The Unintended Consequences of Safety Regulation

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THE UNINTENDED CONSEQUENCES OF SAFETY REGULATION

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I. INTRODUCTION

At the turn of the 21st century, biofuels appeared to be a solution to mounting concerns over greenhouse gas emissions, climate change, skyrocketing fuel prices, and dependence on foreign energy.1 When Congress passed the Energy Policy Act (EP Act) in 2005 with a renewable fuel standard (RFS) provision mandating producers to add ethanol to gasoline,2 it is unlikely that lawmakers thought the act would increase hunger and social unrest in the world’s poorest countries. However, unintended consequences frequently accompany even the most well-intentioned policies.

Lawmakers specifically intended for the RFS provision to address both environmental and energy issues.3 Ethanol is a cleaner fuel with lower carbon emissions than gasoline and is often added to gasoline as an oxygenate, allowing gasoline to burn more completely and thereby reducing carbon emissions.4 The EP Act simply ramped up the already increasing use of ethanol as a fuel additive with the hope of reducing greenhouse gas emissions.5 The law’s proponents expected higher ethanol use to offset rising oil prices by filling at least some of the domestic demand for fuel.6

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1 John Byrne et al., American Policy Conflict in the Greenhouse: Divergent Trends in Federal, Regional, State, and Local Green Energy and Climate Change Policy, 35 ENERGY POLICY 4555, 4558 (2007) (citing the White House statements, which pointed to the administration’s efforts on renewable fuels as a way to address environmental and energy independence concerns).


3 Byrne et al., supra note 2, at 4558.


5 Id. at 13–14.

Further, because most ethanol in the United States comes from domestically produced corn, policy advocates hoped the act would make the country less dependent on imported oil. As an added bonus, the policy would benefit US farmers. At the time, the policy seemed perfect.

As the Environmental Protection Agency (EPA) implemented the policy and further ramped it up in 2007, scholars and environmentalists began to question its environmental and energy benefits. Producing ethanol from corn or other crops consumes energy. For ethanol to be a viable fuel source, it should, on the balance, produce more energy than it consumes. Experts, however, disagree about whether this is the case. Beyond ethanol’s questionable viability as a fuel, the negative environmental impacts of corn production undermine ethanol’s benefits. Corn farming leads to greater soil erosion than the farming of other crops. Higher pesticide and fertilizer use in corn farming compared to the farming of other crops increases water pollution. In addition, ethanol production leads to air pollution and greenhouse gas emissions, offsetting some of the environmental gains from its use as a fuel.

Perhaps the most unexpected consequence of the policy has been its impact on worldwide food prices. The US fuels industry relied heavily on corn ethanol to comply with the RFS requirements. The resulting demand drastically increased the price for corn globally, not just domestically. Higher corn prices effectively reduced purchasing power for lower-income
households across the globe.\textsuperscript{17} As corn prices skyrocketed, farmers switched to corn production from production of other food crops, which reduced the latter’s supply.\textsuperscript{18} At the same time, consumers substituted less expensive rice and wheat for corn, which increased demand and prices for those food staples as well. Overall, the RFS program led to higher food prices around the world.\textsuperscript{19} By some estimates, up to “70–75 percent [of the] increase in food prices was due to biofuels and the related consequences of low grain stocks, large land use shifts, speculative activity and export bans.”\textsuperscript{20} The spike in food prices, coupled with the global economic crisis, halted and even reversed the long-time trend in reducing hunger, as the number of undernourished in the developing world, which had been declining steadily since the 1970s, experienced a sharp increase between 2006 and 2009.\textsuperscript{21} In addition, the spike in food prices may have triggered political instability and food riots in lower-income countries, resulting in dozens of fatalities.\textsuperscript{22}

As the ethanol mandate demonstrates, policies attempting to reduce risk in one area often increase risks elsewhere. In some cases, the increases in countervailing risks may even exceed the reduction in targeted risks, leading to a policy that does more harm than good.\textsuperscript{23} However, while the negative regulatory consequences are usually unintended, they are by no means unforeseeable. Agencies could minimize or avoid them through more careful analysis of proposed regulations before they became law.

While many studies point to the potential negative outcomes of risk trade-offs,\textsuperscript{24} no studies measure the extent to which regulators face such

\begin{itemize}
\item \textsuperscript{17} Tenenbaum, \textit{supra} note 17, at 256 (discussing the negative welfare effects of higher food prices on low income populations).
\item \textsuperscript{18} Mitchell, \textit{supra} note 17, at 10.
\item \textsuperscript{19} Gal Hochman et al., \textit{Are Biofuels the Culprit?}, 100 AMERICAN ECONOMIC REVIEW 183 (2010).
\item \textsuperscript{20} Mitchell, \textit{supra} note 17, at 17.
\item \textsuperscript{21} FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, THE STATE OF FOOD INSECURITY IN THE WORLD (Rome, Italy, Food and Agriculture Organization of the United Nations 2010).
\item \textsuperscript{24} e.g. \textit{Risk vs. Risk} (John D. Graham & Jonathan Baert Wiener eds., Cambridge, MA, Harvard University Press 1995); W. Kip Viscusi, \textit{Risk-Risk Analysis}, 8 JOURNAL OF RISK AND UNCERTAINTY 5 (1994); Randall Lutter et al., \textit{The Cost-Per-Life-Saved Cutoff}
trade-offs. Yet, there are reasons to believe that risk trade-offs in safety regulation will only become more common. Given the nation’s progress in tackling the most prominent environmental and health risks, future risk-reduction efforts will face diminishing returns. As the target risks shrink, the importance of countervailing risks will only grow. Furthermore, as safety regulation addresses increasingly complex systems and technologies, the potential for risk trade-offs arising in regulation will increase as well.

Unintended consequences of safety regulation are not always negative; a regulation reducing a target risk may also reduce another risk, increasing the regulation’s benefits. In fact, agencies already account for ancillary benefits in their analyses to strengthen their case for regulation. However, as I explain later in this paper, agencies have strong incentives to overlook countervailing risks. Similarly, institutional incentives prevent effective congressional, presidential and judicial oversight of agency analysis. Thus, it is important to address agencies’ regulatory incentives to examine potential risk trade-offs.

