Reagan Executive Orders stirred a great deal of controversy, particularly for its efforts to review and control environmental, health and safety regulations. However, in some ways this notoriety was ironic, given the seemingly uncontrolled growth of regulation during the 1980s. The Bush Administration kept these Executive Orders in place, but it replaced OMB, for all practical purposes, with the Competitiveness Council, led by Vice President Quayle, as the regulatory “traffic cop.” The Competitiveness Council quickly surpassed OMB’s reputation for regulatory review.

In 1993, President Clinton abolished the Competitiveness Council and issued his own regulatory review policy in the form of Executive Order No. 12866. Among other provisions, he revoked the Reagan/Bush Administration Executive orders.¹⁴ Although the Clinton Executive Order is substantively very similar to Executive Order No. 12291 (i.e., proposed regulations with an economic impact of \$100 million or more are to be reviewed by OMB), its implementation has been peculiarly quiet. The reason for this is because regulatory review under the Clinton Administration has been essentially nonexistent. As of mid-1994, the number of proposed EPA regulations reviewed by OMB under Executive Order No. 12866 was down 50 percent from the number reviewed under President Reagan’s

Regulatory review under the Clinton Administration has been essentially nonexistent.

Executive Order No. 12291.¹⁵ As of mid-1995, the number of regulations issued by EPA that were reviewed by OMB under the Clinton Executive Order totaled 45 out of 510, and none of these 45 were returned by OMB to EPA for failure to comply with the Executive Order.¹⁶

Regulatory reform has not been the exclusive province of the White House. Over the years, Congress has made several attempts to control regulatory agencies. The Paperwork Reduction Act (PRA) was enacted in 1980 and amended in 1986.¹⁷ One of the main purposes of the PRA is to:¹⁸

minimize federal paperwork burden for individuals, small business and State and local government. . .

The 1980 Regulatory Flexibility Act (RFA) directs agencies to consider the potential impacts of regulations on small business and other small entities, and mandates consideration of regulatory alternatives.¹⁹ Although unstated, Congress hoped that the RFA would influence the substance of agency actions.²⁰ Nonetheless, the PRA, RFA, and other statutes have tended to be procedural in nature and have not been effective at controlling final agency actions. Ironically, perhaps the greatest impact on agencies came from the National Environmental Policy Act (NEPA), a statute that focused not on general administrative reform but on one specific subject area.²¹

In summary, the early efforts at regulatory reform were procedural in nature. More recent efforts have been designed so that procedural requirements are used to gain control (or not, depending on the Presidential Executive order) over the substance of regulations. Little direct effort has been made to control the substance of actions that agencies take. However, this has changed in the 104th Congress.

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HOUSE REGULATORY REFORM EFFORTS

The 1994 elections brought sweeping change to both the House of Representatives and Senate in the form of Republican control. House Republicans had campaigned on the *Contract with America* which included, among other “promises,” passage of a regulatory reform bill during the first 100 days of the 104th Congress. On February 28, 1995, the House passed H.R. 1022 as its regulatory reform bill. Significantly, although the *Contract with America* was the brainchild of House Republicans, H.R. 1022 was passed with a substantial bipartisan majority.

The purpose of H.R. 1022 is:

To provide regulatory reform and to focus national economic resources on the greatest risks to human health, safety, and environment through scientifically objective and unbiased risk

assessments and through consideration of costs and benefits in major rules. . .

Toward this end, H.R. 1022 has several key provisions that are viewed as the most likely to achieve the bill's purpose. These provisions include the requirement of calculating "best estimates" of risk, the cost-benefit Supermandate provision, definition of a "major rule" and judicial review of compliance with these measures. Other provisions of H.R. 1022 also will be discussed, but the aforementioned provisions are viewed as having the greatest likelihood of bringing about significant regulatory reform if enacted into law and will be discussed in greater detail.

Best Estimates of Risk

H.R. 1022 attempts to require that federal regulations be grounded in realistic risk assessments that are developed in public proceedings and that are subject to court review.²² Title I of the bill is entitled the "Risk Assessment and Communication Act of 1995." Its key purpose is:

[t]o present the public and executive branch with the most scientifically objective and unbiased information concerning the nature and magnitude of health, safety and environmental risks [and] to provide for sound regulatory decisions and public education.

To accomplish this, §105 of Title I requires that:

Each significant risk characterization document shall meet each of the following requirements:

(1) ESTIMATES OF RISK. . . If a numerical estimate of risk is provided, the agency shall, to the extent feasible, provide

(A) the best estimate or estimates for the specific populations or natural resources which are the subject of the characterization (based on the information available to the federal agency); and

(B) a statement of the reasonable range of scientific uncertainties.

