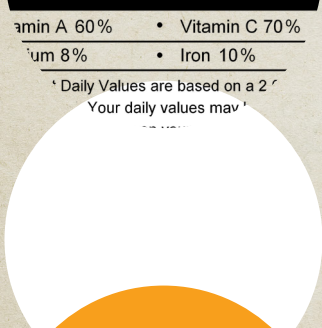
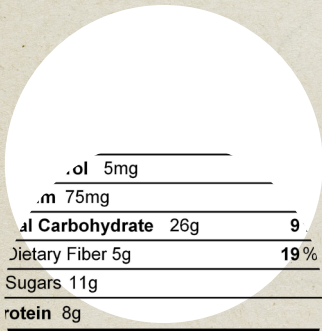




# THE ROLE OF REGULATORY IMPACT ANALYSIS IN FEDERAL RULEMAKING



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**R**EGULATORY IMPACT ANALYSIS (RIA) is a tool regulators use to help guide them through the decision-making process when promulgating regulations. The goals of an RIA are simple and straightforward: to assess whether a problem exists that is systemic in nature and therefore requires intervention, to define the desired outcome sought through intervention, to describe the various alternatives that might address the problem and bring about the desired outcome, and to compare the benefits and costs of each alternative.<sup>1</sup>

Since 1981, presidential oversight of rulemaking has required that RIAs be performed by executive branch agencies. These RIAs, in turn, are to be reviewed by the Office of Information and Regulatory Affairs (OIRA), a statutory office located within the Office of Management and Budget (OMB). Requirements for conducting a well-informed RIA, such as identifying the problem the agency is seeking to solve through regulation and considering a variety of alternative forms of regulation, were codified for presidential oversight of rulemaking by Executive Order (EO) 12866, issued by President Clinton in 1993.<sup>2</sup> The very first principle of regulation listed in the executive order states,

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1. Richard Williams and Jerry Ellig, “Regulatory Oversight: The Basics of Regulatory Impact Analysis” (Mercatus Center at George Mason University, Arlington, VA, September 12, 2011), <http://mercatus.org/publication/regulatory-oversight>.

2. Exec. Order No. 12,866, 3 Fed. Reg. 58 (October 4, 1993).

Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.<sup>3</sup>

Similarly, the executive order also states that “agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating.”<sup>4</sup> In fact, both EO 12866 and OMB guidelines present a wide variety of types of alternatives that agencies should consider.<sup>5</sup>

When identifying a problem, it is important that regulators address root causes of problems, not just symptoms of problems. For example, imagine that a house has a leaky roof. The problem is the hole in the roof. The symptom is a wet floor. The occupants could spend all day mopping the floor and blowing a heater on it—the surface might dry temporarily, but until they patch the roof, the problem will continue. An RIA helps agencies focus on the problem so that proposed regulatory fixes are providing genuine solutions rather than mopping wet floors.

It is also important that agencies consider alternative ways of solving problems. OMB, in its guidance on best practices for regulatory analysis, recommends that agencies consider alternative approaches to solving problems.<sup>6</sup> Ideally, these alternatives should vary in stringency and in the type of option considered (e.g., com-

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3. See *id.* § 1(a). Note that the executive order’s principles are all qualified in section 1(b) by the key words “to the extent permitted by law.”

4. *Id.*

5. Suggested alternatives include information measures rather than regulation, performance standards rather than design standards, different requirements for different geographic regions, different requirements for different-sized firms, and different degrees of stringency, among others. Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Washington, DC: OMB, 2003), 8.

6. *Ibid.*

mand and control versus performance-based standards).<sup>7</sup> OMB also recommends that alternatives be compared against a baseline that represents a realistic portrayal of what the world would look like in the absence of a regulation.<sup>8</sup> A baseline is important because the world is a constantly evolving place. Regulations should not take credit for changes that would have occurred anyway. Similarly, a regulation should receive credit for improving a situation that appears to be deteriorating even after the implementation of the regulation if the situation likely would have been even worse in the absence of the regulation. A well-thought-out baseline gives regulators a reference point against which to gauge the effectiveness of policies.

Once alternatives and a realistic baseline have been identified, agencies should attempt to bring together information about the costs and benefits of various proposals in order to compare the merits of each option. OMB explains why benefit and cost information is useful in its 2012 report to Congress on benefits and costs of federal regulation:

OMB emphasizes that careful consideration of costs and benefits is best understood as a pragmatic way of ensuring that regulations will improve social welfare, above all by informing the design and consideration of various options so as (1) to help in the assessment whether it is worth proceeding at all and (2) to identify the opportunities for minimizing the costs of achieving a social goal (cost-effectiveness) and maximizing net social benefits (efficiency).<sup>9</sup>

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7. Ibid.

8. Ibid., 2.

9. Office of Management and Budget, *2012 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (April 2013): 4, [http://www.whitehouse.gov/sites/default/files/omb/inforeg/2012\\_cb/2012\\_cost\\_benefit\\_report.pdf](http://www.whitehouse.gov/sites/default/files/omb/inforeg/2012_cb/2012_cost_benefit_report.pdf).

When OMB talks about “efficiency,” what the agency really means is producing rules whose benefits exceed their costs by as great an amount as possible. Efficiency may not sound like an exciting goal for the regulatory system, but for regulations related to risk reduction, pursuing efficiency actually has the potential to save thousands of lives.<sup>10</sup> Using resources in a cost-effective manner can maximize the life-saving capabilities of the resources devoted toward risk reduction through regulation. As an example, imagine we have the option of spending \$1 million to comply with two forms of regulation. One regulation will save a thousand lives while the other will save only one life. Which option do we choose? The answer may seem obvious, but often the numbers are not so clear. Economic efficiency helps us identify the option that gets us the most bang for our buck, and helps policymakers save as many lives as possible.