In this study, I examine how risk trade-offs undermine safety regulations. In Part II, I provide a brief background on the most common types of risk trade-offs in regulatory policy and give specific examples for each trade-off type. In Part III, I examine the reasons behind the failure of the regulatory process to conduct better analysis and catch unintended outcomes. In Part IV, I argue that it is crucial to consider potential risk trade-offs of safety regulations, as they are more likely to impact the poorest and least organized groups. Finally, in Part V, I suggest potential policies to minimize or prevent an increase in countervailing risks.

II. TYPES OF RISK TRADE-OFFS

A policy to reduce risk in one area may increase countervailing risks. Patrick Hofstetter and his colleagues use the metaphor of ripples caused by a pebble thrown into a pond to explain countervailing risks. Regulation’s direct impact is throwing the pebble, while the ripples it causes in the water represent the indirect effects. Sometimes the ripples can have a stronger effect than the stone’s original impact. It is important to know the magnitude of countervailing risks to ensure that a regulation does not inadvertently cause more harm than good.

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25 Graham & Wiener, supra note 24, at 11–12.
Lester Lave first proposed a systematic approach to analyzing the countervailing risks inherent in social risk-reducing regulation by using risk-risk analysis. He advocated that policy analysts enumerate and quantify a regulation’s direct and indirect impacts as thoroughly as possible when evaluating regulatory alternatives. Graham and Wiener extended Lave’s framework to propose a risk trade-off analysis. They advocated for formal risk trade-off analysis to be included in the overall regulatory impact analysis that agencies currently perform for major regulations.

In order to systematically examine risk trade-offs, Hofstetter and his colleagues proposed to classify indirect risks by source as follows:

1. Direct risk trade-offs
2. Indirect risk trade-offs
3. Behavioral changes
4. Economy-wide effects

Agencies have to perform rigorous analyses to shed light on countervailing risks. Different indirect risks require different types of analysis. A few examples illustrate these risks and the analyses required to address them.

A. Direct Risk Trade-off

Perhaps the most straightforward risk trade-off cases involve agencies juggling various risks associated with alternative actions. For example, agencies faced a direct risk trade-off between fatalities resulting from an airborne terrorist attack and driving-related deaths and injuries after 9/11 when the Aviation and Transportation Security Act (ATSA) became law. Among other measures, the ATSA established the Transportation Security Administration (TSA) charged with enhancing airport security efforts. Most visibly, the act put the TSA in charge of airport security and baggage screening. Government made these laws to avert similar catastrophic attacks in the future and to reassure the public that flying is safe.

While the heightened airport security may have reduced the threat of
terrorist attacks, it increased travelers’ costs of flying through the hassles of passenger and baggage screening. In 2005 alone, the value of the time lost to screening added up to $2.76 billion.\textsuperscript{36} More importantly, it led 6 percent of passengers to drive instead of fly, particularly on shorter routes.\textsuperscript{37} Flying, however, is comparatively safer than driving. Per mile traveled, driving carries a risk of fatality that is 8.9 times greater than flying.\textsuperscript{38} Unsurprisingly, in the months immediately following the 9/11 attacks, driving-related fatalities spiked. In the fourth quarter of 2002, more than 100 driving-related fatalities could be linked to the increased hassle of flying.\textsuperscript{39} By fixating on reducing the risks of future terrorist attacks, the TSA overlooked the increasing risks resulting from passengers switching their mode of transportation.

In some cases, regulation may reduce risk for one group while increasing it for another. The outcome of the National Highway Traffic Safety Administration’s (NHTSA) rule requiring auto manufacturers to install air bags provides an example. Since the 1960s, consumer advocates have lobbied for higher auto-safety standards.\textsuperscript{40} Ralph Nader, a well-known consumer advocate, gained nationwide prominence after he published his 1965 book \textit{Unsafe at Any Speed}, which claimed that driving was unsafe and criticized the auto industry’s slow response to consumers’ safety concerns.\textsuperscript{41} Prompted by a shifting public opinion and increased consumer advocacy and political lobbying, Congress passed the National Traffic and Motor Vehicle Safety Act in 1966.\textsuperscript{42} The act charged the National Traffic Safety Agency (later reorganized into NHTSA\textsuperscript{43}) with developing and implementing auto safety standards in order to reduce driving-related fatalities and injuries.\textsuperscript{44}

One of the earliest steps to increase auto safety was the requirement that all cars be equipped with seat belts. However, historically low seat belt use rates (only 12.5 percent in 1984)\textsuperscript{45} prompted the NHTSA to require passive

\textsuperscript{36} Jerry Ellig et al., \textit{A Framework for Evaluating Counterterrorism Regulations}, Mercatus Policy Series (Mercatus Center, George Mason University 2006).
\textsuperscript{37} Blalock et al., \textit{supra} note 33, at 732.
\textsuperscript{39} Blalock et al., \textit{supra} note 33, at 752.
\textsuperscript{40} Carol Maclennan, \textit{From Accident to Crash}, 2 \textit{MEDICAL ANTHROPOLOGY QUARTERLY} 233, 238–41 (1988).
\textsuperscript{42} Maclennan, \textit{supra} note 41.
\textsuperscript{43} EDWARD WEINER, \textit{URBAN TRANSPORTATION PLANNING IN THE UNITED STATES} 2 (New York, Springer 2013).
\textsuperscript{45} Department of Transportation, National Highway Traffic Safety Administration,
restraint systems, which included automatic seat belts and air bags, in its 1984 rule. The NHTSA’s analysis accompanying the rule estimated that air bags provided little additional safety for passengers already using seat belts. Thus, its rule targeted primarily the unbelted passengers. The rule gave automakers a choice between the passive restraint systems they could implement (automatic seat belts or air bags) to comply with the safety standards.