In addition to such best estimate or estimates, the risk characterization document may present plausible upper-bound or conservative lower-bounds estimates. Where appropriate, the risk characterization document may present, in lieu of a single best estimate, multiple best estimates based on assumptions, infer-

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ences, or models which are equally plausible, given current scientific understanding.

A “best estimate” of risk is defined as²³

. . . a scientifically appropriate estimate which is based, to the extent feasible, on one of the following:

(A) Central estimates of risk using the most plausible assumptions.

(B) An approach which combines multiple estimates based on different scenarios and weighs the probability of each scenario.

(C) Any other methodology designed to provide the most unbiased representation of the most plausible level of risk, given the current scientific information available to the Federal agency concerned.

These provisions represent an effort to compel agencies to base regulatory decisions on the most realistic risk assessments possible.

These provisions represent an effort to compel agencies to base regulatory decisions on the most realistic risk assessments possible, and to present these assessments to the public. This would be a significant improvement over the current process, which relies on assumptions that are conservatively biased in the extreme, rather than on scientific knowledge and unbiased data.

As the recent Department of Energy study, *Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process*,²⁴ concludes, such biased assumptions have perverse results. They lead to risk estimates that tend to grossly overestimate risk. These overestimates, in turn, distort reality so that regulators make risk management decisions based on false and inaccurate premises. In short, we end up with regulations that appear to be based on scientific risk assessment but are not, and that impose risks and costs that far exceed their questionable benefits.

For example, a recent study of Superfund site risk assessments has estimated that potential risks posed by such sites are systematically overestimated by at least a factor of 100. Such overestimation has led to slow and expensive cleanups that often produce no tangible benefits to public health and the environment.²⁵ The fact of such gross overestimation in the Superfund program is particularly significant because cleanups are generally based on whether sites pose risks that exceed precise trigger levels (e.g., an excess lifetime cancer risk to an individual of 1 in 10,000). For all their “precision,” however, these trigger levels bear little relation to reality because they do not account for the possibility of risk overestimation. Thus, the requirement that federal agencies use their best estimates of risk is essential to reforming regulatory risk assessment. Importantly, more realistic calculations of risk do not necessarily equate to less regulation. Rather, more realistic risk calculations provide a more accurate and factual basis on which to make regulatory decisions.

Cost-Benefit Supermandate

Title II of H.R. 1022 would require federal agencies to conduct a cost-benefit analysis for each proposed “major rule.”²⁶ No final rule could be promulgated unless the agency certifies:²⁷

(1) That the [cost-benefit analyses] are based on objective and unbiased scientific and economic evaluations of all significant and relevant information and risk assessments provided to the agency by interested parties relating to the costs, risks, and risk reduction and other benefits addressed by the rule.

(2) That the incremental risk reduction or other benefits of any strategy chosen will be likely to justify, and be reasonably related to, the incremental costs incurred by State, local, and tribal governments, the Federal Government, and other public and private entities.

(3) That other alternative strategies identified or considered by the agency were found either (a) to be less cost-effective at achieving a substantially equivalent reduction in risk, or (B) to provide less flexibility to State, local, or tribal governments or regulated entities in achieving the otherwise applicable objectives of the regulation, along with a brief explanation of why alternative strategies that were identified or considered by the agency were found to be less cost-effective or less flexible.

Although agencies must “certify” that these criteria have been satisfied, the criteria are made significant by the Supermandate provision that they override all other provisions of federal law and are judicially reviewable under a “substantial evidence” standard. Specifically, under §202(b) of H.R. 1022,

(1) IN GENERAL. Notwithstanding any other provision of federal law, the decision criteria of [subsection 201(a)] shall supplement and, to the extent there is a conflict, supersede the decision criteria for rulemaking otherwise applicable under the statute pursuant to which the rule is promulgated.

(2) SUBSTANTIAL EVIDENCE. Notwithstanding any other provision of Federal law, no major rule shall be promulgated by any Federal agency pertaining to the protection of health, safety or the environment unless the requirements of section 201 and subsection (a) are met and the certifications required therein are supported by substantial evidence of the rulemaking record.

A study of Superfund site risk assessments has estimated that potential risks posed by such sites are systematically overestimated by at least a factor of 100.