These steps—defining the problem the agency seeks to solve, determining the desired outcome, considering a wide variety of alternatives, and doing a benefit-cost analysis of each alternative—are crucial for good policymaking and are the heart of any well-done RIA. Ignoring any of these steps is likely to lead to poorly informed regulations that will fail to achieve their objectives and may have severe unintended consequences.

#### WHAT IS BENEFIT-COST ANALYSIS?

**BENEFIT-COST ANALYSIS** IS the part of an RIA designed to aggregate information in a way that can aid complex decision-making and allow regulators to weigh the various positive and negative consequences of any decision. Benefit-cost analysis is useful both as a policy evaluation tool and as a personal decision-making tool.

In their personal lives, individuals make decisions about trade-offs every day, and use something approximating benefit-cost

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10. John D. Graham, “Saving Lives through Administrative Law and Economics,” *University of Pennsylvania Law Review* 157, no. 2 (December 2008): 395–540.

analysis when making those decisions. For example, when deciding how to get to work each morning, one might consider the relevant trade-offs of various options. Public transportation may be relatively inexpensive compared to filling up a gas tank each week in order to drive to work. At the same time, driving may be more comfortable and the train or bus can be very crowded. Everyone balances the relevant costs and benefits of various alternatives in order to make a decision. We may not write down the costs and benefits in a formal way, but this is approximately the decision-making process each of us goes through.<sup>11</sup>

It is important to stress that benefit-cost analysis is an *aid* to decision-making, not a strict decision rule in itself. It informs decisions; it does not replace decisions. Benefit-cost analysis is just one factor among many that decision makers should consider before setting policy.<sup>12</sup> There are, of course, other factors that regulators should also take into account that may not be captured in figures about benefits and costs. For example, regulators should consider the views of the public, whom they are tasked to serve. This can be done through the notice-and-comment process that allows the public to comment on proposed regulations. This democratic component of the regulatory process may be in conflict with the findings of a benefit-cost analysis if the views of the public are not consistent with economic efficiency. For this and other reasons, a benefit-cost analysis is not the only piece of information for a decision maker to consider. However, not doing benefit-cost analyses or ignoring the findings of benefit-cost analyses, say by implementing rules solely on the basis of popular support, can produce wildly inefficient results and would most likely lead to undesirable outcomes in the long run.

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11. This argument relies on some basic assumptions about the rationality of individuals. The field of behavioral economics calls into question some of the decision-making capabilities of individuals.

12. For example, other policy considerations include current law and setting precedents, political considerations, agency budgets and priorities, and distributional impacts among affected parties.



Benefit-cost analysis is best conducted by impartial analysts, not decision makers with personal stakes in the outcome. Analysts should use benefit-cost analysis to assemble and organize all the relevant information available to them about the consequences of alternative courses of action, and they should organize it in a coherent manner. Once analysts have collected as much relevant information as possible, they can pass that information along to decision makers who can then, to the extent permitted by law, take the benefit-cost analysis as well as other factors into account when deciding how to proceed.

Benefit-cost analysis is one crucial part of an RIA, but it is neither the only element nor the first element in a well-executed RIA. An RIA should start with evidence about the existence and nature of the problem the agency seeks to solve, because there can be no benefits unless the regulation actually solves a real problem such as a market failure or major social problem. Further, alternatives should be specified before benefits and costs are estimated because the purpose of the benefit-cost analysis should be to compare alternatives, not just count up the benefits and costs of a regulation that decision makers have already decided to issue.

## WHY DO A REGULATORY IMPACT ANALYSIS?

IF REGULATIONS ARE designed to protect the public, one might ask why analysis should be done at all, since it might well slow down the regulatory process and prevent beneficial regulations from being implemented in a timely manner. The first reason is for analytical purposes (i.e., providing decision makers with useful information). If regulations are truly going to solve social problems, agencies need some basis for expecting that the regulation is going to work. This requires careful consideration by agencies about the situation that confronts them. Agencies use regulatory impact analysis to present information about a current problem so that regulators are more likely to actually solve problems rather than create new ones.



RIA is also an important tool for transparency purposes. Most regulations require complex decisions involving science, politics, law, and economics. In most cases, complex and uncertain scientific findings, like reductions in the risk of injury, illness, or death or changes to ecology, are difficult to compare to consumer costs such as reduced choices or higher prices. Benefit-cost analysis, when done properly, puts these values into a common metric, usually dollars, so that the inevitable trade-offs between reduced risks and resources become easier to understand. Such an analysis makes the decisions that regulators make easier for stakeholders to understand.

Because of the increased transparency, regulatory impact analysis makes agency decision makers more accountable to the public and Congress. It is important that the parties that are impacted by regulations understand the regulators' reasons for proposing the regulation and why a particular policy is in the broader public interest. Under the Administrative Procedure Act (APA), stakeholders who are likely to be affected by rules are encouraged to comment on agency decisions and the reasoning behind them.<sup>13</sup> Agencies, by law, must respond to those comments. In addition, as regulations have the force and effect of laws, it is Congress's job to oversee these rules. RIA, when done properly, can help all of these parties understand the merits of the regulatory decisions relative to other possible policy options. Agencies must therefore justify their decisions to the public, as opposed to issuing declarations without any supporting evidence to explain why the decision was a good idea.

RIA allows the public to understand how an agency came to choose the option it did. Agencies often appear to outsiders as black boxes, and their decisions can come across as arbitrary. RIA sheds light on the decision-making process and shows what the real-world implications of a particular policy are expected to be. Agencies often have information at their disposal that individual

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13. Administrative Procedure Act, 5 U.S.C. §§ 551–59 (2012).

consumers, firms, or other groups do not have, and these entities have information the government does not have. RIAs go through a notice-and-comment process that is a transparent way for agencies to exchange benefit-cost information with the public.

