



Impacts of the Regulatory Accountability Act

Overturing 65 Years of Law and Leaving Americans Less Protected

November 16, 2011

EXECUTIVE SUMMARY

The Regulatory Accountability Act (S. 1606/H.R. 3010) will grind to a halt the rulemaking process at the core of implementing the nation's public health, workplace safety, and environmental standards. This bill will not improve the federal regulatory process; it will cripple it. Rules that somehow make it through the RAA's process would tilt against the public interest and in favor of powerful special interests.

The RAA would cover every rule and guidance – big and small – proposed by any executive regulatory agency and any independent regulatory agency. It seeks to fundamentally rewrite and expand the Administrative Procedure Act (APA), a 65-year-old statute that can be considered as a kind of Constitution for administrative agencies and the regulatory process. There are now more than 110 separate procedural requirements in the rulemaking process; the RAA would add more than 60 new procedural and analytical requirements. For the country's most important rules, the RAA would add no fewer than 21 to 39 months to the rulemaking process.

While these additional requirements would add tremendous cost and many years of delay to the regulatory process, they would do little to actually improve the quality of rules generated. In fact, experts in administrative law have written that they "seriously doubt that agencies would be able to respond to delegations of rulemaking authority or to congressional mandates to issue rules if this bill were to be enacted." No less an authority than current OIRA Administrator Cass Sunstein once wrote that "the costs of investigation and inquiry are never zero; to the contrary, they are often very high." The costs of these delays should be counted not just in days and dollars: regulations save lives, prevent illness and injury, and stabilize our economy.

Experience at the state level has demonstrated that an RAA-style approach not only wastes time and resources, but actually harms the rulemaking process. After California adopted a RAA-like set of requirements in 1979, the state's rulemaking process became slow, cumbersome, and resource-intensive. State agencies generate boilerplate findings because they do not have the time or resources to perform meaningful analyses. The process is so technical that experienced, specialized lawyers have to supervise every step. As a result, agencies can complete work on fewer regulations – and public health and safety is threatened.

Making the "Least Costly" Rule the Default Choice

The RAA requires that an agency default to the "least costly" rule unless it can demonstrate – out of all the possible alternative rules – that additional benefits of the more costly rule justify the additional costs and offer a public health, safety, environmental, or welfare justification clearly drawn from the authorizing statute. This would override more than two dozen deliberately enacted and long-honored precedents – in fact, most well-known health, safety, and environmental statutes – that ask agencies, in effect, to "do the best they can" to protect Americans.

However, the "least costly" default requirement is not a novel idea – rather, it is closely analogous to the standard found in the Toxic Substances Control Act (TSCA). Even though everyone agrees that asbestos is a serious threat to human health, the Environmental Protection Agency (EPA) has not been able to issue a regulation that meets the TSCA standard and could protect Americans' health. In fact, the CEO of SC Johnson has said, "Your child has a better chance of becoming a major league baseball player than a chemical has of being regulated [under TSCA]."

Super-Mandating Cost-Benefit Analysis

The RAA's requirement that, for any proposed rule, agencies consider all of the "potential costs and benefits associated with potential alternative rules ... , including direct, indirect, and cumulative costs and benefits," would apply "[n]otwithstanding any other provision of law." This would rewrite "much, perhaps most, of the safety and health legislation now on the books." The problems with the RAA's emphasis on cost-benefit analysis as the most important deciding factor are only compounded by how the analyses would be performed. The RAA omits language, found in Executive Order 12,866 and other executive orders, that reiterates that some of the most important considerations cannot be quantified. Certain types of benefits are difficult to quantify, and certain types of costs are inherently speculative. However, empirical research has demonstrated not only that the economic benefits vastly outweigh their costs, but also that cost-benefit analyses typically overestimate costs and underestimate benefits.

The U.S. Supreme Court has ruled that the Occupational Safety and Health Act prohibits OSHA from basing health standards on a strict cost-benefit determination, since protection of health should be the primary consideration. The RAA would override this requirement, making it more difficult to protect workers from chronic health hazards like black lung and silicosis.

Shifting to Formal Rulemaking Processes

It is no accident that most agencies now use informal (*i.e.*, notice-and-comment) rulemaking. Formal rulemaking is generally considered to be expensive, time-consuming, and an inefficient way to resolve most questions at issue during rulemaking; both the American Bar Association and the Administrative Conference of the United States have denounced formal rulemaking as inappropriate for virtually all agency decisions. Overall, formal rulemaking cuts agencies off from everyone except special interests with resources to invest in achieving a particular outcome. Nevertheless, the RAA would automatically require formal rulemaking processes for rules with projected annual costs of more than \$1 billion and would allow any interested party to demand formal rulemaking for major rules (those estimated with annual costs of \$100 million or more). The hearings would encompass not only the issues laid out in the RAA, but also any other issues raised by an interested person (unless the agency can determine within 30 days of the request that a hearing would be unproductive or would unreasonably delay completion of the rulemaking).

One of the most infamous examples of how formal rulemaking procedures fail to achieve any purpose aside from wasting resources and delaying regulations is the Food and Drug Administration's (FDA's) peanut butter rule. In 1961, FDA proposed a rule that peanut butter must contain 90 percent peanuts. The industry petitioned for a formal hearing to argue for the standard to be set at 87 percent. The formal hearing alone added almost five months to the rulemaking process and resulted in a transcript of approximately 8,000 pages primarily discussing whether peanut butter should contain 87 percent or 90 percent peanuts. FDA finalized the standard in July 1968 – yet the battle continued on for another two years while the industry challenged the rule in the Third Circuit Court of Appeals. Formal rulemaking allowed the peanut butter industry to drag out the public's demand for accurate labeling of products by nine years.

Hybrid Rulemaking

Hybrid rulemaking is somewhere between formal (with a hearing and record) and informal (notice-and-comment) procedures. Hybrid rulemakings result from the requirements of a particular statute, such as the Clean Air Act and the Occupational Safety and Health Act. Under the RAA, hybrid rulemaking, like at OSHA, would be converted to formal rulemakings under the substantial evidence test.

This formal rulemaking process would be adversarial in nature and allow for endless challenges to agency evidence and findings. It would make rulemaking more complicated, more litigious, and more costly. It would tilt the process in favor of employer interests that have the ability to expend significant legal resources on the process and disadvantage workers and small businesses that do not have similar resources.