Even such current statutes as Superfund, the Clean Air Act, the Clean Water Act and other health safety and environmental statutes have no requirement that the incremental benefits of regulations justify their incremental costs. The Supermandate would impose such a requirement on these statutes. Federal agency decisions would then be reviewable under a “substantial evidence” standard — that is, they would have to be supported by a significant body of evidence, though not necessarily by a preponderance of evidence. The substantial evidence standard is significantly more demanding than the more usual “arbitrary and capricious” standard of the APA.

Definition of a “Major Rule”

The definition of a “major rule” is important because only “major rules” are subject to the Supermandate provision. H.R. 1022 defines a “major rule” as:²⁸

...any regulation that is likely to result in an annual increase in costs of \$25,000,000 or more . . .

where “costs” are defined as:²⁹

direct and indirect costs to the United States Government, to State, local, and tribal governments, and to the private sector, wage earners, consumers, and the economy, of implementing and complying with a rule or alternative strategy.

Further, under §204 of H.R. 1022, any environmental cleanup (e.g., Superfund cleanup or RCRA corrective action) for which costs are likely to exceed \$5,000,000 would be considered as a “major rule.” H.R. 1022’s definition of a “major rule” is a significant departure from prior definitions of “major rule” under the Reagan and Clinton Executive Orders, where the dollar amount was pegged at \$100,000,000.

Judicial Review

Section 401 of H.R. 1022 would permit a federal agency’s compliance with the requirements of H.R. 1022 to be reviewable under the statute granting the agency authority to act and, where applicable, under the APA as well. Under the APA, agency actions, findings, and conclusions are held to be unlawful and are set aside if they are found by a court to be (in relevant part)³⁰

(A) arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law . . .

Such current statutes as Superfund, the Clean Air Act, the Clean Water Act, etc., have no requirement that the benefits of regulations justify their costs.

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. . .

The meaning of these standards is by no means self-evident.³¹ With respect to the former standard, according to the Administrative Conference of the United States (ACUS),³²

1. A reviewing court normally will not substitute its judgment for that of the agency in making factual decisions so long as the agency's conclusions have a substantial basis in the record; this is particularly true where the subject is technical, on the frontiers of science, or involves a considerable exercise of agency expertise.

2. A reviewing court generally will defer to agency policy judgments, so long as they are "rational" or "reasonable" (concededly vague terms) and are the product of what traditionally been called "reasoned decision-making." To demonstrate that reasoned decision-making has taken place, an agency must explain in its statement of basis and purpose why it has rejected significant alternative options, why it has departed from past policies, and how its conclusions are derived from the facts in the record.

3. A reviewing court will apply these same principles to agency deregulation, with emphasis placed on the need for the agency to fully explain why the deregulatory action is being taken, why prior policy is being revised, and whether less dramatic alternatives were considered and rejected.

A federal agency's compliance with H.R. 1022 would be reviewable.

The legal interpretation of the latter standard was established by the U.S. Supreme Court in *Chevron U.S.A. v. NRDC*.³³ Judicial review of agency statutory interpretations is generally governed by the following two-part test:³⁴

(1) Has Congress "directly" spoken to the "precise" question at issue? "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress"; and

(2) If Congress has not done so, and the statute is "silent or ambiguous with respect to the specific issue," then the question for the court is whether "the agency's answer is based on a permissible construction of the statute." Legislative regulations of the agency are "given controlling weight unless they are arbitrary, capricious or manifestly contrary to the statute."

Despite the apparent deference to agencies on scientific and technical matters under the APA as well as the deference given to agencies under the *Chevron* decision, the statutory language of H.R. 1022 is likely sufficiently clear to provide for meaningful judicial review.

Other Provisions

Title I goes into great detail establishing “principles for risk assessment” and “principles for risk characterization and communication.” To the extent that these provisions cause regulatory agencies to produce more scientific risk assessments and better communicate risk assessment results to the public, they may represent positive regulatory reform. However, they are not nearly as significant to regulatory reform as “best estimates” of risk, which are structured as a mandatory decision-making tool.

For regulatory programs designed to protect human health, safety or the environment, Title III of H.R. 1022 also requires each federal agency to develop a systematic program for independent and external peer review.³⁵ Although the concept of peer review is noble, in practice it has not consistently prevented agencies from promulgating poor quality risk assessments, cost-benefit analyses, or regulations. One reason for this is that agencies are not bound to accept the conclusions and recommendations of peer reviewers even where their expertise dwarfs that of the agencies. Thus a weakness in H.R. 1022 is that it does not explicitly bind agencies to adopt the conclusions and recommendations of peer reviewers.

The statutory language of H.R. 1022 is likely sufficiently clear to provide for meaningful judicial review.