## WHEN RIA IS DONE WELL

BELOW ARE SOME examples where regulatory impact analysis was used well. The examples illustrate RIA's power to improve policy outcomes and advance the well-being of the American people.

### FDA Trans Fat Labels Regulation

In 2001, the newly confirmed administrator of OIRA asked senior government economists for suggestions for regulations that were likely to produce net benefits based on well-done benefit-cost analyses, but had not been issued or were not moving forward. After hearing from various sources such as agency economists, one regulation that was presented to the OIRA administrator was related to trans fat. The regulation in question would require trans-fatty acids to be identified on nutrition labels for foods. Existing regulations did not permit food manufactures to list trans fat on the nutrition label, and thus a regulation was needed to correct a market failure (inadequate information) partly induced by a public institution.

Understanding the potential unrealized benefits from such a regulation, the OIRA administrator sent a letter to the secretary of the Department of Health and Human Services (HHS) and posted it on the OIRA website. The letter stated,

Based on assumptions that the proposal will assist consumers in their efforts to reduce their risk of CHD [coronary heart disease] and provide incentives to producers to reformulate food products to reduce the trans fat content, FDA's preliminary Regulatory

Impact Analysis estimated that, 10 years after the effective date, the rule would prevent 7,600 to 17,100 cases of CHD and avert 2,500 to 5,600 deaths per year. Over a 20-year period, FDA estimated the benefits of the proposed rule would range from \$25 to \$59 billion, while the costs were only \$400 million to \$850 million.<sup>14</sup>

The letter also asked for a response from the agency:

If the regulatory impact analysis still suggests that the potential benefits of this rule far exceed the costs, then I strongly encourage you to finalize this rule or explain the rationale for not moving it forward. This rulemaking appears to be a tremendous opportunity for the FDA to address the nation's leading cause of death—coronary heart disease—and to save thousands of lives.<sup>15</sup>

The FDA responded in 2003 by publishing a final rule requiring the labeling of trans fat on food fact panels by 2006.<sup>16</sup> A final RIA confirmed the information that prompted the OMB letter, even though the RIA was done conservatively so as not to overstate benefits.<sup>17</sup> Many restaurants and other food service firms have subsequently reformulated their foods to eliminate or reduce trans fat content.<sup>18</sup> Although no formal follow-up benefit-cost analysis has been done to evaluate results, a recent research report in the *Journal of the American Medical Association* finds that trans

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14. John D. Graham to Tommy G. Thompson, September 18, 2001, [http://www.reginfo.gov/public/prompt/hhs\\_prompt\\_letter.html](http://www.reginfo.gov/public/prompt/hhs_prompt_letter.html).

15. *Ibid.*

16. Department of Health and Human Services, Food and Drug Administration, "Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims," 68 Fed. Reg. 133 (July 11, 2003).

17. *Ibid.* The RIA is included in the Federal Register Notice.

18. "Food Reformulations to Reduce *Trans* Fatty Acids," *New England Journal of Medicine* 362 (May 2010): 2037–39.

fat blood levels in the United States fell by 58 percent from 2000 to 2009, which was significantly more than predicted by the FDA in its benefit-cost analysis.<sup>19</sup> Data in a recent FDA notice, which made a preliminary determination that a ban of industrially produced trans fat might be called for, estimate that industrially produced trans fat has fallen from 2 percent of caloric intake in 2003 to 0.5 percent in 2012 compared to the 0.04 percent reduction conservatively estimated by the FDA in 2003.<sup>20</sup>

#### USDA Poultry Slaughter Inspection Regulation

Another example where benefit-cost analysis helped inform agency decisions was a 2012 Food Safety Information Service (FSIS) regulation proposing to modernize the poultry slaughter inspection system in the United States.<sup>21</sup> The rulemaking came about after a regulatory review effort the agency conducted in response to President Obama's Executive Order 13563,<sup>22</sup> which asked agencies to do a retrospective review, or "look-back," at old regulations in order to find ways to update, eliminate, or otherwise modernize outdated ones.

The RIA contained in the notice of proposed rulemaking identified how the current inspection system leads to bottlenecks in the production process and causes inspectors to devote time to activities with only marginal effects on food safety. The proposed

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19. Hubert W. Vesper et al., "Levels of Plasma *trans*-Fatty Acids in Non-Hispanic White Adults in the United States in 2000 and 2009," *Journal of the American Medical Association* 307, no. 6 (2012): 562–63, doi: 10.1001/jama.2012.112.

20. See Food and Drug Administration, "Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information," 78 Fed. Reg. 67169 (November 8, 2013). In the 2013 proposed action, the FDA does not appear to be addressing a market failure since consumers and the market are continuing to adjust to the information about trans fat.

21. Department of Agriculture, Food Safety Inspection Service, "Modernization of Poultry Slaughter Inspection," 77 Fed. Reg. 18 (January 27, 2012).

22. Improving Regulation and Regulatory Review, Exec. Order No. 13,563, 3 Fed. Reg. 76 (January 21, 2011).

rule identified areas where inspectors' time could be used more valuably, leading to improvements in health and safety, as well as to faster assembly line speeds.

In the FSIS RIA, analysts identified several alternative forms of regulating that were very similar in terms of the net benefits they would provide to society relative to the status quo. The agency first considered taking no action at all and maintaining the current poultry inspection system. The agency also considered allocating more FSIS food inspectors to the current system to allow faster line speeds in poultry production. Finally, the FSIS considered several variants of the regulation that it ultimately proposed, such as making mandatory some components that were voluntary in the proposed regulation.

