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1. Policy analysis: roots and branches

The premise is simple, really. When government makes a decision that affects the lives of its citizens, it should carefully analyze the impacts of that decision before proceeding. But the implementation of this premise has proven over the past 50 years to be both far more complicated and far more controversial than the premise itself. In this book, I explore the question of why government analysis of its decisions is so challenging. It is my hope that an exploration of the analysis of government decisions will lead to ideas for better incorporating analysis into public sector decision-making, and thereby lead to better decisions.

Of course, not even the most stringent critics of analysis are suggesting that we should do no analysis of the impacts of government decisions. But structuring governmental decision-making in a democratic society requires great care. Ensuring that decisions are both responsive to the public will and reflect gains in the public welfare is a challenge that has been a continual struggle since the early republic. With many more public policy decisions now taking place in the unelected bureaucracy, the battle has taken on enhanced importance and a different character over the past several decades.

Much of the battle over the use of analysis in U.S. policy-making has taken place within the context of regulation. Regulations are issued by agencies of the executive branch of government or by independent commissions. They are issued pursuant to delegations of power from Congress, but these delegations are often vague, and leave critical policy choices to the regulatory agencies. Since the passage of a number of statutes in the 1960s designed to improve public health, clean up the environment, and enhance the protection of workers, the role of regulation has become a larger and larger part of policy-making in the United States.

With the increased importance of regulation has, not surprisingly, come growing attention to the subject. Those burdened by regulation have objected both to the regulations themselves, and their promulgation by unelected officials. Particularly in times of economic downturns (Coglianese et al. 2014), regulation has been blamed for rising unemployment and business failures. One common response to these

complaints has been to require regulatory agencies to more carefully analyze the implications of their decisions (Shapiro and Borie-Holtz 2013).

This context has made regulation an excellent forum in which to study the role of analytical thinking in public policy. The breadth and variety of analytical requirements allow us to observe analysis in different forms and varying settings. In this volume, I look at cost-benefit analysis, risk assessment, environmental impact assessment, and other forms of impact assessment in the regulatory process. I provide examples of analysis having clear impacts on public policy decisions, and cases where it has either been ignored or failed to live up to its potential. Through these examples of when analysis works, and when it doesn't, I find trends in policy analysis that can inform further attempts to increase its role.

As we will see in the chapters ahead, several institutional factors are paramount in the role of analysis in policy-making. Political climates can facilitate the use of analysis or stifle it. Organizational factors such as the timing of analysis, and the placement in the regulatory bureaucracy of analysts, can also play a critical role. The legal structuring of analysis is also important, as exemplified by questions like: are analysts given a deadline, or, how does analysis interact with public participation and with judicial review in the formulation of policy decisions? Finally, the epistemic limits of science and social science, which questions can be answered and which ones cannot, are too often ignored in the practical debates over analysis.

The two questions that I hope to address successfully in this book are: under what circumstances have requirements for analysis in the regulatory process performed well (and when have they performed poorly), and what can we learn from the successes and failures of analysis as we contemplate efforts to adjust the role of analysis in policy-making? Some of these lessons will mirror those from the growth of the policy analysis discipline generally. Others will be new and different. Before we get to these discussions, however, there is a rich literature on the role of analysis in policy-making that informs this discussion. Academic scholars have long debated whether analysis should and could affect policy decisions, and what the long-term implications of an increased role for technocratic analysis are for democracy itself. I review that literature in this chapter.

ANALYSIS: ROOTS AND BRANCHES

In his famous article, "The science of 'muddling through,'" Lindblom (1959) contrasts two modes of policy-making. The first is comprehensive-rational analysis, where all policy options are considered, and the impacts of all options are evaluated, which then leads to a decision. He also dubs this the "root method." The second mode is incremental decision-making, that is, bureaucratic behavior where policy options are eliminated quickly as infeasible, and some potential impacts are not considered because they are irrelevant. He also calls this incremental form of decision-making, the "branch method." While the root method finds its theoretical roots in the then-burgeoning fields of decision science and welfare economics, the branch method is reflective of the bounded rationality school of Herbert Simon.[1]

Lindblom argues that while on the surface comprehensive-rational decision-making appears to be superior, it is impossible to achieve. To truly consider all of the impacts of all possible alternatives is impossible, and even if it were possible it would take years to do so successfully. "In actual fact, therefore, no one can practice the rational-comprehensive method for really complex problems, and every administrator faced with a sufficiently complex problem must find ways drastically to simplify" (Lindblom 1959, p. 84). Meltsner (1976) notes that the goal of the analyst is to be only 90 percent right, but Lindblom would probably see this figure as impossibly high as well.

In contrast, the branch method is a useful way of making decisions simpler.

> Since the policies ignored by the administrator are politically impossible and so irrelevant, the simplification of analysis achieved by concentrating on policies that differ only incrementally is not a capricious kind of simplification. In addition, it can be argued that, given the limits on knowledge within which policymakers are confined, simplifying by limiting the focus to small variations from present policy makes the most of available knowledge. (Lindblom 1959, p. 85)

Hence, according to Lindblom (1959, p. 86), incremental modes of decision-making are in fact superior to attempts to impose a comprehensive assessment of the impact of policy options.

> [F]or all the apparent shortcomings of the incremental approach to policy alternatives with its arbitrary exclusion coupled with fragmentation, when compared to the root {comprehensive} method, the branch method often looks far superior. In the root method, the exclusion of factors is accidental,

> unsystematic and not defensible by any argument so far developed, while in the branch method, the exclusions are deliberate, systematic, and defensible.

Lindblom (1968, 1979) expanded on his assessment of the root method in his book, *The Policy-Making Process* and in several articles. He lists four reasons why analysis does not influence policy in the way hoped for by its advocates. First, analysis cannot help but be fallible and consumers of analysis know it.

> No educator fully understands how children with widely varying backgrounds and personalities should be taught to read. Economists do not know enough to cope very well with simultaneous inflation and unemployment … The choice between synopsis and any form of strategic analysis is simply between ill-considered, often accidental, incompleteness on one hand and deliberate designed incompleteness on the other …
>
> Analysis is also fallible in more blatant ways in that much of it is poorly informed, superficial or biased – not infrequently making shoddy attempts to prove by specious means what someone in power has already decided to think. (Lindblom 1979, p. 519)

Or as Meltsner (1976, p. 268) put it, "a central problem for analysis is not knowing much."

Second, analysis is incapable of resolving conflicts in values. There is no single criterion by which to convince those who lose because of policy choices to support those choices. Third (echoing his earlier concern), analysis is too slow and costly. Finally, analysis cannot be used to determine which problems to tackle.

This framework has been extended considerably in the more than half-century since Lindblom first wrote. Notably, Lindblom's work has been more closely tied to Simon's theories on satisficing as a decision-making alternative to comprehensive-rationality. Simon (1972) argued that individuals do not consider all options (as an advocate of comprehensive-rationality would want them to), but rather they sift through options until one that meets certain minimal criteria is found. Others argue that advocates of analytical requirements assume that presented with the results of analysis, decision-makers will act rationally, and that this is a particularly unrealistic assumption (Cashmore et al. 2004 (the authors are particularly concerned with environmental impact statements)).

Forester (1984) further illuminated Lindblom's argument. While noting the theoretical desirability of comprehensive-rational analysis, he noted a series of obstacles to its actual implementation. The first of these was the cognitive limits on individual decision-makers described by Simon. The

second limit was the fact that multiple decision-makers, even those who agree on goals, may have different skills and insights. The third obstacle is that parties will disagree on political goals and that will affect their ability to rationally analyze policy questions. Finally, these differences do not necessarily represent a pluralist cacophony of views but rather the fact that often some powerful voices speak loudest and drown out others.

Forester concludes (p. 30),

> Technical solutions depend on a stable context and a problem to be solved that can be isolated from that context. Practical solutions depend upon the particularities of the context at hand that define the given problem. Being practical means being responsive to the demands made in a given situation with all of its instabilities … Thus being technical and being practical may well be two very different enterprises.

Sidney A. Shapiro (2011) also draws on Simon and the organizational design literature to argue that regulatory agencies have deliberately structured their decision-making processes in a way that shows they wish to avoid a comprehensive-rational approach.

Analysis is not without its defenders. Many see the comprehensive-rational analysis end of the spectrum as a straw-man and assert that the goals of analysis are not comprehensive but rather incremental in their own way. Taylor (1984), describing environmental impact statements (EISs) (the subject of Chapter 5), argues that the goal of EISs and similar requirements is to work toward incorporating the "science model" of decision-making into the conflict-laden world of politics. He goes on to argue that process changes should be judged by whether they make agreement easier, in addition to whether they lead to better policies.

Analysis has been widely praised as increasing the transparency of governmental decision-making on complex issues (Sunstein 2002). Advocates of analysis have claimed that laying out the consequences of governmental action improves the ability of the public to weigh in on these actions, either directly or through their elected representatives. Rayner (2003), however, argues that these analyses themselves are hopelessly complex and therefore it is nonsensical to claim that they improve transparency. In fact, analysis has served to further deter public participation in government decisions. "Those who understand the modeling techniques, then, can wage debate over ideological issues under the guise of impartial analysis – distorting and submerging the real issues of importance" (Jenkins-Smith 1990, p. 69).

EXPERTISE AND DEMOCRACY

In many ways, the debates over comprehensive-rational analysis are part of a broader (and older) debate over the tension between expertise and democracy. Plato argued against democracy citing its tendency to undermine expertise (Christiano 2015). Imposing analytical requirements on public policy-making has been seen both as a way of solving the tension between expertise and democracy, and exacerbating it.

The nature of science (and even more so of social science) is such that manipulation of science is always a possibility. The questions that policy-makers ask scientists or economists are ones with uncertain answers. Such uncertainty can give elected officials or agency bureaucrats room to question conclusions and the assumptions that went into the models that led to those conclusions (Rushefsky 1986). "It is now recognized that the questions regulators need to ask of science cannot in many instances be adequately answered by science" (Jasanoff 1990, p. 7).