SENATE REGULATORY REFORM EFFORTS

The roots of the Senate’s current regulatory reform efforts go back to the 103rd Congress and its attempt to pass legislation to give EPA Cabinet status. Senator J. Bennett Johnston (D-La.) sponsored an amendment to the EPA Cabinet bill that was intended to improve EPA’s presentation of risk assessments and to include cost-benefit analyses in rulemakings. This amendment was added to the EPA Cabinet bill by a wide margin (95 to 3). However, the EPA Cabinet bill never made it out of the Senate. The Senate’s current effort at regulatory reform is focused on S. 343, sponsored by Senator Robert Dole (R-Kan.) and Senator Johnston.

Key provisions in S. 343 that will be discussed include those covering risk assessment, cost-benefit analyses, the definition of “major rule,” judicial review, repeal of the Delaney Clause, petition for review of a major free-standing risk assessment, and Congressional review of agency rulemaking.

Risk Assessment

In contrast to the H.R. 1022 requirement that risk estimates, to the extent possible, constitute “best estimates,” S. 343 only states, in relevant part, that:³⁶

To the extent feasible and scientifically appropriate, the head of an agency shall

(A) express the overall estimate of risk as a range or probability distribution that reflects variabilities and uncertainties in the analysis;

(B) provide the range and distribution of risks and the corresponding exposure scenarios, identifying the reasonably expected risk to the general population and, where appropriate, to more highly exposed subpopulations; and

(C) where quantitative estimates of the range and distribution of risk estimates are not available, describe the qualitative factors influencing the range of possible risks.

Although the risk range or probability distribution required by S. 343 clearly would include the “best estimate” of risk, the bill itself does not even mention this concept. Instead, it allows the “best estimate” to be buried in a host of improbable estimates. In contrast, H.R. 1022 emphasizes the “best estimate” of risk and contemplates its use in cost-benefit analysis and regulatory decision-making. As an example of why this is important, consider the Superfund program, where cleanups are generally required when estimated site cancer risks exceed 1 in 10,000. Under H.R. 1022, the “best estimate” of risk would be used in determining whether an estimated site risk exceeds the 1 in 10,000 cleanup trigger-level. S. 343 does not emphasize “best estimates” of risk and, presumably, the cleanup trigger-level comparison could be conducted, as it is now, with risk estimates that do not represent the realistic risks posed by sites.³⁷

Cost-Benefit Analysis

Section 622 of S. 343 would require that a cost-benefit analysis be prepared for each “major rule” and be presented in the notice of the proposed rulemaking. Each cost-benefit analysis would be required to contain (1) estimates of the quantifiable and nonquantifiable benefits expected to be achieved by the rule, (2) estimates of the quantifiable and nonquantifiable costs expected to be incurred by the rule, and (3) identification of and cost-benefit analysis for alternatives to the proposed rule.

Under §624 (b) of S. 343, no “major rule” can be promulgated unless:

the agency head publishes in the Federal Register a finding that

S. 343 allows the “best estimate” to be buried in a host of improbable estimates.

- (1) the benefits from the rule justify the costs of the rule;
- (2) the rule employs to the extent practical flexible reasonable alternatives. . . ; and
- (3)(A) the rule adopts the least cost alternative of the reasonable alternatives that achieve the objectives of the statute; or
- (B) if scientific, technical, or economic uncertainties or nonquantifiable benefits to health, safety, or the environment identified by the agency in the rulemaking record make a more costly alternative that achieves the objectives of the statute appropriate and in the public interest and the agency head provides an explanation of those considerations, the rule adopts the least cost alternative of the reasonable alternatives necessary to take into account such uncertainties or benefits. . .

Significantly, these requirements only:³⁸

supplement and not supersede, any other decisional criteria provided by law.

The S. 343 cost-benefit analysis requirement is notably weaker than that of H.R. 1022.

The S. 343 cost-benefit analysis requirement is notably weaker than that of H.R. 1022. First, S. 343 does not really require that a rule’s incremental benefits justify its incremental costs. Section 624 (b)(3)(B) provides an “escape hatch” if there are uncertainties or nonquantifiable benefits that justify selection of other than the least cost alternative. Because there are always “uncertainties” and “nonquantifiable” benefits, and both are highly subjective determinations, this provision would enable agencies to evade easily having to ensure that the benefits of a rule justify its costs. Second, S. 343 specifically excludes the type of Supermandate provision that H.R. employs. Thus, regulations promulgated under other laws that do not have cost-benefit provisions, such as the Clean Air Act, Superfund, etc., would not be subject to the cost-benefit requirements of S. 343. Also, as discussed in greater detail below, there is no meaningful judicial review under S.343 so the requirement of justifying costs with benefits cannot be enforced by a court.