One option was rejected on the basis that it disproportionately impacted small businesses. This example highlights the importance of identifying groups that will capture the benefits and costs of a rule through "distributional analysis." Even when a regulation's benefits outweigh its costs, it is important to remember that the groups burdened by the costs are usually not the same groups that will enjoy the benefits of the rule. This can be particularly problematic if a rule's costs fall disproportionately on vulnerable groups like low-income individuals, minorities, small businesses, or the unemployed.<sup>23</sup>

At the time of this study's publication, the agency had yet to finalize the rule in question, but the FSIS did identify a problem, in this case an outdated regulation, and work to improve the situation by considering a variety of ways to update and modernize its inspection system. The rule also provides a useful example of a

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23. See, for example, Keith Hall, "The Employment Costs of Regulation" (Working Paper No. 13-06, Mercatus Center at George Mason University, Arlington, VA, March 2013), <http://mercatus.org/publication/employment-costs-regulation>; Diana Thomas, "Regressive Effects of Regulation" (Working Paper No. 12-35, Mercatus Center at George Mason University, Arlington, VA, November 2012), <http://mercatus.org/publication/regressive-effects-regulation>.

retrospective review effort that succeeded in identifying problems with the current regulatory system.

#### DOT Positive Train Control Regulation

In January 2010, the Federal Railroad Administration (FRA) within the US Department of Transportation (DOT) finalized a rule requiring railroad companies to install a safety mechanism known as positive train control (PTC) along certain railway tracks throughout the United States.<sup>24</sup> The rule resulted from a law passed by Congress called the Rail Safety Improvement Act of 2008,<sup>25</sup> which required the agency to implement such a regulation.

The analysis by DOT showed that the system Congress directed the agency to implement would impose significant costs on society. In fact, the agency estimated the rule would have costs that exceeded benefits by a ratio of roughly 20 to 1. The regulation was finalized anyway, the Association of American Railroads sued, and DOT agreed to review the regulation in response to the settlement. DOT also reviewed the regulation as part of its look-back in response to Executive Order 13563. The agency's preliminary RIA when revisiting the PTC regulation stated,

Executive Order 13563 requires agencies to review existing significant regulations to determine if they are outmoded, ineffective, insufficient, or excessively burdensome. FRA recognizes that the costs associated with PTC rule compliance outweigh the safety benefits by about 20:1 and, therefore, it is appropriate to reexamine whether FRA should require the installation of PTC on lines that will not be carrying [poison- or toxic-

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24. Department of Transportation, Federal Railroad Administration, "Positive Train Control Systems (RRR)," 75 Fed. Reg. 10 (January 15, 2010).

25. U.S. Rail Safety Improvement Act of 2008, Pub. L. No. 110-432, 122 Stat. 4848, 49 U.S.C. § 20101.

by-inhalation] traffic or regularly scheduled passenger service as of December 31, 2015.<sup>26</sup>

Even though the agency was required to issue the regulation, its analysts conducted an honest appraisal of the merits of the PTC program. Congress often makes decisions based on political concerns, and these decisions often involve a great deal of compromise. Because the analysts at DOT were straightforward about the pros and cons of the regulation, consumers, business groups, and Congress were better informed about the cost effectiveness of the program being implemented. Eventually, a lawsuit was filed against the agency and the regulation was relaxed somewhat. While it is unlikely the RIA had a significant impact on the outcome of the court case, it clearly had an effect on the decision by the DOT when the agency reconsidered the PTC regulation as part of its retrospective review effort in response to Executive Order 13563.

This example also highlights why agencies should not be afraid to consider alternative forms of regulation that lie outside the scope of the legal authority the agency has been given by Congress to address a problem. If there is a better alternative available, it is always helpful to know about it so that Congress has the option to make further improvements to laws in the future. Congress also has authority under the Congressional Review Act to invalidate regulations before final implementation.<sup>27</sup> If Congress becomes aware of a better solution, it can invalidate the rule or grant the agency authority to pursue a more effective solution. However, if analysts never consider alternatives that lie outside of the statutory authority granted by Congress, Congress may never know

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26. Department of Transportation, Federal Railroad Commission, “Positive Train Control Systems: Regulatory Impact Analysis” (August 3, 2011): 7, <http://mercatus.org/sites/default/files/2130-AC27-DOT-Positive-Train-Control-RIA.pdf>.

27. Congressional Review Act of 1996, 5 U.S.C. §§ 801–8 (2012).



that a better alternative exists, and potentially large net benefits to society may go unclaimed.

#### WHEN AN RIA IS DONE POORLY

AS WE HAVE shown, a properly done RIA can be an important tool to guide decision makers, but if an RIA is done poorly, it can lead to many harmful and unwanted effects. However, these problems are not inherent in the process of regulatory impact analysis itself. They can easily be avoided so long as policymakers adhere to sound decision-making principles. Below is a list of common pitfalls that regulators often fall into when conducting regulatory impact analysis.

##### Failure to Identify the Problem That the Regulation Is Designed to Address

Evidence suggests that this simple procedural requirement—identifying the problem that requires intervention—is often ignored by agencies when they put forward regulations.<sup>28</sup> Instead, agencies often cite the underlying statute that requires a regulation as a reason for regulating, rather than documenting a problem that needs to be solved. But it is not always clear whether there was in fact a systemic problem that drove the legislation. Where Congress has not been explicit, or if the legislation was driven by a single event (i.e., an anecdote), RIAs can play a critical role by identifying whether there is a significant problem that regulation might solve. Generally, if a problem is not identified up front, the outcome sought by regulation is not likely to be achieved, and few if any benefits will result from the regulation.

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28. See, for example, Jerry Ellig and James Broughel, “Regulation: What’s the Problem?” (Mercatus on Policy No. 100, Mercatus Center at George Mason University, Arlington, VA, November 2011), <http://mercatus.org/publication/regulation-whats-problem>.