When the NHTSA promulgated the rule in 1984, it had no reliable real-world data on the true cost of air bags or their effectiveness rates. Air bag technology has been available since the 1950s, but few manufacturers installed air bags in cars until Congress mandated air bag installation in 1991. The agency’s estimates were therefore based on experimental crash tests and engineering judgment. The crash tests (conducted using an adult male-sized dummy) promised considerable auto safety improvements. What the agency did not anticipate based on the limited data available was that air bags would lead to the deaths of children. Later studies estimated that while air bags reduced fatalities by 24 percent among adults, they increased fatalities by 34 percent among children under the age of 10.

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51 Id. at 57–58; Department of Transportation, National Highway Traffic Safety Administration, Federal Motor Vehicle Safety Standards; Occupant Crash Protection, supra note 46, at 807–8.

52 Thompson et al., Validating Benefit and Cost Estimates, supra note 50, at 804.

53 Thompson et al., Validating Analytical Judgments: The Case of the Airbag’s Lifesaving Effectiveness, supra note 51, at 64.

54 Department of Transportation, National Highway Traffic Safety Administration, Amendment to Federal Motor Vehicle Safety Standard 208, supra note 48, at 3 (claiming that airbags alone could reduce the number of driving fatalities by 3,780-8,630 lives).

55 Thompson et al., Validating Analytical Judgments: The Case of the Airbag’s Lifesaving Effectiveness, supra note 51, at 64–65.

56 Elisa R. Braver et al., Reductions in Deaths in Frontal Crashes Among Right Front Passengers in Vehicles Equipped with Passenger Air Bags, 278 JAMA 1437 (1997).
NHTSA’s own estimates showed that by 1996, air bags had saved at least 1,664 lives but at the same time had fatally injured at least 32 children.\textsuperscript{57} Thus, the rule shifted traffic fatality risks from adults to children—hardly what the agency intended when it issued the rule. In 1997, the agency amended its rule to allow for less aggressive air bag deployment and other measures aimed at reducing air bag injuries.\textsuperscript{58}

The air bag rule example highlights the importance of thorough analysis in safety regulation. While the agency eventually changed the rule to correct the negative outcomes, the damage it caused was irreversible. Had the agency been more thorough in its original analysis, children’s deaths could have been avoided.

\textbf{B. Indirect Risk Trade-offs}

The term “indirect risk trade-offs” refers to the link between regulation-induced expenditures and increased mortality risks. The logic of indirect risk trade-offs is based on the well-established link between income and mortality.\textsuperscript{59} Scholars have found that differences in income (as well as closely related factors such as education, access to health care, occupation, personal habits, and nutrition) account for differences in mortality in the national population.\textsuperscript{60} Similarly, unemployment is associated with significant risks, including increases in heart attacks, alcoholism, crime, suicides, and child abuse.\textsuperscript{61} Extending these findings, Aaron Wildavsky noted that as regulation-induced expenditures reduce national income, some of which would have been spent on reducing risk and improving health, they increase the population’s health risks.\textsuperscript{62} Thus, regulation’s negative impacts of lower private spending on health and safety offset the positive safety impacts.

Ralph Keeney formalized Wildavsky’s hypothesis by estimating the

\begin{footnotesize}
\textsuperscript{57} Department of Transportation, National Highway Traffic Safety Administration, \textit{Federal Motor Vehicle Safety Standards; Occupant Crash Protection}, supra note 46.
\textsuperscript{58} Id.
\textsuperscript{60} Evelyn M. Kitagawa, \textit{On Mortality}, 14 \textit{Demography} 381, 382 (1977); see also \textsc{Kitagawa \& Hauser}, supra note 60.
\textsuperscript{61} Ralph L. Keeney, \textit{Mortality Risks Induced by Economic Expenditures}, 10 \textit{Risk Analysis} 147, 156 (1990).
\end{footnotesize}
increased mortality from higher regulation expenditures.\textsuperscript{63} He found that if individuals paid for regulations in proportion to their income, safety regulations that cost more than $17 million to $21 million per life saved actually lead to more deaths through increased poverty.\textsuperscript{64} Later studies estimating the threshold at which safety regulations led to more deaths through increased poverty generally confirmed Keeney’s findings. The threshold estimates ranged between $6.5 million and $15 million per life saved in one study to $20 million per life saved in another study.\textsuperscript{65} The high costs of safety regulation may have even stronger negative impacts on low-income families, since low-income families stand to gain the most from having more income to spend on private safety measures such as better health insurance or a safer car.\textsuperscript{66}

C. Behavioral Changes

Attempts to reduce risk through regulation often impact consumer behavior by changing individuals’ incentives. For example, by making an activity safer, regulations may induce some individuals to behave more recklessly. In a seminal article examining the impacts of auto-safety regulation, Sam Peltzman demonstrated that drivers compensate for increased safety by riskier driving.\textsuperscript{67} This behavior became known as the Peltzman effect.

One example of the Peltzman effect is the impact of compulsory auto insurance laws on traffic fatalities. The purpose of auto insurance is to guarantee compensation to accident victims.\textsuperscript{68} Without auto insurance, traffic accident victims would have to demand compensation for health and

\textsuperscript{63} Keeney, \textit{Mortality Risks Induced by Economic Expenditures}, supra note 62; Ralph L. Keeney, \textit{Mortality Risks Induced by the Costs of Regulations}, 8 \textit{JOURNAL OF RISK AND UNCERTAINTY} 95 (1994).

\textsuperscript{64} Values are reported in 2012 dollars.


\textsuperscript{67} Sam Peltzman, \textit{The Effects of Automobile Safety Regulation}, 83 \textit{JOURNAL OF POLITICAL ECONOMY} 677 (1975).

property damages through the courts. If the liable party were unable to pay, the victims would remain without due compensation. Auto insurance reduces the risk that individuals causing car accidents will lack funds to compensate accident victims for the necessary medical care and property damages.