Definition of “Major Rule”

Section 621 of S. 343 defines a “major rule” as:

a rule or set of closely related rules that the agency proposing the rule, the Director [of the Office of Management and Budget], or a designee of the president reasonably determines is likely to have a gross annual effect on the economy of \$50,000,000 or more in reasonably quantifiable increased costs. . . ,

where the term “cost” is defined to be:

the reasonably identifiable significant adverse effects, quantifiable and nonquantifiable, including social, environmental, and economic effects that are expected to result directly or indirectly from implementation of a rule or other agency action.

The \$50,000,000 threshold for review is lower than prior and existing regulatory review Executive orders, but is significantly higher than the \$25,000,000 threshold of H.R. 1022. Additionally, no special provision is made for environmental cleanups as is made in H.R. 1022 (i.e., a \$5,000,000 cleanup is considered to be a “major rule”).³⁹

Judicial Review

The key judicial review provision in S. 343 is the standard of review. Failure to comply with the requirements of S. 343 for cost-benefit analyses and risk assessments can be reviewed by a court⁴⁰

...solely for the purpose of determining whether final agency action is arbitrary and capricious or an abuse of discretion (or unsupported by substantial evidence where that standard is otherwise provided by law).

While this appears to be the same standard as currently available under the APA, it is not. Under §706(2)(A) of the APA, agency action, findings and conclusions are held to be unlawful and are set aside if they are found by a court to be

(A) arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. . .

Significantly, the phrase “or otherwise not in accordance with law” has been omitted from S. 343. The implication of this is that as long as agency action, findings and conclusions are not arbitrary and capricious or an abuse of discretion, both of which are very subjective standards, agency action, findings and conclusions *can* be inconsistent with law, including presumably S. 343 if enacted. For example, if an agency simply failed to perform the analyses specified in S. 343 in promulgating a new rule, that rule could conceivably still be sustained under the judicial review provision. For this reason, judicial review under S. 343 may be illusory.

While S.343's judicial review test appears to be the same standard as currently available under the APA, it is not.

Repeal of the Delaney Clause

Under the provision of the Federal Food, Drug and Cosmetic Act known as the “Delaney Clause,” no food additive⁴¹

...shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . .

Although an apparently sensible provision when enacted in the 1950s, advances in scientific understanding since that time have led to the general conclusion that the Delaney Clause is archaic and regressive. It operates as an absolute prohibition on food additives that are associated with increased risk of cancer, even if such a risk is negligible or has only been demonstrated through animal experiments of questionable relevance to humans.

Section 611(c) of S. 343 would replace the Delaney Clause with a “negligible risk” standard:

In applying [the Delaney Clause]. . .[federal agencies] shall not prohibit or refuse to approve a substance or product on the basis of safety, where the substance or product presents a negligible risk to human health from its intended use.

The replacement of the Delaney Clause with a “negligible risk” standard represents major reform. It would permit the beneficial use of “food additives” and pesticides (that by legal definition become “food additives”) that otherwise would be banned even though they are reasonably known to be safe when used as intended.

Petition for Review of a Major Free-Standing Risk Assessment

S. 343 provides that:⁴²

Any interested person may petition an agency to conduct a scientific review of a risk assessment conducted or adopted by the agency, except for a risk assessment used as the basis for a major rule or a site-specific risk assessment.

An agency must grant such a petition if there is a reasonable likelihood that:⁴³

(1)(A) the risk assessment that is the subject of the petition was carried out in a manner substantially inconsistent with the principles in section 633; or

If an agency failed to perform the analyses specified in S. 343 in promulgating a new rule, that rule could conceivably still be sustained.

Judicial review under S. 343 may be illusory.

((B) the risk assessment that is the subject of the petition does not take into account material new scientific data and scientific understanding;

(2) the risk assessment that is the subject of the petition contains significantly different results than if it had been properly conducted pursuant to [the S. 343 risk assessment requirements]; and

(3) a revised risk assessment will provide the basis for reevaluating an agency determination of risk, and such determination currently has an effect on the United States economy equivalent to that of a major rule.

This provision is sometimes referred to as a “look-back” provision that provides an opportunity to update or correct prior risk assessments. While a potentially positive reform, the potential impact of this provision is limited by the illusory nature of judicial review under S. 343 and the requirement that a change in the risk assessment must have the impact of a “major rule.”