As a result, the debate over the use of expertise in public policy-making has become as polarized as debates over the policy issues themselves. Some worry that government experts are imposing their own preferences, and hence undermining democracy. This worry can come from those who assume government bureaucrats are obsessed with their missions and intent on over-regulating industry, or from those who believe that government experts are "captured" by industry experts and are under-regulating industry. Open or participatory decision-making is often touted as the solution to these problems (Jasanoff 1990). Ironically, analysis is also seen as a check against the tendencies of bureaucrats to either be captured by outside interests or to impose their own ideological preferences (Katzen 2007).

Jasanoff (1990) criticizes both a technocratic approach which looks to scientists for validation of policies in technical areas, and a view that democratic or participatory oversight is needed to counteract the biases of experts. She characterizes the debate over scientific expertise as polarized between those who believe that expertise is inherently biased and therefore fair game for manipulation by political actors, and the view that expertise is inherently superior to popular input. The solution according to Jasanoff is accountability for experts, both to peers within their disciplines, and to the public at large (Jasanoff 2003).

Renn (2008) describes three modes of governmental decision-making into which analysis (he is discussing risk assessment – the subject of Chapter 4 of this book) can fall. The "technocratic mode" is one in which scientists make the key decisions about appropriate risk levels. In the

"decisionistic mode," science is one input into policy decisions. The third mode is the "transparent (inclusive) governance mode" where "science, politics, economic actors, and representatives of civil society are invited to play a role in both assessment and management" (Renn 2008, p. 11). Renn's work clearly favors the third mode as the preferred way of public decision-making.

Without some means of accountability, the fear emerges that analysis (or other forms of expertise) often plays a role in supporting decisions made by other means. This fear goes back to the earliest days of policy analysis. Meltsner (1976) describes analysis of Supersonic Transport (SST) in the 1970s. His interview subjects, policy analysts at the Department of Transportation (DOT), "described their role as 'strictly to support the SST.'" This supportive role is more problematic when analysis is described as playing a role in decision-making but instead is constrained to a particular solution (Wagner 2010a). Wagner (1995) also describes the "science charade" where decisions made based on values are cloaked in the veil of science in order to increase their legitimacy.

In summation, analysis has been seen as undermining democratic decision-making for two reasons. First is Wagner's science charade which could be more broadly classified as an analysis charade; policy-makers declare their decisions as based on comprehensive analysis, thereby muting criticism of policy made because of choices grounded in values. Second, and contradictorily, advocates of democracy have long feared the Platonic ideal, decisions that are made by unelected technocrats who have no accountability to the public.

Despite these persistent fears comprehensive-rational analysis continues to have an appeal. "Nothing that Lindblom or his colleagues had to say about the limits to rationality diminished the advocacy of comprehensive decision-making methods" (Atkinson 2011, p. 9). Some of that appeal is cynical. There is an undeniable appeal to selling your preferred policies as supported by rationality (or science or economics). This is true for politicians, advocates and bureaucrats. "Today what we are left with is … rationalism as a form of symbolic politics that various bureaucratic entities use to project the 'illusion' of rational-comprehensive decision-making as a strategy to legitimize the exercise of political power" (Saint-Martin and Allison 2011, p. 19).

But some of that appeal is also genuine. As policy problems become more and more complex, the attraction of expertise as a means of solving those problems increases. Attempts to require more forms of analysis have proliferated (Shapiro and Borie-Holtz 2013). To evaluate these attempts we need to better understand how different forms of the "comprehensive-rational analysis" criticized by Lindblom have operated

in practice. Very little of the literature on analysis in public policy is empirical, most of it is philosophical. This book attempts to help correct that imbalance.

A VERY BRIEF HISTORY OF THE USE OF COMPREHENSIVE-RATIONAL ANALYSIS

While the debate over expertise goes back centuries, we can date the modern debate over analysis to the 1960s. The use of comprehensive-rational analysis finds its roots in the efforts during the Great Society to apply the techniques pioneered by Secretary of Defense, Robert McNamara, at the Defense Department to guide social policy.[2] "These developments in the social sciences – particularly systems analysis and operations research – largely moved along two pathways: positivism (using the concept of laboratory experiments to differentiate the true from the false) and normative economic reasoning based on the concept of the market" (Radin 2015, p. 4). The goals in the early years of analysis were extremely ambitious. One observer wrote, "the analysis of rational program choice is taken as the one legitimate arbiter of policy analysis. In this mood, policy studies are politically deodorized – politics is taken out of policymaking" (Heclo 1972, p. 101).

Advocates for policy analysis were not blind to its potential failings. One of the most ardent advocates, Yehezkel Dror, argued that numerous preconditions were necessary in order for the policy sciences to succeed. These included political actors who were both more capable of understanding policy analysis and dealing with reasonably presented alternatives, and a public that was sufficiently well-informed to take advantage of policy analysis. He was optimistic that these conditions could be achieved (Dror 1971).

One of the first[3] and most famous manifestations of comprehensive-rational analysis was the use of the Planning, Programming, and Budgeting System (PPBS) which began with Secretary of Defense McNamara. Even in the Defense Department, verdicts on the influence of systems analysis and PPBS were mixed. Some reviewers found the influence was significant while others argued it was minimal (Nelson 1987). As PPBS was expanded by President Johnson to social service agencies, the challenges mounted and the Nixon Administration quickly abandoned the technique for rationally determining program budgets (Wildavsky 1974).

Wildavsky (1974) described a series of case studies of the role of PPBS and found that in no instance had the technique successfully influenced budgetary decisions. "PPB was implemented in form but not

in substance" (Wildavsky 1974, p. 197). In describing the process that agencies and the Bureau of the Budget followed he says, "they produce a vast amount of inchoate information characterized by premature quantification of irrelevant items … Its very bulk inhibits understanding. It is useless to the Director of the Budget in making his decisions" (Wildavsky 1974, p. 202). Why did PPBS fail? The most common argument laid the blame at the feet of politics and bureaucracy, factors that will appear repeatedly in this book. Congressional committees saw power going to executive branch and therefore objected to PPBS. PPBS also required more centralized control than was possible in civilian agencies (in contrast to McNamara's Defense Department). Individual agencies were not willing to give up control to more centrally located entities (Jenkins-Smith 1990).

These arguments, blaming politics and bureaucracy for the failure of PPBS, were prevalent in autopsies of PPBS. In contrast, Wildavsky maintained that failure was inevitable, "Failure is built into its very nature, because it requires ability to perform cognitive operations that are beyond present human (or mechanical) capacities" (Wildavsky 1974, p. 206). This echoes Lindblom's fears from a decade and a half earlier and Simon's arguments on bounded rationality. The limits to the amount of information that humans or organizations can process lead to limits to what analysis can tell us.

So comprehensive-rationality left the budget process. But in its wake it created a new field, policy analysis. Wildavsky (1969) himself had hopes that policy analysis could be "rescued" from PPBS. According to Wildavsky analysis works better on questions that are more circumscribed where alternatives can be meaningfully addressed.

Numerous works have talked about the growth of policy analysis in the federal bureaucracy. Lynn (1989) argued that policy analysis was not a radically new phenomenon but rather one that has always been part of government decision-making. Echoing Lindblom in part he argues that sophisticated analysis has at most a marginal effect on policy. He does give the spread of policy analysis credit, however, for expanding the perspectives available to policy-makers. Williams (1998) laments the decline of the influence of policy analysis over its first three decades.[4] He cites the politicization of analysis, particularly during the Reagan Administration. He blames the increasing influence of the Executive Office of the President, "Honest credible information, sound policy analysis … have never been so difficult to develop than in today's political climate of limited executive branch demand and rising public distrust and cynicism about the federal government and its numbers" (Williams 1998, p. 22). Jenkins-Smith was also pessimistic about the role of policy analysis,

"Analysis supports the status quo, not significant change. Repeated studies have shown that despite the increased provision of analyses, those analyses have little direct effect on policy formulation" (Jenkins-Smith 1990, p. 47).

While these works are important for the topic of this book, they largely talk about how policy analysts have evolved from the comprehensive-rational analysts envisioned by Lindblom as a result of bureaucratic and political factors (Meltsner 1976; Jenkins-Smith 1990; Radin 2013). The field of policy analysis began its evolution in comprehensive-rational analysis but now includes program evaluation, policy mapping, and many other techniques (Radin 2013).

But many of the requirements placed on regulatory decision-making are clearer reflections of the more unadulterated and more comprehensive form of analysis. Cost-benefit analysis, impact analysis, and risk assessment, fall on the comprehensive-rational end of the spectrum of policy analysis. These requirements remain in place, and more are regularly proposed both on the federal and state levels (Shapiro and Borie-Holtz 2013).

Comprehensive-rational analysis is often conflated particularly with economic analysis. And indeed, as I explore in Chapter 3, economic analysis is clearly the favorite son of comprehensive-rational analysis and McNamara's "whiz kids." However, the idea that a policy problem can be thoroughly analyzed and an optimal solution produced is not unique to economics. Supporters of the natural and physical sciences in particular have often claimed that policy issues could only profit from their perspective. This is particularly true when such issues involve interaction with the physical world in policy areas such as risk reduction and environmental destruction.

Hence while policy analysis has broadened beyond its comprehensive-rational origins, pure comprehensive-rational analysis (or mostly pure) is alive and well. It is alive in the application of welfare economics, risk assessment, and environmental impact assessment to the regulatory process. It also has a not-that-distant offspring in the many other forms of impact analysis that regulators are required by statute and executive order to conduct.

FACTORS INFLUENCING THE EFFECTIVENESS OF POLICY ANALYSIS

Both the theoretical work by Lindblom and others, and the work on the history of policy analysis as a discipline provide numerous candidates for

factors that determine whether analysis makes a real difference in policy decisions. Chief among these are factors related to politics and bureaucracy. As mentioned above, many attributed the failure of PPBS to reluctance among politicians and among bureaucrats to surrender power to analysts (Jenkins-Smith 1990, but see Wildavsky 1974).

The academic widely credited with creating the environmental impact statement (the subject of Chapter 5) emphasized the role politics has played: "But policy decisions are more often shaped by political expediency, and less often based upon objective scientific estimates of probabilities. Impact assessment involves both science and art and cannot avoid implications for priorities among values. Hence to some degree it is, in the better sense of the term, a political process" (Caldwell 1991, p. 84).