Allowing Judicial Review of All Agency Judgments

The RAA would greatly expand the courts' ability to review agency judgments, empowering parties to challenge virtually every agency decision to proceed with a rule. If an agency decides to proceed with a review or makes a decision that the rule is not "high-impact" or "major," its decision can be reviewed by the courts. However, if the agency decides to not act, no request for judicial review can be made. In other words, the RAA discourages agencies from acting and makes judges into "super-regulators" who are empowered to substitute their own opinions for the findings of agencies.

Under the RAA, EPA's greenhouse gas endangerment finding, which, on Sept. 28, the EPA's Inspector General found "met statutory requirements for rulemaking," could be delayed and challenged in court. The IG noted that EPA should have made public its review of a technical support document used in the endangerment finding, even though EPA determined that the document was not a "highly influential scientific assessment" as defined by OMB's guidelines under the Information Quality Act (and its peer review guidelines). Even without the IG's findings, anyone could have called for an IQA hearing to publicly debate this point. The results of the hearing would be judicially reviewable. Moreover, even if someone did not petition for a hearing, he or she still could challenge the science used by EPA in court.

Guidance Documents

The RAA would create a much more stringent process for agencies to issue guidance documents. In particular, before issuing a major guidance document, an agency would have to consider certain issues prescribed by the RAA – including, for example, a cost-benefit analysis considering all the direct, indirect, and cumulative costs associated with the guidance – and consult with OIRA. These requirements are predicted to lead agencies to delay issuing guidance, or in some cases forgo it altogether.

Nearly all guidance documents are welcomed, if not requested, by regulated entities because a key purpose of guidance is to allow an agency to explain and interpret the regulations it is responsible for enforcing. Thus, making it harder for agencies to issue guidance would do little more than create unnecessary regulatory uncertainty. For example, statutory language that states that guidelines are non-binding would seriously undermine the ability of OSHA to enforce against serious hazards.



Impacts of the Regulatory Accountability Act: Overturning 65 Years of Law and Leaving Americans Less Protected

The Regulatory Accountability Act (S. 1606/H.R. 3010) will grind to a halt the rulemaking process at the core of implementing the nation's public health, workplace safety, and environmental standards. This bill will *not* improve the federal regulatory process; it will cripple it. Rules that somehow make it through the RAA's incredibly complex process would tilt against the public interest and in favor of powerful special interests. The following examples provide a sample of ways the RAA would undermine agencies' ability to fulfill their missions of protecting the American public.

The RAA would cover every rule and guidance – big and small – proposed by any executive regulatory agency and any independent regulatory agency. From the Consumer Financial Protection Bureau's mortgage disclosure rules and limits on credit card charges; to the Consumer Product Safety Commission's standards for toy safety and infant and toddler car seat strength; to the Food and Drug Administration's efforts to keep *Listeria* out of ready-to-eat food products and implement safe produce standards under the Food Safety Modernization Act – all rulemaking would essentially stop if RAA were passed.

The RAA seeks to fundamentally rewrite and expand the Administrative Procedure Act (APA), a 65-year-old statute that is a kind of Constitution for administrative agencies and the regulatory process. **While the APA is currently about 45 pages long (excluding the Freedom of Information Act provisions), the proposed legislation would add approximately another 30 pages¹ and add tremendous cost and years of delay to the regulatory process.**

The proposed changes would do little to actually improve the quality of rules generated.² In fact, a group of administrative law experts has written that the RAA would make it more difficult for agencies to follow congressional mandates:

We seriously doubt that agencies would be able to respond to delegations of rulemaking authority or to congressional mandates to issue rules if this bill were to be enacted. Instead it would likely lead to rulemaking avoidance by agencies – increasing use of underground rules, case-by-case adjudication, or even prosecutorial actions, to achieve policies without having to surmount the additional hurdles

¹ Testimony of Sidney A. Shapiro, University Distinguished Chair of Law, Wake Forest School of Law, at Hearing on H.R. 3010, The Regulatory Accountability Act of 2011, before the H. Comm. on the Judiciary, 112th Cong. 4 (Oct. 25, 2011) at 11.

² *Id.*

presented by the new Section 553. Executive officials would find it practically impossible to use rulemaking either to create new regulations or to undo old regulations.³

There are now more than 110 separate procedural requirements in the rulemaking process.⁴ The RAA would add more than 60 new procedural and analytical requirements. This means that, for the country's most important rules, the proposed legislation would add to the current process no fewer (and likely much more) than:

- 6-12 months to complete the additional analytical requirements
- 3 months for the Advanced Notice of Proposed Rulemaking (ANPRM) process
- 6-12 months to respond to comments received after the ANPRM
- 6-12 months to complete the formal rulemaking procedures

In total, the RAA would add at least 21 to 39 months – or 1.75 to 3.25 years – to the rulemaking process for major and high-impact rules. **This means that the longest rulemakings could take more than 12 years to complete, potentially spanning four different presidential administrations.**⁵ No less an authority than current OIRA Administrator Cass Sunstein once wrote that "the costs of investigation and inquiry are never zero; to the contrary, they are often very high. We can readily imagine that agencies could spend all their time investigating ancillary risks and never do anything else—a disaster for regulatory policy."⁶ **The costs of these delays should be counted not just in days and dollars: regulations save lives, prevent illness and injury, and stabilize our economy. The failure to protect the public against new risks increases the insecurity of our citizens and degrades our quality of life over time.**

While some of the determinations required by the RAA could be useful in some rulemakings, there simply is no reason to require all of them for all rules. As the American Bar Association's Section on Administrative Law and Regulatory Process wrote to the House Judiciary Committee, "the strength of the APA derives in no small part from the fact that it confines itself to fundamentals. The general act must accommodate the government's need to tailor specific processes to the various tasks Congress assigns agencies. Solutions that work well in many or even most contexts may work poorly in others."⁷ It is clear, for example, that the considerations relevant to determining how much of which contaminant makes drinking water unsafe are not the same considerations relevant to determining how long credit card companies must give cardholders to pay their bills.

³ *Hearing on H.R. 3010, The Regulatory Accountability Act of 2011, Before the H. Comm. on the Judiciary, 112th Cong. 4* (Oct. 25, 2011) (letter from 42 professors of administrative law, regulation, and public administration).