## Failure to Consider a Wide Variety of Alternatives

Sometimes agencies fail to consider an alternative that would have led to a more efficient outcome.<sup>29</sup> Perhaps the agency only considered a few options that are very similar to one another, or maybe the agency failed to consider any alternatives at all, only focusing on the one option that the agency preferred. Both of these problems are quite common.<sup>30</sup> They might occur when a key decision maker tells the analysts that a decision has already been made, before the analysis is conducted.

An example of a rule that only considered a very narrow range of alternatives is a 2008 Department of Transportation regulation establishing new limits on the maximum operating pressure for gas pipelines.<sup>31</sup> The agency considered only its proposed regulation and one alternative, which was to delay implementation of the same proposed regulation. Similarly, a recent proposal from the Environmental Protection Agency related to sulfur emissions from automobiles and light trucks<sup>32</sup> only estimated net benefits for the proposed regulation and failed to even identify, let alone evaluate, any alternatives.<sup>33</sup>

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29. Jerry Ellig and James Broughel, "Regulatory Alternatives: Best and Worst Practices" (Mercatus on Policy No. 105, Mercatus Center at George Mason University, Arlington, VA, February 2012), <http://mercatus.org/publication/regulatory-alternatives>.

30. *Ibid.*

31. Department of Transportation, Pipeline and Hazardous Materials Safety Administration, "Pipeline Safety: Integrity Management Program for Gas Distribution Pipelines," 73 Fed. Reg. 123 (June 25, 2008).

32. Environmental Protection Agency, "Control of Air Pollution from Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards; Proposed Rule," 78 Fed. Reg. 98 (May 21, 2013).

33. Art Fraas and Randall Lutter, "Rulemaking Negligence at the EPA," *Washington Times*, October 8, 2013, <http://www.washingtontimes.com/news/2013/oct/8/fraas-and-lutter-rule-making-negligence-at-the-epa/>.

## Unrealistic Assumptions

Sometimes the assumptions underlying an agency's analysis will be deliberately biased, leading to dramatic problems with the final benefit and cost estimates that are part of a benefit-cost analysis. For example, a risk assessment, which estimates how reduced risks affect factors like human health and safety (i.e., the benefits component of a benefit-cost analysis), may make overly cautious assumptions about existing risks or about the amount of risk reduction that results from a regulatory intervention. Such bias in risk assessments produces bias in benefit-cost analysis. These benefit estimates will be overstated and thus incomparable to cost estimates.

In some cases, risk assessments are actually safety assessments that do not estimate risk at all, but only try to pick a level of risk that is presumed to be either zero or so low that it may be ignored. Safety estimates are produced using animal studies that overdose lab animals (typically rats or mice) in order to search for the dose at which there appears to be no effect from a compound, or the dose below which there is no effect. Safety assessments cannot be used to estimate benefits for a benefit-cost analysis, because these studies do not reveal how risk levels change as a result of changes in exposure to a compound. Safety assessments only identify an exposure level considered "safe."

There are further problems with both risk assessments and safety assessments. For example, agencies divide by "safety factors" when taking results found in animals and using them to predict results in humans.<sup>34</sup> Safety factors are arbitrary numbers designed to protect against uncertainties like differences in human sensitivities, differences between animals and humans, differences in the sensitivities of adults and children, etc. Again, agencies may try to assign benefit values using studies that rely on

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34. Richard Belzer, "Risk Assessment, Safety Assessment, and the Estimation of Regulatory Benefits" (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, 2012), <http://mercatus.org/publication/risk-assessment-safety-assessment-and-estimation-regulatory-benefits>.

safety factors to estimate risk, but these benefits are, for all practical purposes, fiction.

Another problem arises when agencies assume that reductions in exposure to a substance can have only beneficial impacts on human health, when in fact there could also be harmful effects.<sup>35</sup> Or, an agency might identify a baseline that is not a realistic portrayal of what the world would look like in absence of a regulation. This assumption can lead to grossly over- or underestimated costs or benefits.<sup>36</sup> For example, in 1997 the EPA conducted a retrospective analysis of the costs and benefits of the Clean Air Act.<sup>37</sup> The agency's baseline scenario of air quality in the absence of the Clean Air Act assumed that many of America's cities would have levels of pollution comparable to those of developing countries with some of the most polluted cities in the world.<sup>38</sup> The EPA ignored air quality improvements that likely would have occurred even without the Clean Air Act due to improvements in technology and changes in consumer preferences. Using this unrealistic baseline, the EPA claimed that the benefits of Clean Air Act rules lay in the range of \$6 trillion to \$50 trillion, which almost certainly vastly overestimated the true benefits of the EPA's clean air regulations.

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35. For a discussion of how this practice came to be so common, see Edward Calabrese, "The Road to Linearity: Why Linearity at Low Doses Became the Basis for Carcinogen Risk Assessment," *Archives of Toxicology* 83 (2009): 203–25.

36. Jerry Ellig and James Broughel, "Baselines: A Fundamental Element of Regulatory Impact Analysis" (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, 2012), <http://mercatus.org/publication/baselines>.

37. Environmental Protection Agency, "Benefits and Costs of the Clean Air Act," last modified August 15, 2013, <http://www.epa.gov/air/sect812/index.html>.

38. Randall Lutter, "The Role of Retrospective Analysis and Review in Regulatory Policy" (Working Paper No. 12-14, Mercatus Center at George Mason University, Arlington, VA, 2012), <http://mercatus.org/publication/role-retrospective-analysis-and-review-regulatory-policy>.