It is important to resist the temptation to reduce the roles of both political actors and of bureaucrats to caricature, however. The debate over the failure of PPBS contained some such caricatures. Politicians were reluctant to embrace analytical results that contradicted their preferred policies (or the preferred policies of their constituents or favorite interest groups). Bureaucrats also feared analysis both because of their own policy preferences and because of a general reluctance to change or cede power. These stereotypes, however, are not terribly useful and, like many stereotypes, likely vastly oversimplify the reaction of decision-makers to the imposition of analytical requirements.

It is far more useful to ask which factors within a political environment and which factors associated with organizational structure are more conducive to accommodating analytical thinking. Political environments have been spliced many different ways in the political science literature. They can be characterized as "high salience" or "low salience" depending on the level of interest in the issue at hand (RePass 1971). They can be characterized by the complexity of the issue (Gormley 1986). They can be characterized by whether the costs and benefits of a policy decision are concentrated in a small number of parties or a large number of parties (Wilson 1980).

Any of these and numerous others could play a role in the receptiveness of political actors to analytical results. As will be detailed in Chapters 3–6, many proponents of analysis have largely seen political concerns as undermining analytical ones (e.g. National Research Council 1983; Taylor 1984; Hahn and Tetlock 2008): "The literature in the policy analysis field is replete with illustrations of conflict between the two cultures. Most frequently, the dichotomy is established as a conflict between analysts and politicians. It is also defined as a conflict between intelligence and power, and between studying and action" (Radin 2013,

p. 125). However, some of the types of analysis, specifically environmental impact statements and small business impact statements, may give particular interest groups (environmental groups and small businesses respectively) additional tools with which to advocate their causes. This may make these types of analysis more effective, and by explicitly and deliberately intertwining analysis and politics it makes the discussion of analysis much more complicated.

Politics and the legal standing of analysis interact in varying ways. As we will see in Chapter 3, cost-benefit analysis of regulations in the federal government is attached to review of regulations by the President. This ties cost-benefit analysis to the political preferences of the President, and may compromise its effectiveness as a policy-making tool (Arbuckle 2011). On the other hand, environmental impact analyses are judicially reviewable according to the statute which mandates them, the National Environmental Policy Act (NEPA). Judicial review has had mixed effects on the role of environmental impact statements in policy-making (Taylor 1984).

The interaction between bureaucratic organization and the use of analysis has also received considerable attention. Taylor (1984), in a study of the Army Corps of Engineers and the Forest Service, argued that numerous characteristics of agencies determined whether environmental impact analyses were effective. These included the level of knowledge about the subject material in the agency, the interest group environment, and the organizational structure. Jenkins-Smith (1990) also listed three bureaucratic factors, but his three were: the level of conflict over the issue, the level of "analytical tractability" (is there an answer?), and the openness of the decision-making environment. The last of these three is particularly interesting as Jenkins-Smith argued that the more open the forum, the more likely it is that analysis will be used for political means. This argument runs counter to that which argues that one of the chief benefits used to justify analysis is increased transparency.

Bureaucratic factors also interact with the legal setting of analysis, particularly with regards to this question of transparency. In some contexts, particularly risk assessment, there have been calls for increased participation in the process of regulatory analysis. The environmental impact assessment literature is rife with paeans to the necessity of participation in order to make environmental impact statements work. This interaction, however, has largely escaped empirical analysis (Glucker et al. 2013).

In addition to the nature of participation, scholars have also emphasized the location of analysis within the policy-making process. Taylor (1984) focuses on it and notes the trade-off between giving analysts an

independent voice or integrating closely with political decision-makers, "we do not want the analysts to be integrated and influential at the cost of being co-opted, nor do we want them to be so autonomous as to be irrelevant to policy decisions" (Taylor 1984, p. 94). He goes on to note that the analysts themselves preferred independence, "The analysts' greatest fear was dispersal into other functional units. Dispersal would decrease their influence, put them under closer supervision, reduce their specialization, and hinder their ability to allocate their resources according to their own priorities" (Taylor 1984, p. 110).

Meltsner interviewed many policy analysts early in the 1970s, as the field was growing. He noted that many early policy analysts went into federal service hoping to influence the bureaucracy but ended up instead being influenced. "Some analysts adjust to the bureaucracy by becoming bureaucrats while others adhere to the norms of their former professions" (Meltsner 1976, p. 17). He also found that many of his interview subjects had grown frustrated at agencies because of the many layers of review that their work had to pass through before being seen by decision-makers. These layers of review also vary from organization to organization.

Robert and Zeckhauser (2011) describe a spectrum of policy analyst archetypes. Policy analysts range from the dispassionate analyst who puts aside values, favors transparency, and carefully calculates policy impacts, to the analyst-advocate who embraces the value laden aspects of political decisions and sees analysis as one component of those decisions. They argue that the presence of even a small number of analyst-advocates leads to the contagion of strategic behavior among all types of analysts (Robert and Zeckhauser 2011).

These works give us several institutional factors that need to be a part of any discussion of the role of analysis in policy-making. Scholars have identified the political climate of the policy decision at hand, the placement of analysis within a bureaucracy and how it fits within the bureaucratic culture, and how analysis is restricted or enabled by legal requirements as key factors. The questions raised by Lindblom (1959) and Wildavsky (1974) point not to the environment in which analysis takes place but rather to the nature of analysis itself, the degree to which it can answer the questions that policy-makers ask it, as a (if not the) critical determinant of the role of analysis. As I present the varying types of analysis in Chapters 3–6, I will highlight the roles of these four categories of institutional constraints.

ANALYSES OF ANALYSIS

Lindblom framed his criticism of comprehensive-rational analysis in rather absolute terms. The root method for analyzing policy questions is, as even Lindblom tacitly acknowledges, something of a straw-man. If agencies were really required to perform a truly comprehensive analysis, no policy decisions would ever be made in the executive branch. Yet, the continual attempts to impose new analytical requirements on policy decisions reflect a lasting appeal of moving in the direction of a "root" method.

There are many possible reasons for this. Critics of analysis ascribe the desire for root methods in cynical terms. They note that the supporters of analytical requirements often overlap considerably with those who oppose government intervention in the marketplace for self-interested reasons. Hence they argue that proponents of analysis do not want comprehensive-rational analysis per se; rather they want to slow down the regulatory process and make it harder for agencies to issue regulations (McGarity 1992).

The legal system also has played a role in the continual ratcheting up of analytical requirements. In the regulatory world, agencies operate in an adversarial environment (Kagan 2001). Few regulations of significance come without opponents ready to challenge the legality of the agency's action. Any analysis required of the agency can get pulled into a subsequent legal proceeding, whether or not the analysis itself is part of a judicially reviewable requirement. This legal environment creates the incentive for the agency conducting the analysis to be as thorough (or as comprehensive and rational) as possible, in order to avoid the possibility of losing a lawsuit because their analysis is "arbitrary and capricious."

Of course some of the motivation for putting requirements in place for comprehensive-rational analysis should also be taken at face value. As stated at the outset, there is an inarguable appeal to carefully laying out the implications of various policy choices and selecting the "best" one. Even if it is impossible to select the best choice, surely a decision-making process with more analysis will lead to a better choice than one with less analysis. Every attempt to enshrine the root methods of policy determination is accompanied by many who argue from a true faith that these methods will improve policy decisions.

Lindblom's argument about comprehensive-rational analysis is both positive and normative. The normative argument about analysis continues unabated and hopelessly colors perspectives on the positive one. Those who feel analytical requirements are unethical or bad for democracy cite

policy decisions that stretch out for decades (McGarity 1992). Those who feel analytical requirements are necessary for policy decisions that are increasingly complex cite policy failures that would have been easily avoided if only more analysis had been done (Winston 2007).

Empirical work on the actual role that the various forms of comprehensive-rational analysis have played in policy decisions is limited. Meltsner's work (1976), described above, which looked at the early days of policy analysis and some of the work on PPBS are still among the best pieces of work around but they are now nearly 40 years old. Radin (2013) has also explored the shifting role of the policy analysis discipline and has added significant insights. Finally, within the regulatory arena, several scholars have looked at the particular types of analysis covered in this volume and how they affected individual regulatory decisions. I summarize this literature here and review it in more detail in Chapters 3–6.

Morgenstern and Landy (1997) assemble 12 cases of cost-benefit analysis at the Environmental Protection Agency (EPA). They found that analysis did improve regulatory decisions but it did not have nearly the influence hoped for by advocates. Unlike the focus on politics and bureaucracy in the broader literature, their conclusions focus more on qualities of the analysis itself. In particular, they note how the inherent uncertainty in cost-benefit analysis renders it less useful to decision-makers. Uncertainty is also a key player in Graham et al.'s (1991) examination of risk assessment in decisions whether to regulate emissions of formaldehyde and benzene. In the case of both chemicals, different agencies reached different decisions at different times, again showing the limitations of a form of comprehensive-rational analysis.

Taylor (1984) uses EISs to assess efforts at "Making Bureaucracies Think." He wraps in many of the themes mentioned here – politics, bureaucracy, limitations inherent to analysis – and he also brings up other factors that will be discussed in the chapters that follow, such as the legal structure in which analysis is conducted and the role of individual personalities, both analysts and decision-makers.

Requirements for analysis are inherently procedural in nature. Indeed they are often put in place because of difficulties in getting agreement on the substantive goals which they embody (economic efficiency, environmental sustainability (Cashmore et al. 2004)). Hence many of the empirical evaluations of the literature are also procedural. The works described in the paragraphs above are the rare exceptions that attempt to grapple with the substantive impacts of analytical requirements. I hope that this volume adds to this assessment.

This is not to dismiss the importance of procedural evaluations. Analytical requirements can and should be judged on these terms as well. However, five decades in to the experience of placing analytical requirements on public agency decision-making processes, we continue to focus on procedure almost exclusively. At the very least, we should know more than we do about when these requirements lead to changes in public policy, what these changes are, and under what circumstances analysis leads to changes.

ROOTS AND BRANCHES AGAIN

In this book, I hope to grapple with the positive implications of Lindblom's arguments on comprehensive-rational analysis. Can analysis work in our governmental system, and, if so, under what conditions? Many of Lindblom's critics focus on his defense of incrementalism in policy-making (see e.g. Bendor 1995). This book is intended neither as a defense nor a criticism of incrementalism. Instead I am focusing on another critical claim of Lindblom's. Lindblom argues that comprehensive-rational decision-making is not only undesirable but is in practice impossible. This is true whether the changes from the status quo are large or small. It is impossible to analyze all (or most) of the consequences of a policy change. This contention has important implications for how we make policy.