Congressional Review of Agency Rulemaking

Chapter 8 of S. 343 would provide Congress with 60 days to review a “major rule” and to disapprove it. The value of this provision should not be oversold. Although this provision may make it easier to “tee up” specific rules on a timely basis, Congress already has ample authority over agencies and agency rulemakings. Second, given the sheer number of “major rules” that agencies promulgate as well as Congress’ own workload, it is questionable whether as a practical matter Congress will really be interested in, or have the time to micromanage agency rulemakings.

DISCUSSION AND CONCLUSIONS

The provisions of H.R. 1022 attempt to improve the substance of regulatory decisions and could bring real reform to the regulatory process. Taking risk reduction actions on the basis of realistic risk, making the benefits of rules outweigh their costs, and providing adversely impacted parties with the opportunity for a review of a rulemaking by an independent court could dramatically improve the regulatory process. Agencies would be forced to conduct more objective and unbiased risk assessments and cost-benefit analyses and make better regulatory decisions, or face having their rules vacated and remanded by courts.

The replacement of the Delaney Clause with a “negligible risk” standard represents major reform.

The potential impact of a “look-back” provision is limited by the illusory nature of judicial review under S. 343.

There are a host of examples that illustrate the need for such reform. Consider, for example, the failure of the National Highway Traffic Safety Administration to adequately assess the impact of its new car fuel economy standards on vehicle crashworthiness. In 1992 the U.S. Court of Appeals for the D.C. Circuit ruled the agency's action to be arbitrary and capricious, characterizing it as being based on "fudged . . . analysis," "statistical legerdemain," and "bureaucratic mumbo-jumbo."⁴⁴

In contrast to H.R. 1022, the current version of S. 343 is not likely to bring about meaningful reform. At best, it is a process-oriented bill with little focus on substance.

A good example of the risk assessment process in action is EPA's 1989 attempt to ban the use of asbestos in commercial products under the Toxic Substances Control Act (TSCA). EPA's failure to survive judicial scrutiny for substantive, not merely procedural, reasons is commonly viewed as having moderated much of TSCA.⁴⁵ Another example is the 1992 decision from the U.S. Court of Appeals for the 11th Circuit that vacated OSHA's updated permissible exposure limits (PELs) for 428 substances.⁴⁶ OSHA has yet to re-promulgate these updated standards.

In contrast to H.R. 1022, the current version of S. 343 is not likely bring about meaningful reform. At best, it is a process-oriented bill with little focus on substance. There is no requirement that agencies make realistic estimates of risk. So, for example, Superfund cleanup decisions would continue to be made on the basis of grossly exaggerated risk estimates that result in slow, unproductive and expensive cleanups. S. 343 does not require that the benefits of rules outweigh their costs — an approach that is foreign to everyday life. Judicial review is illusory, so no meaningful, independent review of agency action is likely to occur. That S. 343 has been called a "glorified Senate resolution" is not too far off the mark.

As has been repeatedly demonstrated by the nature of the compromises made to reach the current version of S. 343, floor debate is likely to dilute further the provisions of S. 343. If S. 343 does pass the Senate and goes into conference, it is probably unlikely that a conference bill would keep intact the strong provisions of H.R. 1022. Floor debate could further weaken a conference bill. The only saving grace in this scenario is that such an exaggeratedly grim portrait of regulatory reform has been painted that the President for political reasons may veto any regulatory reform bill that comes out of the 104th Congress. The votes to override a Presidential veto may simply not exist.

S. 343 has been called a "glorified Senate resolution."

Some may view the sort of regulatory reform bill that may come out of Congress as a first-step down the path of more significant regulatory reform later; the fact that a bill may be weak and likely to be ineffectual is of little concern to them because they believe that regulatory reform efforts will continue. This line of argument is faulty for several reasons. First, it is not clear that members of Congress will be too eager to be criticized for "jeopardizing the public health and safety and environment" again in the near future. Second, it is possible that weak regulatory reform will undermine any questioning of laws such as Superfund during their reauthorization process, since Congress may think that their problems have

already been addressed. After all, why would a member of Congress want to get beaten up twice over the same issue?

While regulatory reform has proven elusive in the past, the need for it has long been recognized, as indicated by President Franklin D. Roosevelt himself after he created an alphabet soup of federal agencies during the New Deal. Clearly, the 1994 elections and the *Contract with America* have resulted in the current rush to regulatory reform. The key question is whether Congress will enact effective regulatory reform, or whether it will just pass a bill, take credit for regulatory reform, and then move on to the next debate.