As car ownership increased throughout the 20th century, so did the problems related to compensation for traffic accidents, leading to calls for compulsory auto insurance. 69 Massachusetts became the first state to require drivers to purchase liability insurance for their vehicles in 1927. 70 New York and North Carolina followed suit, passing similar laws in the mid-50s. 71 In the 1960s and 1970s, increased public awareness of traffic fatalities helped spread compulsory auto insurance to most states as the number of states requiring auto insurance increased to 22 by 1975 and to 45 by 1997. 72

The compulsory auto insurance laws achieved their intended results: they reduced the number of uninsured motorists. 73 They also, however, created an incentive for greater risk-taking by insured motorists, which increased fatal traffic accidents. The effect of insurance on drivers is substantial: by some estimates, for each percentage point decrease in the number of uninsured motorists, traffic fatalities increased by 2 percent. 74 Regulations requiring auto insurance reduced drivers’ risk of financial hardship and uncompensated injuries and property damages, and the lower financial risk reduced drivers’ incentives to exercise caution while driving. Thus, risk-reducing regulation inadvertently induced drivers to take more risk.

Consumers’ unexpected reactions to safety regulation are another source of offsetting risks. For instance, the 2001 Food and Drug Administration (FDA) advisory on the health risk posed by mercury in commercial fish may have caused more harm than good. Since the early 1990s, consumer advocates have warned that mercury in fish poses risks to small children. 75

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69 See e.g. Marx, Compensation Insurance for Automobile Accident Victims, supra note 69; Keeton & O’Connell, supra note 69; Dowling, supra note 69 (calling attention to the increasing problem with traffic accidents and fatalities).


72 Cohen & Deheha, supra note 71, at 362–63.

73 Id. at 373.

74 In the study, the authors compared states that required auto insurance with the states that didn’t. The authors controlled for the number of registered cars and socio-economic factors. Id. at 388.

75 F.D.A. Warns Women Not to Eat Some Fish, N.Y. TIMES, Jan. 14, 2001, Health.
High doses of mercury can harm an unborn baby’s or small child’s nervous system. In response to increasing public concern, the FDA advised that pregnant women, nursing mothers, and young children reduce their consumption of certain types of fish and shellfish that contain high levels of mercury.

The consumer response to the FDA’s well-intentioned advisory led to adverse effects on public health. The agency expected at-risk consumers to switch from species with high mercury levels to ones with safe mercury levels. Instead, many at-risk consumers reduced their consumption of all fish. But fish is a primary source of omega-3 fatty acids, which are important to healthy development in infants and young children. By consuming less fish, pregnant and nursing mothers have actually increased the health risks to their children. Thus, whatever risks decreased when mothers and children abstained from consuming high-mercury fish were more than offset by the reduced consumption of omega-3 fatty acids and other substances in fish that are vital to healthy development in young children. Despite the FDA’s intentions, consumers failed to differentiate between species with high and low mercury levels and substitute accordingly, leading to an outcome that left consumers with higher risk than the original circumstances.

D. Economy-wide effects

While agencies may intend for their policies to have narrow impacts, regulations may have economy-wide consequences beyond the regulators’ target. Higher compliance costs and changes in consumer behavior may affect prices and production in distant sectors. Given the narrow focus of agencies’ regulatory analysis, economy-wide impacts often catch regulators off guard.

Rising world food prices resulting from the US renewable fuel policies described in the introduction demonstrate this point. When the EPA established the RFS program under the EP Act of 2005, it had environmental concerns in mind. The agency hoped the RFS program would reduce greenhouse gas emissions, lessen the country’s dependency

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79 *Id.* at 679–81.
80 *Id.* at 675.
81 Shimshack & Ward, supra note 79.
82 See supra pp. 1-3.
on fossil fuels, and help expand the domestic renewable fuels sector. In its analysis, however, the EPA failed to foresee the impact the program would have beyond its targets. What the EPA intended as a domestic environmental policy turned out to have a major impact on national security and health far beyond US borders.

III. THE SOURCES OF UNINTENDED RISK TRADE-OFFS

In the risk trade-off examples described above, regulators failed to examine the regulations’ impacts beyond their direct, visible effects. While regulators did not intend some of the regulatory consequences in these cases, a careful analysis might have alerted regulators to potential problems with the promulgated regulations. Yet, placing the entire blame on agency analysts may be too simplistic, since federal rulemaking is a complex process that involves several actors in addition to regulatory agencies and these actors are given multiple opportunities to check agency analysis.

The rulemaking process starts in Congress. Regulations implement congressional statutes and if a statute requires agencies to issue a specific regulation, agencies have no choice but to comply. Many statutes, however, broadly delegate powers to agencies, affording agencies considerable flexibility and discretion to interpret and implement the statutes.

Beyond authorizing regulations through statutes, Congress gets involved in the rulemaking process at the final stage through the Congressional Review Act (CRA). Under the CRA, Congress can disapprove a rule through a joint resolution within the 60-day window prior to the rule’s effective date. While the congressional review is not very effective – Congress disapproved a rule only once in the last 17 years – it is still part of the process. It affords Congress a chance to oversee agency actions and to point out potential countervailing risks.

The Office of Information and Regulatory Affairs (OIRA) is another

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83 See SUSAN E. DUDLEY & JERRY BRITO, REGULATION 23–28 (Arlington, VA, Mercatus Center at George Mason University 2012) (describing the congressional delegation of rulemaking powers to agencies).


major actor in the rulemaking process. As part of the Executive Office of the President, OIRA helps the president manage regulatory agencies.\textsuperscript{87} It reviews regulatory analysis for all major regulations both at the proposal stage and before they become final.\textsuperscript{88} With its reviews, OIRA pursues two primary goals: (1) it coordinates policy across agencies to ensure that agency regulations fit the administration’s policy priorities; (2) it double-checks the quality of regulatory analysis.\textsuperscript{89} Thus, it too has an opportunity to check agency actions and catch potential risk trade-offs missed by agency analysts.