Forester (1984) argues that comprehensive-rational analysis requires: 1) a well-defined problem, 2) a full array of alternatives to consider, 3) full baseline information, 4) full information about the consequences of each alternative, 5) full information about the values and preferences of citizens, and 6) full adequate time, skill, and resources. Like Lindblom, these requirements reduce comprehensive-rational analysis to a caricature. But does their impossibility of achievement mean that we must abandon all hope of analysis in policy-making? Does their impossibility render analysis as a fundamentally political tool that will inevitably be manipulated to political ends?[5] One aim of this book is to look at the regulatory process and understand where the impossibility of these prerequisites has thwarted efforts at informing decisions with analysis and where they have not.

In a sense, the focus on the comprehensiveness and rationality of different forms of policy analysis has obscured their potential usefulness. Advocates of analysis find themselves defending the root method of policy analysis while critics mercilessly try to pull up those roots. But many movements toward better policy analysis are really about building

better branches. Lindblom (1959) himself argued that analysis should look at marginal differences between policy changes and the focus should be on a small number of policy alternatives. Few advocates of analytical requirements would disagree with this premise (Carrigan and Shapiro 2014).

As the chapters ahead will show, the attempts to use comprehensive-rational analysis in the regulatory process can teach us about the effectiveness of even small steps in that direction. It also helps us evaluate attempts to impose comprehensive-rationality on the regulatory process today. Just as Lindblom advocates incrementalism in policy change, the impacts of analytical requirements have largely been incremental in character.

Requiring agencies to undertake some form of comprehensive-rational analysis may have other effects on policy decisions. Analysis could affect decisions more in the long run than in the short run (Cashmore et al. 2004). Embedding analysts within the bureaucracy can change the culture of an agency so it is more inclined toward analytical thinking. It can empower external parties which support analytical thinking (or the underlying goals of the analytical requirements) (see also Taylor 1984).

This book suggests that the broadest fears and greatest hopes associated with comprehensive-rational analysis have not been realized. We have not evolved (or degenerated, depending on your point of view) into a technocratic state where analytical thinkers systematically override the will of the people as some had feared (Jasanoff 1990; Jenkins-Smith 1990).[6] Policy-making in the executive branch (where analytical requirements are prevalent) has not been frozen in its track paralyzed by analytical requirements. But neither have policy decisions become markedly more economically efficient, more environmentally rational, or prioritized according to the level of risk.

Yet, the chapters ahead provide numerous examples of cases where cost-benefit analysis, risk assessment, environmental impact assessment, and other impact assessments have made a difference. Some made marginal improvements. Others involve avoiding decisions that analysis has shown to be particularly poor. Still others promote the goals of particular groups such as environmentalists or small businesses whom specific kinds of impact analysis are designed to empower.

As policy-makers contemplate implementing more and more requirements for analysis, it is time to step back and think about the impacts of existing requirements. There is a need for greater modesty when selling the possible accomplishments of analysis. We need to reframe analytical requirements to help decision-makers rather than drive decisions, and to discern when analysis works and when it doesn't. When does it succeed

on its own terms by making policy decisions better? When does it facilitate democratic decision-making? When can it subvert it?

Briefly, the rest of the book proceeds as follows. In Chapter 2, I review the history of analysis in the regulatory process over the past 40 years. Chapters 3–6 form the bulk of my research on analysis in the regulatory process. These chapters include descriptions of the analytical requirements and the literature on these requirements. I then proceed to describe my interviews with nearly 50 analysts who have collectively worked on analyses of thousands of regulatory issues. Then in each chapter, I describe between one and three cases, including examples of where each type of analysis has succeeded and where it has failed. In Chapter 3, I discuss cost-benefit analysis; in Chapter 4, risk assessment; in Chapter 5, environmental impact assessments; and in Chapter 6, the many other forms of impact assessment required of regulators.

In Chapters 7–9, I present my conclusions from this empirical research. In Chapter 7, I synthesize the results of the case studies and the role that politics, bureaucracy, and law played in these cases. I suggest possible reforms that would improve the relationship between analysis and policy-making in Chapter 8. In Chapter 9, I offer my concluding thoughts. The field of policy analysis is a young one, perhaps just entering its adolescence. We are just now getting a sense of what it can and cannot do. My hope is that this book will help us understand how to better ensure that analysis in the policy process can reach its potential while also better understanding its limitations.

NOTES

1. Simon argued that economists and political scientists who depended upon rationality for their conclusions were dependent upon a false premise. Simon said that rationality was bounded and that individuals (including government officials) engaged in searches to find preferred choices. The searches concluded when an option that was satisfactory was found. This work has been greatly expanded upon in the decades since (Simon 1972; Forester 1984).
2. Nelson (1987) argues that the roots go even deeper. He traces the fascination with analysis back to the progressive movement of the early 20th century. While many others have moved on from the progressive idea that administration could be separated from politics and optimized, advocates of analysis, particularly economists continue to be influenced by this idea. Radin (2015, forthcoming) traces the history to debates over the use of science in policy after World War II featuring Vannevar Bush and Robert Oppenheimer.
3. Porter (1996) argues that the use of cost-benefit analysis in the Army Corps of Engineers from the 1930s through the 1950s is the crucial antecedent to the growth of comprehensive-rational analysis. I discuss the Army Corps experience in Chapter 3.
4. This theme was echoed in the 2014 President's Address before the Association of Public Policy Analysis and Management conference by Professor Angela Evans. She harkened back to a time when policy analysts contributed to debates and there was, "engagement by

a wide array of players, an understanding that perfection was not possible, and a commitment to keep watch over policies as they moved into implementation" (Evans 2015, p. 258).

5. Caldwell (1991) describes analysis as "vulnerable to definitional card-stacking."
6. This fear has not disappeared, it can still be found in the rhetoric of the Tea Party.

2. Regulation in the United States and comprehensive-rational analysis

When students are taught public policy analysis, or its many offshoots, few of them focus on regulation as the type of policy they will be analyzing. Indeed, analysis in its many guises informs many types of public decisions that are not strictly regulatory, including such examples as: the decision whether or not to build the Keystone Pipeline (which required an environmental impact statement (EIS)), and the decision to invest in nanotechnology (risk assessment). In fact, policy analysis in its earliest incarnations was created to analyze questions of national defense, and then expanded to questions of budgeting for social service programs (Radin 2013).

So why is regulation the focus of this book? The first reason is that regulation has grown in importance dramatically as a policy tool over the past several decades. Regulatory decisions made by bureaucratic agencies in the executive branch affect the air we breathe, the food we eat, and implement protections against the risk of terrorism, and the collapse of the financial system. They have costs that are in the billions of dollars per year. The number of lives extended each year due to their protections number in the thousands.[1]

In addition, policy analysis in many of its forms has a long and deep history with the rule-making process.[2] Since the 1970s, when regulation emerged as a significant policy instrument, there have been attempts to require the executive branch agencies that issue regulations to justify their actions with analysis. Decisions to reduce risk must be accompanied by risk assessments. Decisions which have a major impact on the U.S. economy must include an assessment of the economic costs and benefits. Decisions with a significant environmental impact must contain a comprehensive assessment of that impact. And agencies are frequently required to also measure the impact of their regulations on various communities such as small businesses, state and local governments, and families.

Finally, rule-making embodies the type of bureaucratic decisions described in Chapter 1, that Lindblom and others have long debated. Regulatory decisions take place within the bureaucracy but are clearly

subject to political pressures from the President and Congress. They involve the selection of policy options from various alternatives. Theoretically they could be made using the methods described by Lindblom (1959) as the root method or the branch method. As such, an examination of agency decision-making in the regulatory arena is an ideal laboratory to test the claims about the viability of comprehensive-rational analysis.

This chapter proceeds as follows. In the next section I will give an abbreviated history of regulation in the United States up through the early years of the age of analysis. I follow this with a chronicle of attempts to graft analysis on to the regulatory process. I will conclude the chapter with a brief account of where the ever-changing regulatory landscape stands today and introduce the empirical section of this book.

REGULATION IN THE UNITED STATES

In the U.S. Constitution the word "regulation" is never mentioned in the discussion of the powers of the executive branch. Yet the idea of policy-making in the executive, rather than the legislative, branch of government stretches back to the 19th century. Congress created the Interstate Commerce Commission (ICC) in 1887 as an agency to create policy regarding pricing and other aspects of the nation's growing railroad system. The wave of progressivism in the early 20th century saw the birth of many more executive branch agencies including the Food and Drug Administration (FDA) and the Federal Trade Commission (Eisner 2000).

But it was with the advent of the New Deal that scholars and practitioners of governance had to grapple with standardizing a process for policy-making outside of the legislative branch. The agencies created in the first term of President Roosevelt were numerous, and their missions varied greatly. Resistance to policy-making in the executive branch quickly grew, particularly among business interests whose activities were being constrained by the New Deal agencies. Businesses won important victories in court, but as the content of the courts changed with increasing numbers of Roosevelt appointees, it was clear that these victories were short-lived (M. Shapiro 1986).

Business interests turned to Congress to attempt to rein in the executive branch. The American Bar Association produced suggestions for reform of the administrative process that would restrict agency decisions. These proposals were strongly opposed by President Roosevelt and supporters of the New Deal in Congress. Still, one bill passed in 1940, known as the Walter-Logan Bill, which focused particularly on

restricting agency adjudicative processes, then the primary source of executive branch decisions. The bill was vetoed by President Roosevelt and the veto was upheld in Congress (Gelhorn 1986).

Political conditions were changing, however. As President Roosevelt appointed more federal judges, New Deal supporters worried less and less about judicial oversight of agency adjudication. When Roosevelt died and Harry Truman became President, however, these same New Dealers became increasingly concerned about changes in control of the legislative and executive branches. They began to see administrative procedural reform as a way of protecting executive branch agencies from oversight by the political branches of government (M. Shapiro 1986).