## Unintended Consequences

Sometimes a rule can have effects on third parties that are not directly impacted by the rule. For example, a regulation requiring higher levels of ethanol (which is made from corn) in gasoline led to higher global food prices as well as higher prices for livestock feed. These higher prices hit especially the poor in developing countries.<sup>39</sup>

While these ancillary effects of rules cannot always be anticipated, some can be predicted because of lessons policymakers have learned in the past. One example is known as the rebound effect. When products become more energy efficient, energy becomes relatively cheaper and consumers use the product more intensively.<sup>40</sup> Eventually consumers might offset part or all of the original energy savings. Such an outcome is predictable because it has been demonstrated empirically in the past. Thus, it should always be included in a benefit-cost analysis for energy and fuel efficiency requirements. Other examples of predictable consequences are shortages and surpluses that might arise from regulations that impose price controls, such as regulations for Medicare or Medicaid. Analysts should always examine how people might change their behavior in response to regulatory requirements. Such behavioral changes can generate consequences that are not the intended ones and impact benefits or costs or both.

Another type of unintended consequence is called a risk-risk trade-off. A reduction in one risk may lead to increases in other risks, either as an unintended consequence of the rule or because individuals have less income available for risk mitigation. For

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39. For discussion of the effects of the ethanol mandate on food prices in developing countries, see Sherzod Abdukadirov, “The Unintended Consequences of Safety Regulation” (Mercatus Research, Mercatus Center at George Mason University, Arlington, VA, June 4, 2013), 6, <http://mercatus.org/publication/unintended-consequences-safety-regulation>.

40. Robert J. Michaels, “Energy Efficiency and Climate Policy: The Rebound Dilemma” (Institute for Energy Research, 2012), <http://www.instituteforenergyresearch.org/efficiency-rebound-dilemma/>.

example, requiring seatbelts has led people to drive faster, resulting in more accidents.<sup>41</sup> Or, as income falls due to compliance expenditures from a regulation, people may cease to mitigate risks in some areas, thus putting themselves in more danger.<sup>42</sup> This occurs when people cut back on expenditures related to health care, diet, exercise, or other risk-mitigating activities.

#### Failure to Acknowledge Uncertainty

In RIAs, analysts are trying to forecast what the world will look like in the future once a regulation is in place. Whenever possible, analysts should attempt to quantify the range of uncertainty for every key parameter. They can do this by presenting a range of potential outcomes. Some statistical techniques, such as Monte Carlo estimations, are excellent tools to analyze and illustrate uncertainty. Monte Carlo estimations are computer simulations designed to estimate a range of probability distributions that aid in quantifying the level of uncertainty inherent in an analysis. In fact, OMB recommends that all agencies use a Monte Carlo estimation whenever a rule's cumulative impact on the economy would exceed \$1 billion.<sup>43</sup>

#### Failure to Use Analysis in Decision-Making

Unfortunately, it is very common to find that agencies fail to mention anywhere in their notice of proposed rulemaking or their RIA that the RIA was used in any way to inform decisions

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41. Sam Peltzman, "The Effects of Automobile Safety Regulation," *Journal of Political Economy* 83 (1975): 677–725.

42. Diana Thomas, "Regressive Effects of Regulation."

43. Office of Management and Budget, *Circular A-4*, 41.

made about a regulation.<sup>44</sup> For example, the Mercatus Center at George Mason University’s Regulatory Report Card project<sup>45</sup> has found that a majority of the rules analyzed between 2008 and 2012 failed to mention how the agency made use of the analysis when it made decisions about the regulation.<sup>46</sup> For this reason, RIAs often look more as if they were constructed to justify a particular regulation than done to help decide whether and/or how to regulate.

## DIFFICULTIES INHERENT IN BENEFIT-COST ANALYSIS

ALTHOUGH BENEFIT-COST ANALYSIS is a powerful tool to help guide policymakers, it is not without its limitations. However, none of these limitations is insurmountable, and none of them justifies having no analysis in place of an imperfect benefit-cost analysis. For example, there will be times when analysts will not have information on benefits, due to difficulty in monetizing them. Monetizing is the process of converting a value, like a statistical approximation for the number of illnesses prevented or the amount of pollution reduction, into a dollar amount, so that the benefits can be compared to the corresponding costs. Cost estimation is similarly difficult. For example, regulations can infringe on individual choice, liberty, and privacy. Opportunity costs—the costs of forgone activities such as investments or innovations that don’t take place because resources were spent complying with a regulation—are also harder to measure than obvious costs like paperwork burdens.

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44. Jerry Ellig and James Broughel, “How Well Do Agencies Use Economic Analysis?” (Mercatus on Policy, Mercatus Center at George Mason University, Arlington, VA, July 2013), <http://mercatus.org/publication/how-well-do-federal-agencies-use-regulatory-impact-analysis>.

45. For information about the Mercatus Regulatory Report Card, see <http://mercatus.org/reportcards>.

46. Ellig and Broughel, “How Well Do Agencies Use Economic Analysis?”



In cases where analysts find benefits too difficult to monetize, OMB recommends cost-effectiveness calculations.<sup>47</sup> Cost effectiveness measures the cost per unit of whatever outcome is achieved by a regulation, such as the cost per life saved or cost per avoided hospital visit. Cost-effectiveness studies generally provide a less complete analysis than a full benefit-cost analysis. Cost effectiveness starts with the assumption that an intervention is worth doing (i.e., that the benefits are likely to exceed the costs) and that the only need is to find the cheapest way to achieve the benefit. Benefit-cost analysis, on the other hand, does not assume that there is any intervention that would necessarily pass a benefit-cost test, so that one of the outcomes it allows is taking no action.