⁴ See Mark Seidenfeld, *A Table of Requirements for Federal Administrative Rulemaking*, 27 FLA. ST. L. REV. 533 (2000), available at <http://www.law.fsu.edu/journal/lawreview/downloads/272/Seid.pdf>. See also, e.g., Exec. Order. No. 13,586, 76 Fed. Reg. 3,821 (Jan. 18, 2011).

⁵ Shapiro, *supra* note 1, at 6.

⁶ Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533, 1552-53 (1996).

⁷ Letter from American Bar Ass'n, Section of Admin. Law & Reg. Practice, to the Honorable Lamar Smith, Chairman, H. Comm. on Judiciary, Oct. 24, 2011, at 2.

It is important to remember that Congress already specifies factors that an agency should take into account when regulating – in fact, enabling legislation does this routinely. In other words, one-size-fits-all legislation does not work, is counter-productive, and will ultimately end in leaving the public less protected.

Experience at the state level has demonstrated that an RAA-style approach not only wastes time and resources, but actually decreases the quality of the findings. As described by the ABA Section,

In 1947, California adopted APA provisions for rulemaking that were modeled on the federal APA. In 1979, however, the state adopted a much more detailed set of APA rulemaking provisions. The statute calls for specialized findings and explanations and for numerous impact statements. The intense regulation of regulatory agencies contained in the California APA has had a variety of adverse consequences. Specialized and experienced lawyers (rather than staff non-lawyers) must supervise every step of every rulemaking process. **The state's APA generates a large amount of boilerplate findings, because agencies lack resources to perform all of the required studies. The process has become slow and cumbersome and consumes large quantities of staff resources.** As a result, agencies can complete work on fewer regulations, particularly in a time of declining budgets just like the present. This has adverse effects on public health and safety. The detailed provisions of the state's APA also provide many opportunities for lawyers to challenge rules on judicial review because of minor procedural infirmities. **The California experience suggests that a simpler statutory structure like the existing federal APA, regulated sensibly and flexibly by court decisions, is better than a minutely detailed statutory prescription of rulemaking procedure.**

The following examples of how the RAA would affect the regulatory process draw upon the authors' primary expertise in health, safety, and the environment; nevertheless, it is important to emphasize that rulemakings even under such agencies as the Federal Election Commission, the Federal Communications Commission, and the Veterans' Benefits Administration would be affected. **The RAA's procedural requirements would hamstring all rulemaking agencies and squander their resources.**

MAKING THE "LEAST COSTLY" RULE THE DEFAULT CHOICE

The RAA requires that an agency default to the "least costly" rule, unless it can demonstrate – out of all possible alternative rules – that additional benefits of the more costly rule justify the additional costs and the agency offers a public health, safety, environmental, or welfare justification "clearly" drawn from the authorizing statute – a bar that experts say would be difficult to meet. **Thus, the RAA would override a range of laws that "were enacted after a deliberative legislative process in which affected individuals and interest groups had a meaningful opportunity to consult with Congress regarding the statute's tradeoffs among competing values."**⁸

⁸ *Id.* at 14.

Most current health, safety, and environmental authorizing statutes ask agencies to, in effect, "do the best they can" to ensure that Americans have untainted food, unpolluted air and water, lead-free toys, safe workplaces, and the like. The RAA would reverse this: **rather than asking agencies to do the best they can to protect Americans at a cost regulated industries can absorb, the RAA would ask agencies to concentrate on cutting costs without regard to effects on health or safety.**

Though it would override more than two dozen deliberately-enacted and long-honored precedents, the "least costly" default requirement is not a novel idea – rather, it is closely analogous to the standard found in the Toxic Substances Control Act (TSCA). **Experience under TSCA has proven that "least costly alternative" requirements paralyze rulemaking processes.**

Environmental Protection Agency: Asbestos

Asbestos is recognized by the National Institute of Health's National Toxicology Program as a known human carcinogen and the U.S. Surgeon General says there is no known safe level of exposure. After a decade of research and an administrative record that ran to more than 100,000 pages, in 1989, the EPA issued a rule that banned most uses of asbestos, including things like brake linings, roofing, pipes, tile, and insulation.

However, the rule was overturned by the Fifth Circuit Court of Appeals in 1991 because it was not the "least burdensome alternative," which is the standard under the Toxic Substances Control Act. So, despite the overwhelming and uncontested evidence that asbestos causes cancer, it continues to be used in applications including building supplies (asbestos-cement shingles, asphalt roofing shingles, pipeline wraps, vinyl-asbestos floor tile, millboard, asbestos cement pipe and asbestos clothing) and automotive products (clutch facings, friction materials, automatic transmissions components, disc brake pads, drum brake linings, brake blocks, gaskets, and valve and pump packing.)

In the 20 years since the asbestos ruling, the EPA has found the "least burdensome" standard impossible to meet, meaning that many substances known to be toxic are un- or under-regulated. The CEO of SC Johnson, a major consumer products company, has stated that because of the requirements in TSCA (replicated in the RAA), "Your child has a better chance of becoming a major league baseball player than a chemical has of being regulated [under TSCA]."

Consumer Financial Protection Bureau: Mortgage Lenders

While the EPA may find it difficult to meet the health, safety, environmental, or welfare exceptions to enact a rule, agencies like the CFPB would most likely find it impossible. The CFPB would therefore be required to always choose the least costly alternative – whether or not that rule is the best way to prevent "exploding mortgages" or other financial harm to consumers. This would apply to the SEC's rules for publicly controlled companies as well as regulations dealing with sub-prime mortgages and other financial regulations. It is already difficult to develop regulations designed to hold companies accountable, including implementation of the Dodd-Frank Act. The RAA will add to the problem.