The resulting compromise was the Administrative Procedure Act, passed unanimously by Congress in 1946. The APA was in the words of one author a "fierce compromise" (Shepherd 1996). Supporters of the New Deal agreed to judicial oversight of the administrative adjudication process, granting regulated parties greater due process rights than they had previously possessed. However, the APA also created an entirely new policy-making mechanism, and notice and comment rule-making. And the rule-making process, while subject to judicial review, was entirely housed within executive branch agencies and independent commissions.[3]

Notice and comment rule-making requires agencies to publish (with some exceptions)[4] a proposed rule in the Federal Register. The proposed rule describes the regulation that the agency is contemplating, and gives a detailed rationale for the proposal. The agency also gives the public a chance to comment on the rule (usually 30, 60, or 90 days). Upon receiving public comments, the agency must consider the comments, and either change the regulation or explain its rationale for not adopting the suggestions of commenters. The agency issues a final rule upon completion of this process.

Agency regulations can be overturned by courts, according to the APA, for being "arbitrary or capricious." Over the years courts have determined that agencies must (among other things) give reasoned responses to public comments in order to not be considered arbitrary or capricious. The result has been a long preamble to final rules that describes public comments submitted to the agencies, and the agencies' reactions to these comments (West 2004).

The notice and comment process is intended to imbue the promulgation of executive branch agency regulation with a sense of democratic accountability (Davis 1969). Regulations are a form of policy-making that takes place outside the normal U.S. structure specified in the Constitution, which involves Congress passing a law and the President signing it. As such, there has long been concern about whether the

agencies which issue regulations to set public policy are responsive to public preferences. By forcing agencies to solicit public comment, and then respond to it, the hope was that rule-making, like law-making, would reflect the popular will to some degree. Some have argued that the notice and comment process also helps Congress exercise oversight over the regulatory process (McCubbins et al. 1999).

How well has the notice and comment process worked? Academic studies have produced mixed results. Several scholars have concluded that agencies pay little attention to public comment and it has been derided as "Kabuki theater" (Elliott 1992; see also Golden 1998, and Stuart Shapiro 2007). West (2004) found that while comments rarely play a substantive role in agency decision-making, they do function as a way of calling the attention of the political branches of government to issues that cause concern in the interest group community.

Others have found that agencies do respond to public comments. In particular, Susan Yackee, who has conducted the most sophisticated studies of the public comment process, concluded that, "interest group comments can and often do affect the content of final government regulations" (Yackee 2006, p. 119). She acknowledges that she studies only low-salience regulations and that her conclusion may not be generalizable to regulations with a higher political profile (Yackee 2006). In other work, she concluded that business interests were the groups most likely to have their concerns addressed by regulatory agencies (Yackee and Yackee 2006). This finding has been echoed by others (Wagner 2010b; Wagner et al. 2011).

The role of public comment in regulation is important for our understanding of how analysis functions for several reasons. First, analysis is often credited with facilitating participation by making clearer the impacts of regulatory decisions (Sunstein 2002). Indeed, as we will see in the chapters that follow, the interaction between analysis and participation is a key variable in how analysis functions. Second, analysis, like public comment, has been viewed as a "procedural control" on agency rule-making. It forces agencies to undergo another step in the rule-making process, with the stated hope that doing so will lead to "better" regulations (leaving open for the moment the definition of "better"). The successes and failures of public comment may have parallels in the successes and failures of analysis. Finally, some of the reforms suggested for better incorporating analysis into regulatory decisions involve increasing participation, and the story of notice and comment has lessons for the likelihood of success for these reforms.

THE WAVE OF SOCIAL REGULATION AND THE COUNTER-WAVE OF ANALYSIS

The1960s saw (among many other things) the passage of numerous statutes that directed agencies to issue regulations to improve public safety and health. Spurred by books such as Rachel Carson's *Silent Spring*, and Ralph Nader's *Unsafe at Any Speed*, there was a growing sentiment for the need for government regulation of industry. Dubbed collectively "social regulation" (as opposed to "economic regulation" which gave government a role in setting prices or quantities sold, or industrial governance, and was prevalent during the New Deal) these mandates directed agencies to restrict industrial decision-making so as to reduce risks to the public and to workers (Eisner 2000).

Many new regulatory agencies were created in the ten-year period between 1964 and 1973. These included the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the National Highway Traffic Safety Administration (NHTSA). The EPA in particular was given a wide mandate with numerous statutes from this period including the Clean Air Act, and the Clean Water Act. The EPA's authority was later augmented by the Resource Conservation Recovery Act, the Toxic Substance Control Act, and numerous other statutes.

At the same time, the statute that created the EPA also introduced one of the first requirements for comprehensive-rational analysis in the regulatory process. The National Environmental Protection Act (NEPA) required EISs for government decisions (including regulations) that would have a significant impact on the environment. Unlike the later requirements discussed below, this requirement was supported by constituencies that favored government intervention in the marketplace to protect public health. The hope was that by producing a thorough examination of government impacts on the environment, these decisions would be more likely to be environmentally friendly. I discuss the experience with EISs in Chapter 5.

The regulatory agencies of this era were given a great deal of discretion in setting standards for permissible exposures to risk. OSHA must protect workers "to the extent feasible."[5] Among the many standards that the EPA must follow when making regulatory decisions is to restrict emissions to a level that will "protect public health with an adequate margin of safety."[6] Standards such as these, throughout the statutes passed in this period, delegated the details of where to set standards for air emissions, auto safety, consumer product safety, and

worker protection to the agencies of the executive branch. These agencies had to decide what "feasible" and "adequate" meant.

The tool most readily available to agencies to set generally applicable standards was notice and comment rule-making. Throughout the 1970s, agencies issued hundreds of significant regulations using the rule-making process outlined in the APA. The EPA, with its multiple statutory charges, was particularly active. Also during the 1970s, the economy suffered under the weight of the oil embargo, and unemployment and inflation both climbed during the presidency of Jimmy Carter. The regulatory actions by bureaucratic agencies were blamed by their critics for the declining economic conditions (Eisner 2000).

It did not take long before industry opponents of executive branch agency regulation were on the counter-attack. One of the tactics they rallied behind was the need to analyze the impacts of agency regulation. Another was the argument that agency experts were biased against economic concerns (Jasanoff 1990). Throughout the 1970s, hearings were held and bills were proposed in Congress that would focus on the burden regulations imposed on small businesses, and the amount of paperwork that the executive branch was requiring the American public to fill out. After numerous failed attempts, Congress passed and President Carter signed the Paperwork Reduction Act (PRA)[7] in 1980 and the Regulatory Flexibility Act (RFA)[8] in early 1981 (Shapiro and Moran 2016).

The PRA required agencies to calculate the burden they imposed on the American public every time they collected information from ten or more individuals. Many of these information collections were contained in regulations. It also created a new office, the Office of Information and Regulatory Affairs (OIRA) which was charged with reviewing and approving agency requests to collect information. The RFA required these agencies to estimate the impacts of their regulations on small business any time a regulation had a "significant impact on a substantial number of small entities." The two statutes were manifestations of requirements for comprehensive-rational analysis that would grow in the decades ahead.

Industry interests also attacked the science behind agency regulations. They argued that regulatory agencies like the EPA and the FDA made assumptions in their analyses of public health hazards that were systematically designed to find harms to public health, and therefore regulatory science was inherently biased against industry. Defenders of regulation responded that agencies had a statutory responsibility to be protective, and make assumptions that tilted in a conservative direction. This did little to stem the call for more transparent risk assessment at executive branch agencies (Jasanoff 1990).

THE ADVANCE OF ANALYSIS

Meanwhile, the executive branch was busily imposing its own requirements for comprehensive-rational analysis in the regulatory process. President Nixon required "Quality of Life" reviews and President Ford mandated "inflationary impact statements," though these were easily ignored by regulatory agencies. In 1978, President Carter created the Regulatory Analysis Review Group (RARG) to review economic impacts of regulations. There were no requirements that agencies balance costs and benefits, however; and there was no authority within the RARG nor within the Office of Management and Budget (OMB) to reject rules that failed cost-benefit criteria (Tozzi 2011).

Comprehensive-rational analysis received its biggest boost since the passage of NEPA with the issuance of Executive Order 12291[9] by President Reagan shortly after he took office in 1981. The order required agencies – for each rule that would have an impact on the economy of more than US$100 million – to conduct a Regulatory Impact Analysis (RIA) which would contain:

> (1) A description of the potential benefits of the rule, including any beneficial effects that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits;
> (2) A description of the potential costs of the rule, including any adverse effects that cannot be quantified in monetary terms, and the identification of those likely to bear the costs;
> (3) A determination of the potential net benefits of the rule, including an evaluation of effects that cannot be quantified in monetary terms;
> (4) A description of alternative approaches that could substantially achieve the same regulatory goal at lower cost, together with an analysis of this potential benefit and costs and a brief explanation of the legal reasons why such alternatives, if proposed, could not be adopted; and
> (5) Unless covered by the description required under paragraph (4) of this subsection, an explanation of any legal reasons why the rule cannot be based on the requirements set forth in Section 2 of this Order.[10]

The newly created OIRA was charged with reviewing these RIAs and determining whether they were satisfactory. Agencies could not proceed with their regulatory efforts without OIRA approval (Tozzi 2011).

The new requirements for RIAs were immediately controversial. The criticisms will be detailed further in Chapter 3. In short, the RIA requirement (and implicitly cost-benefit analysis and comprehensive-rational analysis) were derided for being unethical in practice (Kelman 1981), a cover for political goals (Olson 1984), and as one of several

factors "ossifying" the regulatory process and making it impossible for regulatory agencies to promulgate regulations (McGarity 1992).

As the use of economic analysis became enshrined in the regulatory process, so too did the role of risk assessment, at least in the promulgation of those regulations designed to reduce exposure to risk. Risk assessment began as a practice in response to concerns about radiation exposure. It was also used by the FDA in the 1970s in response to statutory requirements that the FDA prohibit food additives that presented any risk of cancer. The FDA did risk assessments to attempt to show that the risk of certain additives was so low as to be effectively zero (Graham 1995). EPA under administrator William Ruckelshaus also began to emphasize risk assessment (Graham 1995).