Finally, the general public also has a chance to weigh in on regulations during the commenting process. With few exceptions, agencies open all proposed regulations for public comments.\textsuperscript{90} Any party that could be adversely affected by a regulation can raise their concerns directly with the agency. While agencies are not required to respond to each and every comment,\textsuperscript{91} they are likely to consider major unintended risks once alerted by the public. Should agencies fail to comply with procedural and statutory rulemaking requirements, which in some cases command agencies to produce extensive analysis,\textsuperscript{92} the affected parties could challenge agency actions in court.\textsuperscript{93} Thus, judicial review provides the affected parties an additional venue to settle their grievances and concerns with regulation.

The rulemaking process involves all three branches of government, as well as the general public, and it includes multiple checks along the way. Yet, as the examples in the paper indicate, major regulations that go through this elaborate process may still contain unintended countervailing risks. In order to understand how major countervailing risk could pass unnoticed

\textsuperscript{87} See Stuart Shapiro, \textit{Politics and Regulatory Policy Analysis}, 29 REG. 40 (2006) (describing OIRA prioritizing the administration’s political preferences over quality of regulatory analysis); see also Terry M. Moe & Scott A. Wilson, \textit{Presidents and the Politics of Structure}, 57 LAW & CONTEMP. PROBS. 1, 37–42 (1994) (describing the president’s use of regulatory review to control the bureaucracy).

\textsuperscript{88} \textsc{Dudley & Brito}, supra note 84, at 40–42.


\textsuperscript{90} \textsc{Dudley & Brito}, supra note 84, at 39–40.

\textsuperscript{91} See William West, \textit{Administrative Rulemaking}, 65 PUBLIC ADMINISTRATION REVIEW 655, 661–62 (2005) (discussing the studies on commenting process, which found that agencies generally modify rules in response to comments but rarely make fundamental changes).


\textsuperscript{93} Judicial review of regulations is generally provided by the Administrative Procedures Act, see Administrative Procedure Act, 5 U.S.C. § 706 (2000).
through the rulemaking process, one has to consider the institutional incentives for all actors along the process.

A. Congress

Congress can consider the potential trade-offs and mitigate the potential countervailing risks at the legislation stage. In addition, Congress can review and disapprove final regulations before they take effect. If legislators believe that an agency failed to account for potential risk trade-offs, they can force the agency to produce better analysis.

Yet, Congress faces two major challenges in its attempts to mitigate the potential risk trade-offs. First, it lacks expertise. Weighing the potential risk trade-offs of a policy at the legislation stage typically requires in-depth analysis, which Congress lacks the expertise and resources to conduct in house. Instead, Congress relies on agency experts to provide careful analysis of various policy alternatives.\(^94\) Yet, if agencies fail to account for some countervailing risks, Congress has little expertise to provide an effective check on agency analysis.\(^95\)

Second, the CRA’s structure does not allow for effective congressional oversight.\(^96\) Even if third parties alert Congress to the adverse effects of regulation that agencies failed to consider in their analysis, Congress would find it difficult to intervene. Under the CRA, Congress can only disapprove a regulation through a joint resolution, which requires majorities in both chambers, and it must act within the 60-day window between the day the regulation is published in the Federal Register and the day it becomes effective. Both conditions make disapproving a regulation an uphill battle for Congress. The potential threat of a presidential veto could increase the threshold for successful action even further by requiring two-thirds majorities in both chambers to make the joint resolution veto-proof. If Congress fails to act, the regulation becomes effective.

B. Regulatory Agencies

In contrast to Congress, regulatory agencies have both the expertise and


resources to produce high quality analysis for complex policy issues. Broad congressional delegation of rulemaking powers gives agencies considerable discretion to interpret and implement congressional statutes. Thus, they have both the authority and the tools necessary to account for potential risk trade-offs.

In the rulemaking process, agencies can mitigate countervailing risks at two different stages. First, prior to proposing a new rule, agencies conduct a regulatory impact analysis for major regulations. At this stage they collect data and survey the relevant literature in order to examine the costs and benefits of various policy alternatives. A thorough analysis of regulation’s costs would include potential countervailing risks. Thus, even if agencies proceed with the regulation, they may take steps to mitigate the potential countervailing risks.

Yet, better upfront analysis may not always be possible. To mitigate countervailing risks, agencies could revisit their regulatory decisions with a thorough retrospective analysis. Retrospective analysis allows agencies to check whether a regulation achieved its intended goals and whether it may have inadvertently led to some unwanted outcomes. Over the years, Congress required agencies to conduct retrospective analyses for some major regulations, most notably the regulations implementing the Clean Air Act. In addition, Congress mandated retrospective review for major regulations under the Regulatory Flexibility Act (RFA). Together, the prospective and retrospective analyses allow agencies ample opportunity to minimize countervailing risks. However, agencies face a considerable challenges in trying to avoid unintended risks.

1. Tunnel Vision and Behavioral Biases

Tunnel vision can prevent agencies from considering the regulation’s broader policy implications. Supreme Court Justice Stephen Breyer called tunnel vision a “classic administrative disease,” which leads agencies to carry a “single-minded pursuit of a single goal too far.” In their exclusive focus on the target risk, agencies often overlook the regulation’s impacts in
other areas. As discussed earlier, the TSA narrowly focused on passenger security in the nation’s airports and airplanes. While its actions may have reduced the threat of airborne terrorist attacks, they also led to increases in traffic fatalities as many passengers decided to drive instead of fly.

A variant of tunnel vision is what Justice Breyer calls “the last 10 percent”—a situation where most risk can be eliminated at a reasonable cost but eliminating the last bit requires a prohibitively high expense in return for very little improvement. This situation occurred when the EPA banned asbestos-containing materials. Asbestos is a hazardous material that can lead to lung cancer or mesothelioma. The regulation aimed at reducing consumers’ exposure to asbestos in order to reduce its harmful health effects. However, the potential exposure levels from asbestos materials were very low, while the cost of banning these materials was prohibitively high. The proposed regulation would have achieved its goals at a cost as high as $74 million per life saved, the point at which the negative indirect health effects of regulation may outweigh its benefits. While reducing asbestos exposure in general is beneficial, pushing for the last 10 percent may in fact be counterproductive.