Environmental Protection Agency: Lead in Gasoline

Lead is a potent neurotoxin that has damaging, long-lasting impacts on human health, especially in children, in whom it can cause both physical and significant mental effects. Today, we consider the ban on lead in gasoline an obvious rule which has worked well to protect public health. However, industry fought hard to keep this rule from occurring. If the Regulatory

Accountability Act had been on the books when EPA was working this rule, the agency would have been forced to consider – and perform detailed analyses on – a wide variety of regulatory approaches, including doing nothing at all about the problem. Here is a brief sample of some of the alternatives that EPA might have been required to consider:

- Different compliance timelines for reducing the amount of lead added to gasoline. In fact, in its proposal, EPA extended the compliance timeline by one year.
- Different compliance times for different sized refineries. In fact, EPA’s final rule gave smaller refineries a longer compliance timeline than larger refineries. Note that the EPA added this provision voluntarily—the Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act were not the law at the time.
- Different lead in gas reduction levels. The EPA rule compelled an 80-percent reduction by the end of the compliance timelines. Would a more “cost-effective” rule compel a 60-percent reduction? A 70-percent reduction? 75-percent? 79-percent?
- Lead was added to gasoline to improve engine performance, and eliminate “knocking.” The agency might have been forced to consider a rule that only required the reduction of lead in gasoline if a suitable alternative additive was found, even though this would have posed a direct threat to children's health and IQs.
- One of the reasons that the EPA wanted to reduce lead in gasoline was because the element impaired the function of catalytic converters, which EPA was requiring automobile manufacturers to install on their cars to reduce other harmful automobile emissions such as carbon monoxide and oxides of nitrogen (NOx). Perhaps industry might have suggested that the most cost-effective solution would be to repeal the catalytic converter rule, rather than impose the lead in gas rule.

SUPER-MANDATING COST-BENEFIT ANALYSIS

The RAA's requirement that, for any proposed rule, agencies consider all of the "potential costs and benefits associated with potential alternative rules ... , including direct, indirect, and cumulative costs and benefits," would apply "[n]otwithstanding any other provision of law." **This would override at least 25 authorizing statutes and rewrite "much, perhaps most, of the safety and health legislation now on the books."**⁹ **Many of these are wildly popular pieces of "landmark" legislation, like the Occupational Safety and Health Act and the Clean Water Act.** As the ABA Section of Administrative Law and Regulatory Practice has put it, "[t]he APA would thus become, in several respects, an 'Administrative Substance Act.'"¹⁰ The ABA Section was emphasizing that the APA should not prescribe how to analyze rules, but rather remain focused on laying out procedures for agencies to abide by.

Current authorizing statutes require that different considerations be weighed for different types of rules. **In fact, the U.S. Supreme Court has ruled that some statutes prohibit decisions from being based on cost-benefit analysis at all. The RAA would run roughshod over these carefully-considered differences,** requiring that cost-benefit analysis be performed not only for every rule, but also that it be performed much earlier in the rulemaking process and for every possible alternative rule. (The requirement to conduct a cost-benefit analysis also applies to all major guidance, which is further discussed below.)

⁹ *Id.* at 12-3.

¹⁰ *Id.* at i.

The problems with the RAA's emphasis on cost-benefit analysis as the most important deciding factor are only compounded by how the analyses would be performed. **The RAA omits language, found in Executive Order 12,866 and other executive orders, which reiterates that some of the most important considerations cannot be quantified.** As many experts have pointed out, certain types of benefits are difficult to quantify and certain types of costs are inherently speculative. However, empirical research has demonstrated not only that the economic benefits of most rules vastly outweigh their costs, but also that cost-benefit analyses typically overestimate costs and underestimate the benefits of federal standards and safeguards.¹¹

Moreover, the RAA's emphasis on indirect and cumulative costs and benefits is an exercise in futility. Adding in the requirement to assess indirect costs is like going into a black hole never to come out again. If the desire is to kill a rule, it is easy to require additional endless analyses to slow down the rule. Since indirect costs provide an opportunity to add in extraneous costs, and the RAA makes the least costly option the choice for moving forward, the conclusion of rulemaking will result in less protective rules. Since the Clinton Administration, the Office of Management and Budget has concluded that attempting to include cumulative costs in these analyses would result in unfair, apples-to-oranges comparisons – thus vitiating the value of any such analysis for policy purposes.

Occupational Safety and Health Administration and Mine Safety and Health Administration

The Occupational Safety and Health Act (OSH Act) and Mine Safety and Health Act (MSH Act) would be significantly weakened by the Regulatory Accountability Act because the bill would replace an effective process for rulemaking and public hearings included in both statutes, with a complex, unworkable formal rulemaking for most regulations.

Under both the OSH Act and MSH Act, the Secretary of Labor is required to set workplace safety standards that provide workers protection from “material impairment of health” or “loss of functional capacity” due to exposure to risks or toxins over a working lifetime. Under the OSH Act, these standards are limited by considerations of technological and economic feasibility. The U.S. Supreme Court has ruled that the OSH Act prohibits OSHA from basing health standards on a strict cost-benefit determination, since protection of health is to be the primary consideration of the law and rules developed under it. **The RAA would override this requirement and mandate OSHA and MSHA to adopt the least costly standard, rather than the most protective standard.** The agencies could adopt a more costly alternative only if a cost-benefit analysis showed that benefits exceeded costs (which is currently prohibited by both the OSH Act and MSH Act). This requirement would make it extremely difficult for both OSHA and MSHA to protect workers from chronic health hazards like black lung and silicosis, where the costs accrue at the end of a worker’s lifetime due to the chronic nature of these diseases, as well as standards on critical safety issues, like explosive dust hazards.

After years of decline, dust-related diseases among coal miners are on the rise with clear evidence that current standards are not protective enough. OSHA is in the process of developing a new silica standard, with a rulemaking that began in 1997. (The current standard is more than 50 years old.) There are hundreds of silicosis deaths and thousands of new silicosis cases every year.

¹¹ See, e.g., Isaac Shapiro, *The Combined Effect of the Obama EPA Rules: Total costs of proposed and finalized rules represent only about 0.1 percent of the economy and are far outweighed by cumulative benefits*, Economic Policy Institute Report, Sept. 19, 2011.

Unregulated safety hazards have likewise led to hundreds of preventable explosions in dusty factories – often with deadly results – like the 2008 explosion at the Imperial Sugar Refinery in Port Wentworth, Georgia, that killed 14 workers and injured 40 others. Recent inspections have found thousands of violations of existing standards on explosive dust in many industries – including hundreds that OSHA deemed “willful” or “repeated,” but such incidents continue in part because of current gaps in essential standards. OSHA’s rulemaking on explosive dust would be severely hampered if the RAA took effect.