The use of risk assessment, however, became much more common in regulatory decisions due to three developments. First, agencies needed to be able to calculate risk reductions in order to measure benefits for their RIAs required under Executive Order 12291. Second, the Supreme Court[11] told the OSHA that risk assessment was a useful way to demonstrate the need for regulation of workplace hazards (Graham 1995). Finally, anti-regulation forces, as described above, made flaws in agency science a centerpiece of their lobbying efforts (Jasanoff 1990).

Many anticipated that the role of economic analysis in regulation would diminish once a Democratic president took office. These expectations were not realized when, in 1993, President Clinton issued Executive Order 12866.[12] The order scaled back several of the requirements in President Reagan's Executive Order 12291 (most importantly the benefits of a regulation now needed to "justify" the costs rather than "exceed" them). More importantly, however, the Clinton order reaffirmed the importance of cost-benefit analysis in regulatory decision-making. From this point forward there have been few serious attempts to eliminate RIAs, although academic criticisms of economic analysis have continued well into the 21st century (Stuart Shapiro 2011).

The Republican Congress that came to office in 1995 added several analytical requirements. The Unfunded Mandates Reform Act[13] required both cost-benefit analysis in certain circumstances (when annual economic burdens on industry or state and local governments crossed the US$100 million threshold), and required the examination of impacts of regulations on state and local governments. The 104th Congress also amended the Regulatory Flexibility Act by passing the Small Business Regulatory Enforcement Fairness Act[14] that had among its provisions requirements that certain agencies (EPA and OSHA) provide information on impacts on small businesses earlier in the regulatory process.

The Clinton Executive Order was reaffirmed by both Presidents George W. Bush and Barack Obama. President Bush's appointee to head OIRA, John Graham, turned to strengthening the role of scientific analysis in the regulatory process. During his tenure OIRA wrote guidelines implementing the Information Quality Act (IQA), a statute passed as an appropriations rider at the end of the Clinton Administration. The IQA and the implementing guidelines set up a process for the public to object to information used to support an agency regulatory decision if that information did not meet certain quality standards (Wagner 2003).

Graham also oversaw the updating of OIRA's standards for agency risk assessment.[15] Finally, OIRA issued a bulletin[16] for regulatory peer review. This bulletin set up standards for agencies to conduct peer review of significant documents supporting their regulatory efforts. These efforts, combined with Graham's expansion of the OIRA staff (the staff had been contracted significantly since the 1980s) to add a number of scientists and risk analysts, were intended to increase the oversight of agency science and risk assessment.

President Obama also appointed a champion of comprehensive-rational analysis to lead OIRA in his first term. Like Graham, Cass Sunstein was a controversial choice. He had long been an advocate of cost-benefit analysis, hailing its ability to improve the transparency of regulatory decisions, as well as its democratizing effects (Sunstein 2002). For the second time in 16 years, a Democratic President supported by advocacy groups opposed to cost-benefit analysis had affirmed his support for the technique as an aid in the regulatory process.

Sunstein attempted to increase the lessons from behavioral economics to individual regulations (Sunstein 2013). He did not attempt to add any new comprehensive-rational analytical techniques to the regulatory process but was a strong advocate for the retrospective review of older regulations. Retrospective review, embodied in President Obama's Executive Order 13563[17] requires agencies to analyze the impacts of their regulations *after* they have been in effect for a certain period of time. The idea is that if agencies find that regulations are not achieving their goals (or if the costs are higher and/or the benefits lower than expected) agencies should rescind or modify these rules.

Comprehensive-rational analysis has been very popular in Congress during the Obama Administration. After the Republican takeover of 2010, the House of Representatives has considered and passed a number of bills that would expand the use of analysis in the regulatory process. Several bills would expand the use of cost-benefit analysis to independent agencies. Others would strengthen the existing requirements in Executive

Order 12866 by putting them into law and perhaps adding a Congressional review component. Still others required new impact analyses including a "distributional impact analysis" that would require agencies to determine whether regulations unduly burdened the poor.[18] As this book went to press, none of these statutes has been passed into law.

CONCLUSION: REGULATION AS ANALYTICAL REFUGE

At the dawn of the age of comprehensive-rational analysis, the era of social regulation was also dawning. It is possible that both grew out of a common impulse that well-thought-out government actions could ameliorate undesirable social conditions. Indeed some have traced both movements to the Progressive Era of the early 20th century (Nelson 1987). On the analytical side, this meant using techniques such as the Planning, Programming, and Budgeting System (PPBS) to evaluate government programs and maximize the effectiveness of government spending. On the regulatory side, this meant using government power to compel private actions to correct social ills. At first, these two outgrowths proceeded on separate tracks.

Comprehensive-rational analysis faded from the federal budgetary process with the decline of PPBS, despite the growing prevalence of individuals trained in public policy analysis. Meanwhile, opponents of regulation turned to analytical approaches as a possible counterbalance to executive branch agencies that were issuing regulations throughout the 1970s. By the early 1980s, cost-benefit analysis, increased use of risk assessment, and numerous forms of impact analysis joined EISs as requirements for various subsets of agency regulatory proposals.

The decades that followed reaffirmed the existing forms of analysis in the regulatory process and added a few new ones (mostly different forms of impact analysis). As regulatory decisions entered national debates about the slow recovery from the Great Recession, proposals to increase the role of analysis in the rule-making process picked up speed. Similar calls for forms of comprehensive-rational analysis were largely not echoed in other venues of policy-making.

Therefore, if one wants to evaluate the performance and potential of comprehensive-rational analytical techniques to influence policy, the regulatory process provides the best, and perhaps the only, place to do so. The promise of analysis is improved policy. Have these various forms of analysis led to better regulations? The alleged potential curses of analysis are paralyzed decision-making, the subversion of democracy, and the

devaluing of non-quantifiable policy goals. Has our experience in the regulatory process justified any of these fears?

The goal of the second part of this book is to explore these questions by examining the use of various forms of comprehensive-rational analysis in the regulatory process. In each relevant chapter, I will start by reviewing the literature on the use of that form of analysis in regulatory decision-making. I will then report on a series of interviews with federal agency personnel engaged in performing analysis to support agency regulatory decisions and presenting cases of successful and failed uses of analysis. I will conclude each chapter by assessing the performance of analysis in regulatory decisions and evaluating the factors that made it a success or failure.

In the next chapter, I begin with the form of analysis that most clearly mirrors the comprehensive-rational analysis described by Lindblom, cost-benefit analysis. Chapter 4 follows with an examination of risk assessment in the regulatory process. In Chapter 5, I turn to the subject of EISs and their use in regulatory decisions. Finally, in Chapter 6, I look at the various forms of impact analysis (regulatory flexibility analysis, analysis of impacts on state and local governments, and numerous other impact statement requirements).

NOTES

1. The Office of Management and Budget reports annually to Congress on the costs and benefits of regulations. The annual reports can be found here: http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress (last accessed July 20, 2015).
2. Rule-making is the term used in the Administrative Procedure Act for the process that agencies must follow when issuing regulations.
3. Administrative Procedure Act 1946 Public Law No. 79-404, 60 Stat. 237.
4. Agencies are allowed to issue "direct final rules" for minor policy changes where they expect no public comment (but must retract the rule if there is an objection). They may also issue an "interim final rule" in cases of public emergency. The interim final rule takes effect immediately but the agency also solicits comment and may change the rule later (Asimow 1999).
5. Pub. L. 91-596, 84 Stat. 1590 (1970).
6. Pub. L. 88-206, 77 Stat. 392 (1983).
7. Pub. L. No. 96-511, 94 Stat. 2812 (1980).
8. Pub. L. 96-354, 94 Stat. 1164 (1981).
9. Executive Order No. 12291, 3 C.F.R. 127, 128 (1982).
10. Executive Order No. 12291 Section (3)(d).
11. Indus. Union Dept. v. Amer. Petroleum Inst. 448 U.S. 607 (1980).
12. Executive Order No. 12866, 58 Fed Reg. 51735, Admin Mat 45070 (September 30, 1993).
13. Pub. L. 104-4, 109 Stat. 48 (1995).
14. Pub. L. 104-121, 110 Stat. 857 (1996).
15. See http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-24.pdf (last accessed July 20, 2015).

16. See http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-03.pdf (last accessed July 20, 2015).
17. Executive Order No. 13563, Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821 (January 18, 2011).
18. For a complete list of the bills considered by the 113th Congress, see http://regulatorystudies.columbian.gwu.edu/regulatory-reform-bills-113th-congress (last accessed July 20, 2015).

3. Cost-benefit analysis and the regulatory process

All of the types of analysis described in this book have their roots in the movement toward comprehensive rational analysis that flowered in the 1960s. But of all the branches of comprehensive-rational analysis that are employed at various stages of the regulatory process, cost-benefit analysis most clearly mirrors its progenitor. It also most clearly reflects the hopes of proponents of analysis and evokes the fears voiced by Lindblom and others about the dangers of too much analysis.

Cost-benefit analysis finds its origins in welfare economics. While the early proponents of Program Planning and Budgetary Systems (PPBS) were trained in the new field of decision science, much of the impetus for an increased role for analysis in public policy-making came from economists. As PPBS faded from the budgetary process in the early 1970s, proponents of comprehensive-rational analysis found a new policy area that, in many ways, seemed more amenable to economic analysis. That new area – regulatory policy – was becoming increasingly prominent in political debates.

Government regulation of the private sector had long been of interest to economists. Among the most prominent economists in the United States were those who argued that regulation would inevitably serve the needs of powerful organized interests (Stigler 1971; Peltzman 1976), and those who argued that government agencies could use regulation to pursue their own goals (Niskanen 1974). The intellectual foundations of the idea that government regulation could reduce social welfare were coupled with the self-interested motivation of the business community which felt it was being over-regulated by the agencies created in the statutes written to protect public health between 1964 and 1973.

These movements, in reaction to the passage of the Clean Air Act, the Clean Water Act, the Occupational Safety and Health Act, and other public health oriented statutes, resulted most directly in two branches of analytical requirements for regulatory agencies. One, which will be described in Chapter 6, was the movement toward requiring agencies to detail impacts of their regulations on particular communities, especially small businesses. The other was to require that agencies conduct a more

comprehensive and rational analysis of their regulatory proposals prior to their promulgation. This branch led to the adoption of cost-benefit analysis (within the context of a broader "regulatory impact analysis").