#### Valuation of Nonmarket Goods

One difficulty in benefit-cost analysis is estimating the value of benefits that are not actively traded in a market. For example, what price can one put on a scenic view, or cleaner air, or the protection of an endangered species? It may seem that these types of nonmarket goods can't be priced, and some might argue that they shouldn't be.<sup>48</sup> This is a mistake, however. People do in fact place monetary values on these nonmarket goods. For example, the fact that people spend money to travel to the Grand Canyon shows that many people place a monetary value on a scenic view. The fact that people donate money to environmental organizations shows that people place a monetary value on the environment. The choices regulators make are about finding ways to pursue policies that use society's scarce resources wisely. As the cases just mentioned illustrate, people's actions reveal that they see protecting the environment as an important goal; however, not all environmental protection may be worth the cost it imposes. For example, a society would not

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47. Office of Management and Budget, *Circular A-4*, 11.

48. See, for example, Lisa Heinzerling, "The Rights of Statistical People," *Harvard Environmental Law Review* 24 (2000): 196–207.

want to devote all of its resources to preserving a particular type of toad that could become extinct due to commercial activity. The costs of environmental and ecological preservation are real, and therefore benefits must be estimated in a way that ensures regulators don't adopt policies whose costs are completely out of proportion to the benefits they produce.

One way of estimating these types of benefits is through a statistical technique called "hedonics." Hedonic analysis attempts to infer the value people place on a good not traded on any market, using prices that are available for other, related goods. For example, we may not be able to put an exact price on a scenic view. However, we might be able to impute a price of the view by comparing the prices of houses that have a scenic view with similar houses that don't have a scenic view. The difference in price is an approximation of the value people place on the scenic view.

Another method of estimating these benefits is called "revealed preference." People may reveal their valuations of nonmarket goods through their actions. For example, what is the value of a human life? Is it priceless? Actually, people demonstrate with their own actions every day that they do not place an infinite value on their own life. There is a cost to safety, and people are willing to trade off a little bit of safety in exchange for paying a lower price. For example, some people are willing to buy larger, more expensive, and safer vehicles. Others may not think the extra expense is worth it. Implicitly, people are demonstrating their willingness to pay to reduce their risk of death. Another example comes from differences in wages in the labor market. Jobs that are riskier, like construction jobs, tend to pay more than jobs that require similar levels of skill but are much safer. This tells us something about the amount of money people require in order to accept an increase in risk. Using this information, economists can estimate how much value people place on safety. While sometimes this reduction in risk is referred to as the "value of a statistical life," it is important to remember that economists are actually measuring the value people place on reductions in small risks through the choices they make, not the value they place on life itself.

A final method for estimating prices of nonmarket goods are stated preference surveys, sometimes called contingent valuation surveys. These surveys ask people how much they value a certain good (e.g., a view or an endangered species). There are many problems with these surveys, however.<sup>49</sup> One of the biggest problems is that there is no real income constraint limiting people's valuations like there is in the marketplace. There is nothing stopping me from saying on a survey that I value a particular species of fish at \$1 million per fish. In the marketplace, my limited income forces me to make trade-offs between particular goods, thus giving a better approximation of my true valuation of the fish (more like \$4.99 per pound, the price we see at the supermarket). In addition, the way the survey is worded, or "framed," can produce dramatically different estimates, or respondents may respond strategically, since the respondent might expect more of a response from the surveyor if an inflated number is reported.<sup>50</sup> For these reasons and others, contingent valuation surveys are deeply problematic and should be viewed with skepticism.

### Distributional Concerns

Benefit-cost analysis seeks to identify the most efficient alternative. Economic efficiency is often an intuitive and appealing standard to guide decision-making. After all, if all benefits and costs (including the values of nonmarket goods) are reasonably well accounted for in the RIA, why would anyone want to consciously choose a policy alternative that makes society poorer?

One big reason is that every regulation creates winners and losers, and nothing in the regulatory process requires agencies to ensure that the winners compensate the losers for their

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49. See, for example, Richard B. Belzer and Richard P. Theroux, "Criteria for Evaluating Results Obtained from Contingent Valuation Methods," in *Valuing Food Safety and Nutrition* (Boulder, CO: Westview, 1995).

50. John Graham, "Saving Lives," 428.

losses. If the winners are already rich and the losers are poor, a policy that is efficient may nevertheless strike many people as unfair. This is really a problem with using economic efficiency as the sole criterion for decisions, not a flaw in benefit-cost analysis itself, which is only supposed to be one factor in the decision-making process.

Nonetheless, what if a regulation benefits a single, wealthy individual by \$1 billion and imposes costs of \$9,999 on 100,000 of the poorest citizens in the country? This regulation passes a benefit-cost test and is efficient from an economic point of view. But is it fair? Most people would probably say no.

Decision makers must also realize that a benefit-cost analysis based solely on average values may mask significant differences in benefits or costs for different people.<sup>51</sup> For example, as one's income rises, one has a higher willingness to pay for any "normal" good.<sup>52</sup> Because most benefit-cost analyses use a mean (i.e., average) estimate of the willingness to pay by everyone in society, this benefit estimate will generally overestimate the value low-income individuals place on regulatory benefits, and underestimate the value high-income people place on it.<sup>53</sup> For example, a wealthy person might be willing to pay a significant amount of money to combat global climate change. A poor person might not be willing to pay much at all. Using the average of their willingness to pay to estimate benefits of the regulation will produce a reasonable estimate of the aggregate benefits to society, but the average overestimates the benefits to the poor and underestimates the benefits to the wealthy. The same may be true for future generations, who presumably will be wealthier, due to

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51. For discussion along these lines, see Cass Sunstein, "Are Poor People Worth Less Than Rich People: Disaggregating the Value of Statistical Lives" (Working Paper 04-05, AEI-Brookings Joint Center for Regulatory Studies, Washington, DC, January 2004).