Regulators may also be subject to the distorting impacts of cognitive biases. They may resort to heuristics to simplify the complex issues they have to address, leading regulators to overlook countervailing risks arising from regulation. For example, Viscusi and Hamilton demonstrate that the EPA’s decisions in managing the Superfund, a program to clean up hazardous waste sites, were subject to cognitive biases as EPA regulators established more stringent cleanup targets for highly publicized chemicals. The decision reflects the regulators’ availability effect bias in which individuals emphasize risks they can easily think of. Consequently, chemicals that the media frequently mentioned received greater scrutiny and

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103 BREYER, supra note 102, at 11.
105 Id. at 1208.
106 Id.
107 Id. at 1223.
108 See supra p. 8-9.
were assigned more stringent targets than the less publicized but equally risky chemicals.

2. Political Constraints

In some cases, agencies may prefer to limit their inquiries into regulation’s full impacts as better analysis may expose politically sensitive choices. When regulations transfer risk from one group to another, as in the airbag rule case, risk trade-off analysis may force agencies to face unpalatable choices. Alternatively, some risks may be less visible than others. For example when approving new drugs, the FDA faces a risk trade-off between approving a risky drug and delaying the approval of a lifesaving drug. Yet, if the FDA approves an unsafe drug that is later recalled, as was the case with Vioxx, it faces public outrage and even congressional inquiry. In contrast, the cost of delaying a lifesaving drug is largely hidden, which makes it a politically easier option for agencies.

Similarly, a comprehensive retrospective analysis would measure agency performance and cold reveal shortcomings in implementation or ex ante regulatory analysis that agencies are reluctant to make public. Consequently, agencies have strong incentives to produce analysis that supports their original decisions or to produce perfunctory reviews that do not truly measure performance.

3. Limited Analytical Requirements and Oversight

To counter agencies’ narrow focus on target risks, Graham and Wiener proposed to formally include risk trade-off analysis in the agencies’ regulatory impact analysis requirements. In 2003, Office of Management and Budget (OMB) issued Circular A-4 guiding agencies to consider countervailing risks in their cost and benefit estimates. However, the OMB guidance limited itself to direct risk trade-offs and did not require agencies to consider indirect risk trade-offs or economy-wide impacts. In

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113 Greenberg, supra note 112.


115 Wiener & Graham, supra note 103, at 243–44.

addition, Circular A-4 advised agencies to disregard speculative or minor risks, which allowed agencies considerable discretion as to which countervailing risks they considered important enough to be included in formal analysis. Thus despite OMB’s guidance, few agencies conduct a thorough risk trade-off analysis.  

In addition, limited analytical requirements hinder the effectiveness of retrospective reviews. First, statutory requirements for agencies to reexamine existing regulations cover only a fraction of all rules. Congress required agencies to review regulations under section 610 of the RFA, which applied only to regulations that have significant impact on small businesses or governments.  

In addition, Congress included retrospective review requirements within specific statutes such as the Clean Air Act. Yet, there is no broad statutory requirement for retrospective analysis that would cover all major rules similar to regulatory impact analysis requirements for new regulations. While executive orders 12866 and 13653 instructed agencies to periodically reexamine existing regulations, few agencies have systematically followed through with retrospective reviews.

Second, vague statutory mandates for retrospective review left compliance at agencies’ discretion with little external oversight. In particular, the RFA failed to define key terms, including what constitutes “significant impact” or “substantial number of small entities,” letting the agencies decide when rules triggered the RFA requirements. In addition, the RFA did not specify the requirements for retrospective review. As a result, many reviews limited themselves to soliciting public comments and failed to examine the continuing need for regulation or the need for substantive changes to the regulation. Overall, the retrospective review practices lacked a systematic standard-based approach and thorough documentation and the quality of reviews varied substantially.

Limited requirements and oversight impact agency priorities in

117 While exact statistics are not available, even a cursory search for terms like “risk trade-off” and “countervailing risk” in the Federal Register, which publishes federal regulations, yields few results. See https://www.federalregister.gov
120 Lutter, supra note 99.
123 Id.
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g better analysis. Producing comprehensive analysis can be costly and would require agencies to devote more time and resources to each regulation, which budget-conscious agencies often hesitate to allocate. Agencies generally prioritize producing new regulations over reviewing existing ones, especially given their accountability incentives.

C. OIRA

In addition to agencies, OIRA is another actor with the expertise to consider regulatory issues and trade-offs in-depth. Staffed with economists, OIRA reviews regulatory impact analysis for all major regulations to ensure its quality. In contrast to agencies, OIRA is not limited by a narrow mission. In fact, part of OIRA’s mission is to review regulations in the broader policy context and to coordinate agency actions across the executive branch to ensure that advancing one agency’s mission does not hinder another agency’s ability to do its job. Thus, OIRA is well placed to counter agency tunnel vision. However, it faces its own challenges in trying to reduce unintended consequences of regulation.

1. Resources

Limited resources constrain OIRA’s oversight. OIRA is a relatively small office with only 50 full-time employees in charge of reviewing all major regulations issued by the executive branch agencies. While the regulatory agencies’ staff and budgets have increased over time, OIRA’s staff followed the opposite trend: it fell from 90 full-time employees at its inception in 1981 to almost half that today. Its workload, however, did not decrease – the number of major regulation issued annually has stayed relatively constant over the last decades. Constrained by its resources yet

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126 DUDLEY & BRITO, supra note 84, at 40–42.
still facing the deadlines for its reviews, OIRA’s economists can only devote limited time to reviewing individual rules and may not be able to conduct a thorough oversight of agency analysis.

2. Political Constraints

Political constraints may also limit OIRA’s effectiveness in countering agency tunnel vision and ensuring that agencies produce better analysis. OIRA’s primary function is to help the president manage regulatory agencies and to ensure that regulations fit into the administration’s broader political agenda. Consequently, OIRA is less likely to scrutinize regulations that are important to the administration, even if they lack high quality analysis. In addition, it may be politically difficult for OIRA, an executive branch agency, to publically criticize other executive agencies’ analysis.