Cost-benefit analysis had been used in government decisions since the 1930s. The Army Corps of Engineers was required to conduct such analyses of its major projects. The Flood Control Act of 1936[1] said that Corps flood control projects could go forward only if "the benefits to whomsoever they may accrue are in excess of the estimated costs." Over the next several decades the Corps regularly conducted cost-benefit analysis but these analyses were often controversial. As Porter (1996, p. 160) says about the estimates of the benefits of Corps projects, "The multiplication of benefits provided a helpful general strategy for getting projects over the cost-benefit hurdle."[2] Porter gives numerous examples of the Corps estimates for both benefits and costs being disputed by other interested parties.

Porter also describes some actions by the Army Corps that would find echoes in the later regulatory experience with cost-benefit analysis. He describes how analytical findings were most contorted in very politically controversial decisions, and how analyses on most water projects followed established routines. There was an attempt to systematize these routines in an interagency working group entitled, "Proposed Practices for Economic Analysis of River Basin Projects" (Subcommittee on Benefits and Costs 1950). Porter (1996) also describes how differences over analytical approaches between agencies with competing goals led to frequent calls for an outside independent voice to conduct the analyses.

Cost-benefit analysis first surfaced in the regulatory process several decades later, in the 1970s. As detailed in Chapter 2, the Nixon, Ford, and Carter presidencies took cautious steps toward incorporating cost-benefit analysis into agency regulatory decision-making. Caution was thrown to the wind, however, in 1981, when President Reagan issued Executive Order 12291 requiring a tabulation of the costs and benefits for all agency regulations with an impact of more than US$100 million in any calendar year. This requirement has existed in one form or another ever since.

In this chapter I will review the role of cost-benefit analysis in regulatory decision-making, with a particular eye toward discerning its impacts on bureaucratic decisions. In the next section, I review the literature on this subject. I then detail my interviewing protocol and describe the agency economists with whom I spoke. Finally, I discuss the results of these interviews and some recent regulatory cases where cost-benefit analysis made a difference in decisions, and others where it did not.

LITERATURE ON REGULATORY COST-BENEFIT ANALYSIS

The rhetoric supporting the adoption of cost-benefit analysis in the regulatory process centered on a few arguments. Economists argued that cost-benefit analysis would lead to regulations that achieved the goals of regulatory statutes at lower costs (Weidenbaum 1975). DeMuth and Ginsburg (1986) argued that analysis and regulatory review by the President, which was also introduced in the Reagan order, were complementary because they both encouraged accountability and a broad, balanced view of regulatory decisions. As such these requirements were a corrective to agencies biased by their focus on their missions. Other arguments in favor of cost-benefit analysis have included forcing regulators to consider other factors they might not otherwise think about, increasing capacity building in regulatory agencies, and increasing information about regulatory consequences both to the public and government officials (Harrington and Morgenstern 2004).

However, the early academic literature on cost-benefit analysis consisted much more of criticisms of the new requirement than praise for it. Many of these criticisms echoed the arguments made earlier against comprehensive-rational analysis but in a more concrete, less theoretical form. Echoing one of Lindblom's points, Steven Kelman (1981) made the argument that cost-benefit analysis was prima facie unethical. He argued that the very act of monetizing components of public welfare served to devalue them, and that cost-benefit analysis inevitably led to immoral decisions. Later scholars built upon this line of reasoning and argued that cost-benefit analysis inevitably would be biased against regulations that were intended to protect public health (Dreisen 2006).

A second criticism echoed other concerns about comprehensive-rational analysis (Jenkins-Smith 1990). The role of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) as arbiter of the sufficiency of the agency analyses led some to suspect that rules that were rejected for insufficient analysis were really being subverted for political reasons. Olson (1984, p. 53) wrote, "As one key OMB official notes, 'debate on the merits of economic analysis doesn't help resolve the real issues where OMB has budgetary philosophical, or political problems with a rule, the regulatory analysis is used as a key in holding up or changing [Environmental Protection Agency] EPA action.'" According to this argument, because cost-benefit analysis is dependent on so many subjective assumptions, its abuse by political actors is inevitable (Cole 2012).

The third main criticism of cost-benefit analysis was that requiring that it be conducted prior to the issuance of any significant regulation would make the regulatory process exceptionally burdensome to federal agencies. According to these critics, these burdens would result in long delays in regulations designed to protect public health and might even lead to agencies abandoning rule-making as a policy-making option (Mashaw and Harfst 1990; McGarity 1992). This worry contains clear echoes of the argument voiced by Lindblom that comprehensive-rational analysis was, in practical terms, impossible.

With the numerous academic arguments that cost-benefit analysis was dangerous to the advancement of public health through regulation, one might imagine that opponents of such regulation would be thrilled with its adoption (and its later reaffirmation by President Clinton). One would be wrong. Largely these proponents of cost-benefit analysis have argued that the analyses conducted by agencies were insufficiently rigorous to achieve the goals of making regulatory policy more economically efficient. Hahn and Tetlock (2008) reviewed the literature on the effect of cost-benefit analysis and came away unconvinced that it had much of an impact. (They note, however, that in a world where regulatory impacts are frequently measured in the billions of dollars, even small improvements attributable to cost-benefit analysis do matter.) They criticize as anecdotal much of the evidence presented to date in support of the conclusion that cost-benefit analysis has had a significant impact.

Shapiro and Morrall (2012) looked at 109 regulations in an attempt to determine whether more complete analysis led to more cost-effective policy decisions. They found no correlation between the level of information in the analysis and the net benefits of the regulation. Instead they determined that political factors were much more important in regulatory policy decisions. The less politically salient regulations were the ones most likely to have high net economic benefits. Similar critiques can be found in other recent studies (Ellig and McLaughlin 2012; Ellig et al. 2013). These studies all look at whether the analyses contain important information but they do not directly measure the quality of the analyses. One study has looked at whether, as required by executive orders, regulatory impact analyses (RIAs) include examination of distributional impacts and found them wanting (Robinson et al. 2014) while also noting the difficulty of examining the distributional consequence of regulations.

The frequent criticism of cost-benefit analysis in the regulatory process from across the ideological spectrum has led to continual calls for its repeal or reform. Supporters of cost-benefit analysis have focused their suggestions for reform on improving the existing use of cost-benefit analysis. Typical of these proposals is an article by Hahn and Sunstein

(2002) calling in its title for "deeper and wider" cost-benefit analysis. Often these arguments focus on ensuring a more uniform application of cost-benefit analysis and better agency compliance with OMB guidance on the subject.[3]

Hahn and Sunstein (2002) (and others) have also called for judicial review of agency cost-benefit analyses as a means of strengthening the quality of the analysis. As I will discuss in Chapter 5, judicial review has had ambiguous effects on the influence of environmental impact analyses. Several of the regulatory reform proposals that Congress has considered have contemplated an independent body to review or perhaps conduct regulatory analysis (see also Niskanen 2003).[4]

In recent years, supporters of regulation, who have traditionally opposed the use of cost-benefit analysis, have, in some cases, called for reform of the method rather than its repeal. Most prominent among these have been Richard Revesz and Michael Livermore (2008). They say, "Yet cost-benefit analysis is only inherently antiregulatory if proregulatory groups are gulled into passivity by that belief. Proregulatory groups must shake off their torpor. Their opposition to cost-benefit analysis, even if it was understandable at the outset[,] has become very counterproductive." Revesz and Livermore argued that there are many ways to reform cost-benefit analysis to ensure that it leads to fairer (pro-regulation) outcomes and urged liberals to make these arguments. Among the reforms they suggest are using cost-benefit analysis to analyze deregulatory actions as well as regulatory ones, a qualitative listing of costs and benefits, and more careful use of discounting when evaluating future benefits of regulation.

The call by Revesz and Livermore for a qualitative listing of costs and benefits has found echoes in other calls for reforming regulatory impact analyses. Harrington, Heinzerling, and Morgenstern produced a set of recommendations very similar to those of Revesz and Livermore, including one to "Include in RIAs a detailed description of expected consequences as physical or natural units, without monetization or discounting" (Harrington et al. 2009, p. 225). Carrigan and Shapiro (2014) note that the length of an RIA has increased fourfold between 2000 and 2012[5] and propose simplifying the analysis and doing it earlier in the regulatory process to make it more useful to decision-makers.

The works cited above all look at the output of the cost-benefit analysis process, the analyses themselves. The suggestions for reform may very well have merit (although some of them conflict with each other; deeper and wider cost-benefit analysis vs. simpler cost-benefit analysis), but they are hard to evaluate without understanding how

analysis is actually produced and used. Reading the critiques of cost-benefit analysis, one can easily be left with the dual impressions that analysis has played an outsized role in regulatory policy and that it has played no role at all. To find where in between these extremes the truth lies, I believe one must go inside the bureaucracy to understand economists and the role they play.

There have been relatively few works that have delved inside the bureaucracy to examine the process of conducting a cost-benefit analysis and how that analysis affects actual decisions. The most important work to do this was a compilation of 12 case studies of Environmental Protection Agency (EPA) regulations in the 1980s and 1990s (Morgenstern and Landy 1997). Each case study was written by an economist who worked on the cost-benefit analysis of the regulation. The authors of each case detailed the key concerns in development of the economic analysis and then how (and if) the analysis was used by decision-makers. The cases had an impressive degree of variance with some where analysis clearly played an important role in decision-making, and others serving largely a decorative function.

Morgenstern and Landy (1997, p. 456) synthesized the cases in the conclusion of the volume. They say,

> In all the cases examined, the economic analysis did in fact contribute to improving the rules; the value of such improvements likely dwarfs the one-time cost of conducting the analyses. Despite this finding, in many instances the analyses did not prove terribly useful to decision-makers. It is certainly fair to say that significant opportunities for real improvements were missed in many cases. Numerous factors, including politics could explain this situation.

The authors go on to cite three factors (Morgenstern and Landy 1997, p. 472) that limited the role of analysis.

- The underlying scientific and risk information was so uncertain that it provided an insufficient basis on which to conduct an economic analysis.[6]
- The economic analysis was technically flawed in one or more critical ways.
- The economic analysis was not designed to address a sufficiently rich array of policy options and was thus rendered irrelevant to actual policy and regulatory decisions.