52. A normal good is a good that people demand more of as their income rises.

53. W. Kip Viscusi, "The Benefits of Mortality Risk Reduction: Happiness Surveys vs. the Value of a Statistical Life," *Duke Law Journal* 62 (2013): 1735-45.

economic growth, than those alive today. A similar complication occurs with benefits going to people in different age groups since individuals' willingness to pay to reduce risks tends to vary over the course of their lifetime.<sup>54</sup>

For these reasons, the Office of Management and Budget recommends that agencies consider distributional impacts of their regulations.<sup>55</sup> Presidential executive orders do the same.<sup>56</sup> To aid decision makers in this task, analysts should not only count up the benefits and costs of regulations, but also evaluate who will benefit and who will bear the costs. Whenever possible, this should be done by breaking down the costs and benefits by demographic group and presenting the information in an easy-to-read table. Analysts can also estimate each demographic group's willingness to pay in order to better determine how much each group is really benefiting from, or being burdened by, a particular policy.

Agencies should also consider impacts on other groups, such as small businesses, that may be disproportionately affected by a regulation.<sup>57</sup> Regulations that benefit large corporations but price start-up entrepreneurs out of the market may be economically efficient, but they may also seem grossly unfair. Similarly, regulations can have important employment effects, creating jobs for some individuals while eliminating jobs for others.<sup>58</sup> Thus a regulation may impose significant employment-related costs on individuals (costs that include lost earnings over time or health effects resulting from the stress of job loss or loss of

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54. Joseph E. Aldy and W. Kip Viscusi, "Age Differences in the Value of Statistical Life: Revealed Preference Evidence," *Review of Environmental Economics and Policy* 1, no. 2 (2007): 257.

55. Office of Management and Budget, *Circular A-4*, 14.

56. Executive Order 12866 and Executive Order 13563.

57. Small Business Administration, Office of Advocacy, *The Impact of Regulatory Costs on Small Firms*, by Nicole V. Crain and W. Mark Crain, No. 371 (Springfield, VA: National Technical Information Service, 2010).

58. Keith Hall, "Employment Costs of Regulation."

health insurance) even if the net job creation or destruction is zero. Since regulatory compliance jobs often require higher levels of skill and training than production jobs destroyed by regulations, the regulatory system may also increase income inequality over time if it favors highly skilled workers at the expense of lower-skilled workers.

Calculation of benefits and costs alone cannot determine whether the effects of a regulation on different groups are just or equitable. Decisions about justice or equity require an ethical theory that defines what is just or equitable. Congress and decision makers in agencies, not analysts, attempt to make these determinations when considering various policy proposals. However, analysis can, and should, explain how particular groups are affected by a regulation. This is information an objective analyst can legitimately provide a decision maker. Without this information, it is difficult to understand how decision makers could know whether an outcome is “just” since they won’t know what results the regulation will likely produce.

#### Comparison of Costs and Benefits Occurring at Different Times

Benefits and costs often occur at different points in time. People typically value benefits and costs differently depending on when they occur. Generally, a benefit that occurs sooner is more valuable than the same benefit if it occurs later, and a cost that occurs later is less burdensome than the same cost if it occurs sooner. Benefits and costs that occur at different times can be compared by calculating their “present value.” Present-value analysis was developed in finance; income received in the future or costs paid in the future are “discounted” to reflect the fact that they are less valuable. Some people puzzle over why nonmonetary goods or services such as future lives saved or scenic vistas preserved should be discounted to the present. Even the term “discounting

our future” sounds ominous.<sup>59</sup> But the logic of discounting reflects two economic concepts: (1) time preference (people prefer having resources available to use now versus waiting to have them in the future), and (2) opportunity cost of capital (resources that are spent today to comply with a regulation intended to provide future benefits could have been invested in something else that would yield positive returns, providing even greater benefits in the future).

In fact, by failing to discount, analysts actually ignore the well-being of future human beings. What if there were a project that cost \$1 million today and would save an estimated 100 people in 100 years. Is this a good investment? It may sound like it is. But just putting that same million dollars in an investment account for 100 years at 7 percent interest would leave over \$800 million dollars for future citizens. Perhaps this money could be used in the future to save many more lives. We use a discount rate to provide a realistic baseline against which to assess policies. We do this because we *do* care about the people in the future and we recognize that there are different ways to go about saving lives and improving human well-being. Discounting is a way of taking these trade-offs into account.

The Office of Management and Budget recommends that agencies use 7 percent as a “base case” discount rate when considering benefits and costs that occur in the future. This number represents the historical average before-tax rate of return on private capital in the US economy. OMB also recommends using a 3 percent discount rate as a comparison, which comes from the before-tax real rate of return on long-term government debt; it is an approximation of the rate at which society is willing to trade off consumption through time.<sup>60</sup>

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59. This is the title of a key critic’s article recommending against discounting certain public amenities. Lisa Heinzerling, “Discounting Our Future,” *Land and Water Law Review* 34 (1999): 71.

60. Office of Management and Budget, *Circular A-4*, 31–37.



## CONCLUSION

WHILE THE DIFFICULTIES inherent in the benefit-cost analysis portion of regulatory impact analysis are real, they are not insurmountable, and they certainly do not justify completely rejecting benefit-cost analysis or regulatory impact analysis as an aid in decision-making. Organized, objective, and transparent information is generally necessary for good decisions, especially if they are complicated. “It’s complicated” is not an excuse for not doing benefit-cost analysis. In fact it is a reason to do it. Imperfect information is better than no information as long as it is not intentionally biased.

The most legitimate criticisms of regulatory impact analysis are that specific analyses may have been poorly done, ignored by decision makers, or done after the fact to justify a policy action. All these problems are real and deserve attention. Yet for all these limitations, regulatory impact analysis remains a powerful tool that, when used properly, has the potential to extend thousands of lives, improve quality of life for citizens, and bestow enormous net benefits on the public. At the same time, RIA improves the process for generating regulation, makes agencies more transparent, and makes decision makers in Washington more accountable to the public they have pledged to serve.

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