To date, Congress has done a poor job of establishing the need for regulatory reform with the American public. Current regulatory reform efforts are extremely complex, yet are being rushed through Congress so that few truly understand the need for them. As a result, regulatory reform efforts have been erroneously and sometimes savagely criticized by the media, and much of the public erroneously believes that regulatory reform will jeopardize its health, safety, and environment.

In fact, those who are against current regulatory reform efforts may secretly favor the direction in which Congress is heading. If regulatory reform winds up looking like the S. 343, the reform effort will have been wasted. The political implications of this are significant. How can parties credibly complain about the regulatory process when the Congress they just elected gave them the regulatory reform they wanted?

For the sake of regulatory reform, it could be that no bill is better than a bad bill.

RECOMMENDATIONS FOR EFFECTIVE REGULATORY REFORM

Effective regulatory reform can largely be achieved by several simple principles:

1. Risk assessments should produce estimates of risk that approximate, as much as possible, actual risks. If a risk assessment relies on conservative assumptions that tend to overestimate risk, regulatory action based on that risk assessment should be required to consider the likelihood and magnitude of such overestimation. Whether an agency has done its best to present best estimates of risk should be judicially reviewable.

The only saving grace in this scenario is that the President may veto any regulatory reform bill that comes out of the 104th Congress.

Those who are against current regulatory reform efforts may secretly favor the direction in which Congress is heading.

2. The benefits of rules should exceed their costs. In essence, regulations should “do more good than harm.” Whether a rule’s benefits justify its costs should be judicially reviewable.

3. The requirements for “best estimates” of risk and for justifying costs and benefits should supersede all other federal laws. If there truly are necessary exceptions to this principle, Congress can re-enact them on a case-by-case basis.

4. Large environmental cleanups in excess of \$5,000,000, such as those under Superfund, should be considered to be “major rules” subject to provisions for “best estimates” of risk, cost-benefit justification, and judicial review.

5. The Delaney Clause should be replaced with a “negligible risk” standard, the determination of which is based on “best estimates” of risk and is judicially reviewable.

6. Parties adversely affected by existing risk assessments that can be shown to be obsolete should have the ability to petition agencies for review of such risk assessments. The agency decision on whether to grant the review should be judicially reviewable.

7. As a general matter, parties affected by regulations should have a real, not illusory, opportunity for judicial review. The S. 343 provision that permits regulations to be inconsistent with its substantive provisions operates as a device to evade judicial review. The “substantial evidence” test should replace the “arbitrary and capricious” standard for review of risk assessments and cost-benefit analyses. The “substantial evidence” standard is what the Occupational Safety and Health Act requires of rules promulgated by the OSHA. Other agencies should be similarly constrained.

8. History demonstrates that federal agencies have been reluctant to embrace tools that in any way limit their authority to regulate. In the past, voluntary regulatory reform efforts have been illusory. Judicial review is the only mechanism to enforce any regulatory reforms enacted into law.

Parties affected by regulations should have a real, not illusory, opportunity for judicial review.

ABOUT THE AUTHOR

Steven J. Milloy has written extensively on the issues of risk assessment and regulatory reform. He was the chief author of the highly acclaimed U. S. Department of Energy study, *Choices is Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process* (1994). He is also the author of *Science-Based Risk Assessment: A Piece of the Superfund Puzzle* (1995). Mr. Milloy is currently the Director of Science Policy at the National Environmental Policy Institute. Mr. Milloy has appeared on radio and television discussing risk assessment and Superfund; has testified on risk assessment and Superfund before the U. S. Congress; and has lectured on risk assessment before numerous organizations and groups. He holds a B.A. in Natural Sciences from The Johns Hopkins University, a Master of Health Sciences in Biostatistics from The Johns Hopkins University School of Public Health, a Juris Doctorate from the University of Baltimore, and a Master of Laws in Securities Regulation from the Georgetown University Law Center.

ENDNOTES

¹⁵ U.S.C. §§551-559, 701-706, 1305, 3105, 3344, 5372; originally enacted June 11, 1946 by Pub. L. No. 404, 60 Stat. 237, Ch. 324, §§1-12.

² Administrative Conference of the United States (ACUS), *Federal Administrative Procedure Sourcebook: Statutes and Related Materials*, Office of the Chairman. Washington, D.C. (1985).

³ U.S. Department of Justice, *Attorney General's Manual on the Administrative Procedures Act*, Washington, D.C. (1947).