MSHA has proposed a stronger standard to reduce exposure to coal dust and to prevent black lung and has a rulemaking planned on silica. Under the RAA, the costs to coal operators and other employers would be primary, and consideration of the health of workers secondary. This is totally contrary to both the MSHAct and OSHAct. Moreover, **the definition of “cost” would be greatly expanded by including “indirect” and “cumulative” costs with the direct costs, stacking the calculation to exaggerate costs to regulated industry.** A business thumb is on the scale.

Environmental Protection Agency: Cooling Water

Under the Clean Water Act, the EPA is supposed to issue regulations that require “the best technology available for minimizing adverse environmental impact.” In 2001, the agency found that closed-cycle recirculating cooling systems were the best technology available for newly constructed power plants but did not extend the rule to existing plants.

Several hundred power plants still use a once-through cooling system, which kills billions of fish each year and disrupts marine ecosystems via releases of super-heated water. Closed-cycle recirculating systems reduce the number of fish killed and the amount of water removed from the ecosystem by more than 95 percent.

The EPA used a cost-benefit analysis to weight the ecological benefits of the closed-cycle systems against what it would cost industry to implement them. The U.S. Supreme Court found that the EPA is *allowed*, though not *required*, to use cost-benefit analysis under current law. Writing for the minority, Justice John Paul Stevens pointed out that the benefits of conservation had been massively underestimated: the benefit calculations considered only commercially or recreationally harvested species, which constitute less than two percent of the species that are impacted by the cooling systems.

As an amicus brief filed in the case put it, **“The application of formal CBA to environmental regulation rests on the untenable assumption that complex effects on ecological and human health can be quantified and expressed in dollar terms.”**¹² The RAA would sweep away any considerations that cannot be quantified in a cost-benefit analysis.

Environmental Protection Agency: Lead in Gasoline

As documented in a seminal administrative law article by Lisa Heinzerling, Frank Ackerman, and Rachel Massey¹³, the EPA’s critical 1973 rule significantly reducing the amount of lead refiners

¹² Brief for OMB Watch as Amicus Curiae, p. 3, *Entergy Corp. v. Riverkeeper, Inc.*, 129 S. Ct. 1498 (2009).

¹³ Frank Ackerman, Lisa Heinzerling, and Rachel Massey, *Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?*, 57 ADMIN. L. REV. 155 (2005).

could add to gasoline would not have seen the light of day if rules at the time were required to be cost-benefit justified. The benefits were simply too uncertain at the time. The rule turned out to be a tremendous bargain, however, as unhealthy levels of lead in children's blood – enough to cause permanent brain damage, behavioral problems, etc. – were greatly reduced.

One of the biggest benefits of the lead-in-gas rule was preventing brain damage in children that, in turn, reduces their IQ level. Though it did not do so at the time, the EPA currently values each child's IQ point at \$8,800. This is based exclusively on a calculation of the reduction in the amount of money that a child will earn over the course of his or her lifetime, discounted to reflect that some of these benefits occur "in the future."

Of course, our children's IQs mean more to us than what difference they will make on their future earning potential. A child's IQ and ability to learn also impacts his or her happiness, self-esteem, ability to get along with others, and more. **These values defy quantification and monetization, and would not be properly accounted for in a cost-benefit analysis, particularly one under the Regulatory Accountability Act, which, unlike E.O. 12,866, does not caution agencies to account for benefits that defy quantification and monetization.**

The great irony of this case study is that a subsequent rule to regulate lead in gasoline – one that phased out the use of lead completely – is often touted as an example of cost-benefit analysis being used to justify strong regulations. This second rule would never have been developed if the first one had not been put in place first, thereby providing us with the necessary data for conducting a useful cost-benefit analysis – something that almost never occurs in the real world – and this first rule would have never been developed if RAA-style cost-benefit analysis had been the requirement of the day.

SHIFTING TO FORMAL RULEMAKING PROCESSES

Over the last fifty years, scholarly reviews and evaluations have consistently confirmed that formal hearing requirements are "time-consuming and resource-intensive."¹⁴ Furthermore, it is generally recognized that formal hearings are an inefficient mechanism for "resolving the broad, complicated policy issues that are the focus of most agency rulemaking proceedings [because] [t]he agency becomes so enmeshed in testimony concerning specific facts that its attention is diverted from the important policy considerations that should dominate the process of formulating general rules."¹⁵ **Nevertheless, the RAA would automatically require formal rulemaking processes for rules with projected annual costs of more than \$1 billion and would allow any interested party to demand formal rulemaking for major rules (those with estimated annual costs of \$100 million or more).** The hearings would encompass not only the issues laid out in the RAA, but also *any other issues raised by an interested person* (unless the agency can determine within thirty days of the request that a hearing would be unproductive or would unreasonably delay completion of the rulemaking).

¹⁴ Stephen M. Johnson, *Competition: The Next Generation of Environmental Regulation?*, 18 SE. ENV'T L.J. 30, 31 (2009).

¹⁵ *Id.* at 33 (citing RICHARD J. PIERCE, JR., SIDNEY A. SHAPIRO & PAUL R. VERKUIL, *ADMINISTRATIVE LAW AND PROCESS*, 328-29 (5th ed. 2009)) (referring also to the ACUS recommendation 76-3 stating that trial-type procedures should never be required for "resolving questions of policy or of broad or general fact.")

Both the American Bar Association and the Administrative Conference of the United States have denounced formal rulemaking as inappropriate for virtually all agency decisions. ACUS Recommendation 93-4 states that "[s]tatutory 'on-the-record' and 'hybrid' rulemaking provisions that require adjudicative fact-finding techniques such as cross-examination ... can be unnecessarily burdensome or confusing and should be repealed." This is not a controversial position: **there has not been "a single scholarly article written within the past thirty years that expresses regret about the retreat from formal rulemaking."**¹⁶

Studies have shown not only that formal rulemaking slows down the regulatory process, but also that the regulated parties will use formalized proceedings as a bargaining chip, "threatening to insist on their right to trial type proceedings, bogging down an agency in protracted proceedings."¹⁷ The author of one leading study has written that "[i]n practice, ... the principal effect of imposing rulemaking on a record [*i.e.*, formal rulemaking] has often been the dilution of the regulatory process rather than the protection of persons from arbitrary action."¹⁸ Another study, carried out by a professor who was later appointed by President Reagan to the D.C. Circuit Court of Appeals, documented that giving regulated parties the right to invoke formal hearings gives them a distinct tactical advantage over the rulemaking process.