D. General Public

Various interest groups have every incentive to alert agencies to potential adverse outcomes of regulation, particularly when they are directly affected by it. They get a chance to raise their concerns directly with the agencies during the commenting process. Given the diversity of interest groups affected by regulation, the commenting process should act as an ultimate remedy to tunnel vision by providing a wide variety of perspectives on a given regulation. Yet, public participation is hindered by the varying ability of different groups to advance their interests. When regulations transfer risk from powerful concentrated interests to the broader public or a vulnerable group, agencies may overlook or dismiss countervailing risks.

The unintended consequences of the RFS program are a good example. The voices of environmentalists and the US agricultural industry were prominent in pushing for wider renewable fuels use. For the environmental activists, the policy addressed increasing concerns over greenhouse gas emissions. The agricultural industry enjoyed the windfall profits stemming from a higher demand for corn and other crops. The one group excluded from the rulemaking process was consumers, especially the world’s poorest consumers. Had they been given a voice, they might have raised concerns over rising food prices disrupting their livelihoods. They might have pointed out that the harm to the poor resulting from the RFS program might exceed the program’s environmental benefits. Yet, given their minimal resources, the world’s poor have a limited ability to influence US politics.

131 See supra note 87 and accompanying text.
133 Wiener & Graham, supra note 103, at 230–33.
While the rulemaking process provides the public with a chance to comment, typically only the organized interests have the knowledge and resources to influence regulatory policy. The poorest consumers simply cannot afford to stay abreast of, let alone shape, policy.

IV. SHOULD AGENCIES CONSIDER RISK TRADE-OFFS?

No discussion of the unintended consequences of regulation would be complete without addressing the debate on whether agencies should include risk trade-offs as part of their cost-benefit analysis. Advocating for formal risk trade-off analysis, John Graham and Jonathan Wiener claimed that institutional incentives undermined the ability of actors within the rulemaking process to identify and mitigate countervailing risks. In contrast, Richard Revesz and Michael Livermore argued that emphasis on risk trade-offs would bias agencies’ cost-benefit analysis since regulations produced both ancillary benefits and countervailing risks. Let’s consider these arguments in detail.

Concentrated interests are more effective than dispersed interests in their ability to mobilize and influence the regulatory process. It is in the interest of both concentrated and dispersed groups to track and comment on regulations that could affect them; yet, concentrated interests are more likely to engage in the commenting process. In contrast, the voices and concerns of dispersed interests are typically absent in the rulemaking process. Consequently, the regulation’s adverse impacts on dispersed interests are less likely to be identified through public participation. So the unintended consequences of regulation will likely fall on dispersed groups.

In addition, differences in the groups’ capacity to mobilize may impact the types of policies that succeed in the rulemaking process. Regulations pit different interests against each other by providing benefits to some groups and imposing costs on the others. Since concentrated interests are more effective in pursuing their political goals, the policies that are most likely to succeed are the ones that provide concentrated benefits and impose dispersed costs. Thus, the political process is systematically biased to

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134 Wiener & Graham, supra note 103.
135 REVESZ & LIVERMORE, supra note 27, at 55–66.
138 WEINER, supra note 44, at 230–33.
139 OLSON, supra note 138.
produce policies that impose more dispersed costs and provide fewer dispersed benefits. As regulation impacts on dispersed interests are more likely to be unintended, the unintended consequences of safety regulation are more likely to impose costs than provide benefits. Consequently, the regulatory process is biased towards producing more countervailing risks than co-benefits.

Revesz and Livermore counter this argument by pointing out that most policies affect diverse interest groups.\textsuperscript{140} Almost invariably, a rule would receive enthusiastic support and face strong opposition from powerful concentrated interests. Even if some unorganized dispersed groups are missing from the rulemaking process, the regulation’s powerful opponents may still bring their concerns to the agency’s attention. The regulation’s opponents would use the potential countervailing risks falling on less protected groups as an argument against regulation. While they may not be interested in the wellbeing of the dispersed groups, seeking out and publicizing the potential countervailing risks strengthens their case against the regulation.\textsuperscript{141} Thus, to the degree that differences in mobilization levels could bias the process towards bad unintended outcomes, the diversity of competing interests would serve to correct these biases.

Ultimately, Revesz and Livermore conclude that the unintended consequences would be randomly and equally distributed among countervailing risks and ancillary benefits. Risk trade-off analysis would bias the agencies’ cost-benefit analysis against the regulation by focusing exclusively on the countervailing risks and failing to account co-benefits. Since positive and negative unintended consequences will likely cancel each other out they should not impact the overall decision to regulate.

Unfortunately, there is little systematic evidence on the prevalence of countervailing risks and ancillary benefits of regulation. Both proponents and opponents of risk trade-off analysis marshal mostly anecdotal evidence to support their positions.\textsuperscript{142} However, mobilization bias may still skew the rulemaking process towards countervailing risks. First, lawmakers have a strong incentive to seek out policies that provide concentrated benefits and impose dispersed costs, so that they avoid angering powerful constituencies. Second, if a policy negatively impacts powerful organized groups, lawmakers would likely appease these groups by making concessions.

\textsuperscript{140} \textsc{Revesz & Livermore}, \textit{supra} note 27, at 55–66.

\textsuperscript{141} This is known as the “Bootleggers and Baptists” phenomenon, where public interest groups (Baptists) and special interests (bootleggers) form alliances to pursue a public policy. While the public interest groups serve as a sympathetic face of the policy, the special interests use their resources to push the policy through the political process. See Bruce Yandle, \textit{Bootleggers and Baptists}, 7 \textsc{Reg.} 12 (1983).

\textsuperscript{142} See e.g. \textit{Risk Vs. Risk}, \textit{supra} note 25; \textsc{Revesz & Livermore}, \textit{supra} note 27.
during the legislative negotiations to reduce the groups’ opposition. Thus, it is unlikely that interests on both sides of regulation would be equally matched. The very fact that the legislation authorizing a regulation has been enacted may indicate that the regulation’s supporters were more powerful than its opponents.