⁴ *Ibid.* p. 9.

⁵ Informal rulemaking is also known as “legislative” rulemaking. Informal rulemaking differs from “formal” rulemaking in that informal rulemaking is generally judicially reviewable under a less burdensome standard for the agency (i.e., arbitrary and capricious vs. substantial evidence) and formal rulemaking requires that there be an oral hearing with cross-examination of witnesses presided over by an administrative law judge and that there be no ex parte communication with the decisionmaker (i.e., no lobbying). (ACUS 1991, 44).

⁶ Administrative Conference of the United States, *A Guide to Federal Agency Rulemaking (Second Edition)*, Office of the Chairman, Washington, D.C. (1991).

⁷ *Toward Common Measures: Recommendations for a Presidential Regulatory Policy*, Federal Focus Inc., The Institute for Regulatory Policy, Federal Focus, Inc. Washington, D.C. (1991), p. 29.

⁸ Executive Order No. 12291: Federal Regulation, Executive Office of the President (EOP), *Federal Register* 46:13193, (1981).

⁹ *Ibid.*, §3.

¹⁰ *Ibid.*, §2.

¹¹ Presidential Executive orders do not have the force of law and cannot be judicially enforced. Essentially, they constitute policy directives from the President. Although agencies are not legally bound by Executive orders, given that most agency heads serve at the pleasure of the President, there is often a high degree of compliance with Executive orders.

¹² Executive Order No. 12498: Regulatory planning process, Executive Office of the President, *Federal Register* 50:1036 (1985).

¹³ EOP 1985, §1(d), citing §4 of the report of the Presidential Task Force on Regulatory Relief, “Reagan Administration Regulatory Achievements.”

¹⁴ Executive Order No. 12866: Regulatory Planning and Review, Executive Office of the President, *Federal Register* 58:51735 (1993).

- ¹⁵*Daily Environment Report* No. 157, A1, Bureau of National Affairs (August 17, 1994).
- ¹⁶Environment Week No. 18, Vol. 8, King Communications Group, Inc. (May 4, 1995).
- ¹⁷U.S.C. §§3501-3520.
- ¹⁸U.S.C. §3501.
- ¹⁹U.S.C. §§601-612.
- ²⁰ACUS 1991, p. 107.
- ²¹42 U.S.C. §§4321-4347.
- ²²H.R. 1022, U.S. House of Representatives, 104th Congress, 1st Session (1995).
- ²³*Ibid*, §110.
- ²⁴*Choices in Risk Assessment: The Role of Science Policy in the Environmental Risk Management Process*, prepared for Sandia National Laboratories by the Regulatory Impact Analysis Project, Washington, D.C. (1994).
- ²⁵Milloy, S. J., *Science-based Risk Assessment: A Piece of the Superfund Puzzle*, National Science Policy Institute, Washington, D.C. (1995).
- ²⁶H.R. 1022, §201(a).
- ²⁷*Ibid*, §202.
- ²⁸*Ibid*, §5(3).
- ²⁹*Ibid*, §5(1).
- ³⁰5 U.S.C. §706(2)(A) & (C).
- ³¹*A Guide to Federal Agency Rulemaking*, pp.323-324.
- ³²*Ibid*, pp. 333-334.
- ³³467 U.S. 837, *reh. denied*, 468 U.S. 1227 (1984).
- ³⁴ACUS 1991, pp. 337-338.
- ³⁵H.R. 1022 §301.
- ³⁶S. 343 §633(f)(1).
- ³⁷NEPI, 1995.
- ³⁸S. 343 §624(a).
- ³⁹An earlier version of S. 343 would have make environmental cleanups costing in excess \$10,000,000 subject to the risk assessment and cost-benefit analyses provisions. However, this provision was deleted by voice vote. *Daily Environment Report*. No. 135, AA 1, Bureau of National Affairs (July 14, 1995).
- ⁴⁰S. 343 §625(d).
- ⁴¹21 U.S.C. §348(c)(3)(A).
- ⁴²S. 343 §634(a).
- ⁴³*Ibid*. §634(c).
- ⁴⁴*Competitive Enterprise Institute v. NHTSA*, 956 F.2d 321 (D.C. Cir., 1992). On remand, another panel of the Court upheld the agency, but noted that it still found the agency's treatment of the safety issue to be troubling. *CEI v. NHTSA*, 45 F.3d 481, 486 (D.C. Cir. 1995).
- ⁴⁵*Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).
- ⁴⁶*AFL-CIO v. OSHA*, 965 F.2d 962 (11th Cir. 1992).