Requiring formal rulemaking procedures not only to delays vital rules unnecessarily, it also decreases the opportunity for public input. **"Although the formal rulemaking process is *in theory* as open to the public as the informal process, it is not as open *in practice*."**¹⁹ Formal rulemaking procedures require not only that the agency submit its findings to cross-examination, but also that anyone else who wishes to participate in the hearing (*i.e.*, the public) submit their evidence to the same process.²⁰ Although not required to seek counsel before participating a hearing, parties are likely to feel the need to do so. **This may have the particular impact of alienating scientists and other experts whose contributions are critical in seeking to develop the best possible rules.**²¹ Overall, formal rulemaking cuts agencies off from everyone except special interests willing to invest their time and resources in achieving a particular outcome. **Requiring formal rulemaking processes will cause enormous delay in the rulemaking process and add more litigation without resulting in improved rules.**

Food and Drug Administration: The Peanut Butter Rule

The Food and Drug Administration's (FDA's) peanut butter rule, proposed in 1961, is often cited as a prime example of how formal rulemaking procedures have failed to achieve any purpose aside from delaying important regulations, wasting much needed agency resources, and

¹⁶ Letter from American Bar Ass'n, *supra* note 7, at 21.

¹⁷ *Id.* at 22.

¹⁸ Robert W. Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CAL. L. REV. 1276 (1972).

¹⁹ Johnson, *supra* note 12, at 32.

²⁰ Steven P. Croley, *Theories of Regulation: Incorporating the Administrative Process*, 98 COLUM. L. REV. 1, 106 (1998).

²¹ Robert W. Hamilton, *Rulemaking on a Record*, 26 FOOD DRUG COSM. L.J. 627, 633 (1971); William R. Pendergrast, *Have the FDA Hearing Regulations Failed Us?*, 23 FOOD DRUG. COSM. L.J. 524, 530 (1968).

producing a costly “record,” that rarely, if ever, serves as the basis for a court’s decision to overturn an agency rule.

In July 1959, after a press release revealed that the largest brands of peanut butter only contained 20 percent peanuts, FDA began the rulemaking process according to the formal rulemaking procedures provided in the Food, Drug, and Cosmetic Act (FDCA). FDA’s proposed rule provided that peanut butter must contain at least 95 percent peanuts; however, after recognizing that consumers preferred peanut butter that spread more easily, FDA reduced the standard to 90 percent in 1961. The industry petitioned FDA for a formal hearing (in accordance with the formal rulemaking provisions in the FDCA) to argue for the standard to be set at 87 percent. The formal hearing alone added almost five months to the rulemaking process and resulted in a transcript of approximately 8,000 pages primarily discussing whether peanut butter should contain 87 percent or 90 percent of peanuts.

Nine years later, in July 1968, the FDA finalized the standard at 90 percent. Yet, the battle continued on for another two years as a result of the industry’s challenge of the rule in the Third Circuit Court of Appeals. Ultimately, the court affirmed the agency’s finding, noting that, based on the formal record, even if 87 percent was a reasonable alternative, the FDA’s 90 percent standard was equally reasonable, and thus it should not be overturned. **Formal rulemaking allowed the industry to drag out the public’s demand for accurate labeling of products by nine years.**

National Oceanic and Atmospheric Administration: Taking of Beluga Whales

In October 2000, NOAA published its notice of formal hearing scheduled for Dec. 5, 2000. The hearing lasted only three days, but the judge did not issue his recommendation for over a year. The agency was finally able to issue interim regulations in 2004, but another hearing was required to set regulations for 2005 and beyond. Again, the presiding judge did not submit the recommendation until over a year later. Once able to move forward with other preliminary requirements, the agency finalized the rule on Oct. 15, 2008. Only a week after the eight year rulemaking process, the beluga whale was added to the Endangered Species list.

HYBRID RULEMAKING

Hybrid rulemaking is somewhere between formal (with a hearing and record) and informal (notice-and-comment procedures). Hybrid rulemakings result from the requirements of a particular statute, such as the Clean Air Act or the Occupational Safety and Health Act. Some hybrid rulemaking variations include: multi-stage rulemaking, creation of an informal record, and issuance of detailed findings and reasons; it generally subsumes procedural aspects reserved for adjudication, such as a formal hearing in which interested parties are sworn and subject to cross examination. Under the RAA, hybrid rulemaking, like that at OSHA, would be converted to formal rulemakings under the substantial evidence test.

Occupational Safety and Health Administration and Mine Safety and Health Administration

The RAA would override the hybrid rulemaking procedures that are mandated by the OSH Act and MSH Act and have worked well. Both of these statutes include their own special rulemaking procedures, separate from the APA, that provide the opportunity for a public hearing if one is requested, conducted under rules established by DOL. Under these provisions, OSHA provides for a public hearing on the record conducted by an administrative law judge (ALJ) with the opportunity for cross examination of the agency and other witnesses. MSHA provides for a public hearing on the record conducted by a representative of the agency. Both the OSHA and

MSHA proceedings are non-adversarial hearings for the purpose of building a record of evidence. Most of the participants are workers or affected employers with experience on the issue. This type of rulemaking provides good opportunity for public input, presentation of evidence, and interaction with the agency.

The RAA would replace this successful hybrid rulemaking process at OSHA and MSHA with formal rulemaking under the APA for most rulemakings. **This formal rulemaking process would be adversarial in nature and allow for endless challenges to agency evidence and findings. It would make rulemaking more complicated, more litigious, and costly.** It would tilt the process in favor of employers that have the ability to expend significant legal resources on the process and disadvantage workers and small businesses who do not have similar resources.

For example, in October 2010, MSHA proposed a new standard to protect miners from black lung caused by exposure to coal dust. In addition to providing more than six months for written comments on the proposed rule, MSHA conducted seven public hearings around the country over a three-month period, where miners, union representatives, coal operators, and experts testified. This process not only provided the opportunity for input by all interested parties, it also identified several key issues, on which MSHA requested additional written comments. Under the RAA, this evidence-building hearing process would be replaced by an unproductive, adversarial hearing process.