Another shortcoming of Revesz and Livermore’s approach is that they treat countervailing risks and ancillary benefits as equivalent; both would be added with positive or negative sign to the regulation’s overall cost-benefit calculations. Yet, failing to account for countervailing risks has larger impact than not accounting for ancillary benefits. If agencies miss ancillary benefits, they may fail to enact a potentially cost-beneficial regulation. But if they miss countervailing risks, not only would they enact a regulation that is not cost-beneficial, they would also miss a chance to mitigate these risks. Risk trade-off analysis presents actionable information that could help agencies improve their regulation. For example, had NHTSA analysts known from the start that airbags could be harmful to small children, they could have tailored their regulation to require airbags to deploy only for adult passengers. That was ultimately what NHTSA required but only after it learned about the countervailing risks. Learning about the countervailing risks would not have stopped NHTSA from issuing the airbag rule, but it would have helped the agency improve the rule and avoid fatal outcomes.

V. AVOIDING UNINTENDED CONSEQUENCES

Better analysis could help agencies avoid or minimize countervailing risks. Unfortunately, agencies have little incentive to invest in more thorough analysis. Thus, potential solutions to risk trade-offs have to address agencies’ institutional incentives. I discuss a few proposals below.

A. Strengthen Analytical Requirements

The reforms in this category would clarify the analytical requirements for risk trade-off analysis and retrospective analysis in order to provide guidance to agencies and to limit their discretion. In addition, they would ask agencies for a more detailed regulatory analysis focusing on the potential unintended consequences of regulation. For risk trade-off analysis, strengthened requirements would include both direct and indirect risk trade-offs. For retrospective analysis, strengthened requirement would ask

143 GAO made similar recommendation to improve the quality of retrospective reviews. See Government Accountability Office, Reexamining Regulations, supra note 123.

144 Currently, OMB Circular A-4 requires agencies to consider only the direct risk trade-offs. See supra p. 18.
agencies to produce formal analysis rather than basic review.\footnote{There is a difference between retrospective review and analysis. Retrospective review focuses on the administrative process of evaluating the appropriateness of existing regulations. In contrast, retrospective analysis measures the actual impacts of a regulation to evaluate its costs and benefits. Retrospective review may or may not include analysis. As the GAO report demonstrates, few agencies chose to produce full retrospective analysis in the review process. See Lutter, supra note 99.} In addition, the retrospective analysis requirement would apply to all major regulations rather than small subset of regulations currently subject to reviews.

\section*{B. Strengthen Internal Oversight}
Reforms in this category would enhance inter-agency and OIRA review in order to bring in competing policy perspective and counter the agencies’ tunnel vision. Specifically, the reforms would increase OIRA’s resources to oversee the increasing volume of regulations. This would allow OIRA analysts more time to subject regulatory analysis to greater scrutiny. In addition, the reforms would direct OIRA to coordinate inter-agency review to allow agencies with relevant expertise to provide input on regulations.\footnote{Former OIRA administrator Cass Sunstein indicated that OIRA often coordinates interagency reviews and solicits input from other agencies as part of OIRA’s review, yet this is not a formal requirement for the process. Making interagency review a formal requirement would signal the importance of soliciting broad perspectives for each major rule. See Sunstein, supra note 129.} In addition, the reforms could establish OIRA oversight for agency compliance with retrospective review requirements.

\section*{C. Strengthen External Oversight}
Given OIRA’s political constraints in publicly challenging other executive branch agencies, more effective reforms would require stronger external oversight. One reform proposal would be to place regulatory oversight with the legislative branch by creating a Congressional Office of Regulatory Analysis.\footnote{Bills advocating such office go back to 105th Congress. See Rosenberg, The Critical Need for Effective Congressional Review of Agency Rules, supra note 87; See also Susan Dudley, Congress Needs Its Own Regulatory Review Office. REGBLOG (Aug. 10, 2011), https://www.law.upenn.edu/blogs/regblog/2011/08/congress-needs-its-own-regulatory-review-office.html; Robert E. Moffit, Why Congress Must Confront the Administrative State, CPI Lecture 5 (Heritage Foundation, Washington, DC), Jan. 26, 2012.} The new congressional agency would essentially replicate OIRA’s functions, but would not face the same political constraints. Thus, it might be more effective in forcing agencies to consider the potential risk trade-offs of safety regulations and countering the agencies’ narrow mission focus.
CONCLUSION

Unintended consequences can undermine even the most well-intentioned polices. Regulations aimed at reducing risk in one area often increase countervailing risks elsewhere. Thus, regulators often face risk trade-offs when deciding between regulatory alternatives. Some risk trade-offs are straightforward, as in the cases when each alternative carries some risk. Regulators must choose the option that reduces the overall risk by taking countervailing risks into account. In other cases, countervailing risks are indirect. Regulatory costs reduce national incomes, leaving consumers with less to spend on private risk-reducing actions like purchasing insurance or a safer car. Regulations with a high cost per life saved may reduce incomes enough to induce a fatality. In addition, regulations may increase risk by changing consumers’ preferences. Alternatively, risk-reducing regulations may affect prices in far-off sectors of the economy, increasing risk in areas that are not directly related to the targeted sector.

The consequences of regulations discussed in this paper were unintended but not unforeseeable. A formal risk trade-off analysis would allow agencies to evaluate the potential countervailing risks resulting from regulations. Similarly, consumer testing may help agencies avoid unexpected consumer responses. Finally, a thorough retrospective analysis would give agencies a chance to evaluate and modify regulations if necessary.

Agencies often fail to account for countervailing risks. A thorough analysis is costly, and budget-conscious agencies may hesitate to devote additional time and resources to each regulation. In addition, they may want to avoid making potentially controversial choices. In addition, the population facing the increased countervailing risks may not be represented in the regulatory process, biasing policy-makers’ decisions toward organized special interests.

To minimize or avoid unintended consequences, agencies must formally consider countervailing risks. Given agencies’ incentives against considering risk trade-offs, additional analysis may have to be part of the regulatory impact analysis requirements. In addition, strong oversight is necessary to ensure agencies’ compliance.