ALLOWING JUDICIAL REVIEW OF ALL AGENCY JUDGMENTS

The RAA would greatly expand the courts' ability to review agency judgments, empowering parties to challenge virtually every agency decision to proceed with a rule. If an agency or OMB decides to proceed with a review and makes a decision that the rule is not "high-impact" or "major," its decision can be reviewed by the courts. However, if the agency or OMB decides it is a "high-impact" or "major" rule, no request for judicial review can be made. In other words, the RAA discourages agencies from acting.

Once a rule is deemed "high-impact" or "major," virtually every step in the process can be challenged in the courts. The RAA also radically changes the judicial criteria for overturning regulations, favoring the regulated industries. Under current law, courts may set aside regulations based on a finding that the agency's actions were "arbitrary" or "capricious." The RAA would overturn many years of case law, making judges into "super-regulators" who are empowered to substitute their own opinions for the findings of agencies. The standard would be changed to "substantial evidence," instead of "arbitrary and capricious." **This will not only make it more difficult for agencies to fulfill their missions, but will also put tremendous stress on the federal court system,** which is already overburdened by increasing workloads, persistent judicial vacancies, and decreasing resources.²²

The RAA states that courts "shall not defer" to an agency's interpretations and determinations unless the agency followed specified procedures but instead should make their own findings regarding the facts at issue (these could be, for example, the costs and benefits of a proposed rule or risk assessment). **That is, courts are asked to make policy judgments that authorizing statutes entrusted to agency experts.** Because a judge who hears such a case is not likely to have the training or expertise necessary to accurately evaluate competing economic models or scientific studies, the ABA's Section of

²² Shapiro, *supra* note 1, at 12.

Administrative Law and Regulatory Practice has characterized this change as "unwarranted."²³ Judicial review of rulemaking is likely to become more complicated and more expensive. **Even more important, irregular and unpredictable judicial intervention could undercut the ability of agencies to coordinate complex regulatory programs.** Agencies will be forced to squander their increasingly limited resources on defending lawsuits and responding to petitions rather than developing important health and safety regulations.

Additionally, the RAA would add more opportunity to delay or stop a rule through Information Quality Act (IQA) challenges. Currently, challenges under the IQA can be filed; an agency reviews the merits; and an agency's decision can be appealed. The RAA adds two more elements. First, the challenges under the IQA can be reviewed by a court, thereby forcing courts into assessing scientific methodology, analysis, and outcomes. Second, anyone can petition for a hearing under the IQA, presumably creating a separate hearing from the formal rulemaking hearings described above, which would also be judicially reviewable.

IQA challenges would take the form of a petition to exclude a particular piece of information from being considered by the agency; if the petition was not immediately granted but "presents a prima facie case," the agency would be required to hold a trial-like hearing, complete with cross examination of witnesses, within sixty days. Professor Sid Shapiro has noted that "**[r]egulated industries would have a strong incentive to submit several IQA challenges at once, knowing that the agency's limited resources and the tight timeline for resolving these petitions would likely force the agency to exclude several pieces of information or evidence that it would have needed to justify a stronger regulation.**"²⁴ If an agency's resources did not allow it to make a final determination within the specified timeframe, it would have two choices: it could either adopt a weaker rule than the available information would have called for, or it could proceed with a rule that is quite likely to be struck down by a judge. **There is little reason to believe that even if an agency is able to convene a hearing that it will ultimately improve the quality of the rule:** cross-examination is most useful for determining the credibility of witnesses, not the reliability of data.²⁵

Agencies already receive tens of thousands of IQA petitions each year, with one study demonstrating that almost three-in-four IQA challenges come from by regulated industry.²⁶ According to the Office of Management and Budget, most IQA challenges "hinge on the interpretations of science or analyses."²⁷

Environmental Protection Agency: Greenhouse Gas Endangerment Finding

Under the RAA, EPA's greenhouse gas endangerment finding, which, on Sept. 28, 2011, the EPA's Inspector General found "met statutory requirements for rulemaking" could be delayed and challenged in court. The IG noted that EPA should have made public its review of a technical support document used in the endangerment finding, even though EPA determined

²³ Letter from American Bar Ass'n, *supra* note 7, at 34.

²⁴ Shapiro, *supra* note 1, at 14.

²⁵ Letter from American Bar Ass'n, *supra* note 7, at 24.

²⁶ OMB Watch, *The Reality of Data Quality Act's First Year: A Correction of OMB's Report to Congress*, at 6-7, July 2004.

²⁷ Office of Management and Budget, *Information Quality: A Report to Congress*, at 8, Apr. 30, 2004.

that the document was not a “highly influential scientific assessment” as defined by OMB’s guidelines under the IQA (and its peer review guidelines). Even without the IG’s findings, anyone could have called for an IQA hearing to publicly debate this point. The results of the hearing would be judicially reviewable. Moreover, even if someone did not petition for a hearing, they still could challenge in court the science used by EPA.

Environmental Protection Agency: Atrazine

Mere days after the IQA took effect, petitioners challenged the EPA's dissemination of a study of the endocrine-disrupting effects of atrazine, a widely used weed-killer, in a report that examined the environmental risks of the pesticide. The petitioners claimed that the study was unreliable because the EPA had not yet established protocols for testing the endocrine effects of chemicals. EPA denied the petition and refused to amend its report. Under the RAA, the petitioners could have called for a hearing and/or gone to court.

National Heart, Lung and Blood Institute: Salt Intake Guidelines

The Salt Institute and the U.S. Chamber of Commerce filed an IQA petition that challenged the data behind the National Heart, Lung and Blood Institute's statements about the health impacts of salt intake and demanded that the Institute release data from a study. The National Institutes of Health denied the request, pointing out that petitioners could request the data through the Freedom of Information Act. The petitioners filed a lawsuit, in which the judge ultimately ruled that the IQA is not judicially reviewable – a stance that would change under the RAA.

National Toxicology Program: Barium

The Chemical Products Corporation, a barium producer, requested that National Toxicology Program remove an abstract of a draft technical report from its website because a contaminated sample used in the study invalidated the entire report. Although NTP added information about the contaminant to its website, CPC appealed, which resulted in NTP deciding to remove the abstract entirely.

Environmental Protection Agency: Lead in Gasoline

The EPA relied on several studies that demonstrated the link between leaded gasoline and adverse human health outcomes. These studies were challenged during the comment period, and the EPA responded to these challenges in the final rule’s preamble. Under the Regulatory Accountability Act, the powerful refinery industry could have submitted separate but frivolous petitions challenging all of these studies under the IQA. Lacking the necessary resources to defend all of these petitions, the EPA would likely have been forced to exclude several of them. As a result, the agency may not have been able to justify as strong a rule as was needed to protect America's children from harm or the rule it issued may have been susceptible to a successful court challenge, which would have forced the EPA to rewrite the rule, adding several years of delay before its safeguards could have gone into effect. This, in turn, would have led to millions more children developing learning disabilities and behavioral problems as a result of lead poisoning.

Examples like these demonstrate that IQA challenges are used not to improve the quality of science used by federal agencies but to challenge widely accepted scientific evidence and push discussions into adversarial judicial settings.

GUIDANCE DOCUMENTS

"Guidance documents" are issued by agencies seeking to reduce regulatory uncertainty, either by clarifying agency policy (these are sometimes referred to as "policy statements") or by explaining how an agency will interpret existing law ("interpretive rules"). Guidance may take a range of forms: manuals, memoranda, statements, circulars, letters, computer programs, and audio and video recordings.

The RAA would create a much more stringent process for agencies to issue guidance documents. In particular, before issuing a major guidance document an agency would have to consider certain issues prescribed by the RAA – including, for example, a cost-benefit analysis considering all the direct, indirect, and cumulative costs associated with the guidance – and ensure that the guidance's benefits "justify" its costs. The agency would also have to issue a description of alternatives to the guidance (including their costs and benefits) and submit the guidance to OIRA for review.

Testifying before the House Judiciary Committee about the RAA, Professor Sid Shapiro noted that even if some of the requirements found in the RAA could improve some guidance documents, it is nevertheless a bad idea to issue a universal mandate that strips agencies of all flexibility.²⁸ He predicted that the guidance requirements in the RAA would lead agencies to delay issuing guidance, or in some cases, forgo it altogether.

Nearly all guidance documents are welcomed, if not requested, by regulated entities because a key purpose of guidance is to allow an agency to explain and interpret the regulations it is responsible for enforcing. **Thus, making it harder for agencies to issue guidance would do little more than create unnecessary regulatory uncertainty and place preventable burdens on American businesses.** For example, statutory language that states that guidelines are non-binding would seriously undermine the ability of OSHA to enforce protections against serious hazards.

Occupational Safety and Health Act: Heat and Violence in Night Retail Establishments

For example, under the OSHAct, employers have both the obligation to comply with individual standards and a general duty obligation to protect workers against recognized hazards that are causing or likely to cause death or serious harm. This general duty clause is used by OSHA in enforcement cases where there are recognized hazards, but no standards.

When OSHA publishes guidelines, it generally says that the guidelines do not alter compliance obligations that exist under the statute or standards. For example, a 2009 guideline on preventing violence in night retail establishments has the following disclaimer:

"This publication provides a general overview of a particular standards-related topic. This publication does not alter or determine compliance responsibilities which are set forth in OSHA standards, and the Occupational Safety and Health Act of 1970. Moreover, because interpretations and enforcement policy may change over time, for additional guidance on OSHA compliance requirements, the reader should consult current administrative interpretations and decisions by the Occupational Safety and Health Review Commission and the courts."

²⁸ Shapiro, *supra* note 1, at 17.

In September 2011, OSHA issued a compliance directive on workplace violence that outlined how it would deal with workplace violence under the general duty clause. This is an important initiative since homicide is the second leading cause of occupational fatalities, and there is no OSHA standard to protect workers against workplace violence.

Similarly, there is no OSHA standard limiting exposure to heat, but OSHA uses industry practice and National Institute for Occupational Safety and Health recommendations to recognize hazards and will enforce against employers when there are serious, life-threatening situations. **The RAA's onerous procedures for issuing guidance documents would make it nearly impossible for OSHA to explain to employers what their responsibilities are with regard to critical workplace threats under the OSH Act's general duty clause, creating unnecessary regulatory uncertainty and leaving workers inadequately protected.**

IRS Letter Rulings

IRS letter rulings, which help businesses and other taxpayers comply with applicable tax laws, would be covered. Courts and others have relied on these rulings to assist them in understanding how the tax code should be enforced. The RAA may have an adverse impact on that process by delaying the issuance of these letters.

CONCLUSION

There could be hundreds of examples to demonstrate the combined impact of all these provisions, but one is a pending rule at the United States Department of Agriculture (USDA) that would declare six highly-virulent, pathogenic strains of *E. coli* as adulterants in beef products. The USDA action was opposed by the American Meat Institute in 2010, and one of its arguments was that the new rule would “significantly impact international trade,” with countries whose beef was denied access to U.S. markets because of this new rule, retaliating by blocking the export of U.S. meat, thereby “curtailing U.S. beef exports.” If the RAA were in effect, the meat industry would have many new avenues to challenge and delay not only the rule itself, but also the USDA’s scientific findings and its cost-benefit analyses.

The rule has been roundly applauded by food safety advocates for protecting the American public from tainted meat – yet, if the Regulatory Accountability Act were enacted, it is virtually certain that the rule would be delayed by industry interests. USDA would be forced to divert its resources to performing cost-benefit analyses on every alternative that the industry (and its legions of attorneys) could devise, defending scientific findings to non-expert judges required to hear Information Quality Act challenges, and ultimately would be required to develop the final rule based on what would be cheapest for producers to comply with – not what would keep Americans from getting sick. **More importantly, Americans would continue to be sickened and killed by *E. coli* infections that could have been prevented.**

At its core, our regulatory state has been developed to protect Americans against very real threats to their health, safety, and well-being. **The Regulatory Accountability Act is nothing less than an attempt to roll back our critical public safeguards and promote industry interests instead of protecting American citizens.**

*If you have questions about this report, please contact Jessica Randall at OMB Watch:
jrandall@ombwatch.org or 202.234.8494.*

The Coalition for Sensible Safeguards is an alliance of consumer, small business, labor, scientific, research, good government, faith, community, health, environmental, and public interest groups, as well as concerned individuals, joined in the belief that our country's system of regulatory safeguards provides a stable framework that secures our quality of life and paves the way for a sound economy that benefits us all. For a list of member organizations and other information about the coalition, see [http://www.sensible safeguards.org/about us](http://www.sensible safeguards.org/about_us).