These issues (along with a few others) are echoed in my interviews below.

In an unpublished working paper, Richard Williams (2008) interviewed a dozen senior economists and surveyed them regarding their perceptions about the use of their work. Most economists (perhaps like most people in a large organization) feel that their work is underutilized. Williams, a supporter of economic analysis, recommends that economists should be separated from program offices, decision-makers should be better trained in how to use economic analysis, and more economists should be in managerial positions.

The purpose of this chapter mirrors that of Williams and it serves to supplement and update the EPA analyses discussed by Morgenstern and Landy (it also looks at a much broader array of agencies and policy-making contexts). Also, both of these impressive works focus more on discussions of factors that inhibit the role of cost-benefit analysis. As will be seen below, there are also times when it does play a role, and it is my hope to come up with some general factors that determine both when analysis plays a role and when it doesn't. By talking to economists who have written cost-benefit analyses within agencies, my hope was twofold. First, I wanted to focus on the institutional factors that inhibit or enhance the role of analysis in regulatory decision-making. Second, I wanted to develop a few simple case studies of analysis influencing or being ignored as agencies made regulatory policy decisions. Before proceeding to describe the results of the interviews, I need to describe the protocol used for the interviews.

METHODOLOGY

The process I followed for the interviews of economists was also used in my interviews of risk assessors and environmental impact assessors in Chapters 4 and 5. Interview subjects were tracked down using personal contacts and membership in professional societies (the Society of Benefit Cost Analysis, the Society of Risk Analysis, and the National Association of Environmental Professionals). Further interview subjects were found through the process of snowball sampling (Goodman 1961) whereby interview subjects were asked for other possible contacts who were knowledgeable on the relevant subjects. Where I conducted a particular case study, I asked the economists involved with the analysis to suggest other subjects who were aware of the rule-making in question.

I interviewed 16 economists who are either currently employed in federal agencies or have recently retired from government service. The 16 economists had experience at 11 different federal agencies (some worked at more than one agency during their careers). The agencies

covered were: the EPA, the Food and Drug Administration (FDA), the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Consumer Product Safety Commission (CPSC), and the Departments of Transportation, Homeland Security, Health and Human Services, Labor, and Agriculture. The economists had collectively either developed or reviewed over 700 RIAs over their careers.

The interview subjects were promised confidentiality. Hence, no names of anyone I interviewed will appear anywhere in this book. Such guarantees of confidentiality are standard in good qualitative research in order to ensure that interview subjects are comfortable speaking freely (Rubin and Rubin 2011). They are particularly important in this context given that subjects were asked about government decisions made during their tenure that they may have disagreed with.

The interview protocol can be found in Appendix 1. For the economists, after a few introductory questions to gauge the subject's experience with creating or reviewing RIAs, I asked each subject to come up with three cases. The first was an analysis they had recently worked on, and I probed to get their perceptions about whether the analysis played a role in the regulatory decision. I then asked the interview subjects to come up with a case from any time in their career when an analysis had clearly affected a policy decision, and one where it had clearly been ignored and the policy decision was made contrary to the analytical conclusions. Finally, I asked for their views on generalizable factors which helped to determine the role that analysis played at their agencies.

INTERVIEWS

The picture painted by my interview subjects is much more nuanced than that typically featured in the debates over cost-benefit analysis. It is true that the people I spoke with pointed to instances of regulations that were stopped in their tracks when economists demonstrated that the costs far outweighed the benefits. They also came up with a number of stories that described how policies were made long before economists were brought into the decision-making process and they were asked to justify decisions rather than evaluate them. One of each of these instances is described in the case studies below.

But the general picture is one that is more of a give-and-take between economists and the other forces within the bureaucratic agencies in which they work(ed). Economists conducting cost-benefit analyses on regulations contend with political, legal, and bureaucratic constraints on

their work. At times they are successful in this endeavor. Not surprisingly, at times they are not. Their experience tells us a great deal about the ability to impose comprehensive analytic rationality on a process designed with many goals.

How does Cost-Benefit Analysis Fit in the Regulatory Process?

There is tremendous variation both within agencies and across agencies (and over time) regarding how cost-benefit analysis fits within regulatory decision-making. In some cases agency economists described regulatory processes where they were brought in right at the beginning of a decision-making process. Other times it was after the agency had made its decisions and selected its preferred policy alternatives. As one agency economist said, "It varies dramatically. Sometimes it is an afterthought, sometimes in the very beginning because they know have a problem in getting the economic analysis through the process."

The economists were nearly unanimous in agreeing that the earlier they were brought into their agency decision-making process, the more influence they could have. One economist described the struggle to be at the table in the beginning as "an ongoing campaign." Another pointed out the benefits to the agency if economists were there from the beginning, "we often found that the agency had committed to an approach that we thought was wrongheaded. It would save time if we had been brought in to the development of the rule earlier." Earlier involvement also benefits the quality of analysis itself. One person I spoke with said, "Often, we just plunge into the analysis, largely because we get started so late and have so little funding that we focus on 'getting things done' rather than thinking carefully first. Scoping and screening could also help us develop more flexible models, which can accommodate unexpected policy changes or new information."

Most agencies have rule-making teams that work on significant rule-makings. If an economist is well integrated into this team, their role is important but hard to distinguish. As one interview subject put it, "When the team is working well, you don't even realize it … If you have a good team, that [economic influence] gets done without anyone knowing it." Several economists also described their roles in the agency as educating program staff who knew only about their own area of interest. One economist described the surprise when program staff were asked to come up with alternatives to their preferred policy, "Agencies come up with whatever they want and when you ask for alternatives they say, 'What do you mean alternatives, this is what we want to do.'"

What determines when economists are brought in to a rule-making process? My interview subjects had different views on this issue. Some argued that they were more likely be brought in early and listened to on complex rules. On simpler rules, the agency personnel felt as if there was no role for economists to play and economists were just asked to justify the decisions. Others pointed to political factors but had different views on the role of these factors. If the regulation was a pet project of an agency head, then economists were unlikely to be consulted until the last moment. But in other cases, the high political salience of a regulation led to bringing economists in early to ensure that the cost of a rule would not derail its chances of being promulgated. And there was variation in the stage when economists were consulted from agency to agency.

Cost-Benefit Analysis Making a Difference

Several of the agency economists interviewed agreed that the biggest role that they played in the regulatory process was invisible to the general public. They noted the regularity of stopping ideas where the costs were high and the benefits were negligible. One said, "I have had people stop working on rules after my presentations. They realize they don't have the data." Another noted, "We at least stopped the most egregious cases." Economists also noted that occasionally major changes in policy occur long before regulations are made public as a result of the RIAs casting light on significantly flawed proposals within the agency.

This stopping "egregious cases" is largely absent from the literature on cost-benefit analysis in the regulatory process.[7] Because these cases never even make it to the stage of public comment, the public (and the scholars that study regulatory cost-benefit analysis) never see these examples. If my interview subjects are correct, however, this may be one of the most profound influences of comprehensive-rational analysis. It may not do what it is advertised as far as selecting the best alternative policies, but it may help to avoid selecting the worst.

The economists also noted an important interaction between cost-benefit analysis and public comment. They noted the role highlighted in the literature regarding the increase in transparency about agency decisions that comes from cost-benefit analysis (Sunstein 2002). They also noted that economists were often brought in to evaluate economic claims made by public commenters; "I would say that having the analysis available helped resolve differences between the original agency position and public comment," said one in describing a particular rule. Do public claims of huge costs have merit? The agencies seem to need economists trained in cost-benefit analysis to evaluate such claims.

One of the important differences between cost-benefit analysis and the other types of comprehensive-rational analysis found in this book is the role of the OIRA. OIRA is specifically instructed to review the regulatory impact analysis that accompanies an economically significant rule. No well-placed office plays the same role for risk assessment or environmental impact assessment (although OIRA may take that role upon itself). Does the presence of OIRA increase the role of economic analysis in regulatory decision-making?

My interview subjects largely agreed that it does, but not in the way that is perceived in external debates about OIRA. These debates often focus on OIRA review and the changes that occur during this review (Haeder and Yackee 2015). Agency economists said that OIRA's largest function was that it allowed them to assert themselves within agency discussions. By arguing with program staff and general counsel offices that unless the rule was modified, it "would never get through OMB," agency economists had a way to influence agency deliberations. OIRA is often treated as a boogeyman in the public debate. Agency economists have used this image to increase the influence of economics in regulatory decision-making within their agencies. This is quite different to how OIRA is often portrayed in academic debates where scholars focus on its role in delaying regulations or as an instrument of presidential influence (Stuart Shapiro 2011).

One counter-example comes from an economist at an independent agency. Independent agencies are free from OIRA review. An economist at the CPSC, though, asserted that this independence often increased the role of economics. This economist pointed to an example when the CPSC had three commissioners, one who was very pro-regulation, one who was anti-regulation, and a "swing vote." The swing vote was very interested in what the economic analysis had to say and often was swayed by it.

This instance, however, points to one other factor that affects the role of economics in both independent and executive agencies. Again and again, interviewees mentioned the role of personality, both of economists and of agency leaders, as being a crucial factor. If the economist was good at "selling the analysis" and working the bureaucracy (a factor mentioned by Meltsner (1976)), then economics played more of a role. If the agency head (or even one of the commissioners) was disposed toward economic thinking, then economists had an audience for their ideas. If not, they were much more likely to be ignored.

Cost-Benefit Analysis being Ignored

One factor was mentioned by more of my interview subjects than any other as leading to the wholesale ignoring of the results of economic analysis. If an agency promulgated a regulation under a statute that left agency decision-makers with little discretion on policy choices, then there was no room for analysis to affect the regulatory decision. This was particularly important in homeland security regulations (both those issued by the Department of Homeland Security (DHS) and the bioterrorism regulations issued by the FDA), where Congress passed very prescriptive statutes and the regulations were merely implementing policy decisions made in the legislative branch.

Politics within the executive branch was also a common scapegoat for the sidelining of economic analysis. If a regulation was a priority for the White House, or for a particular agency head, then the analysis was less likely to sway the selection of a policy alternative. One former agency economist described this in broad terms, "Sometimes the political winds sneak things through. Sometimes you know to look the other way." Another said that some political leaders had "more of an inclination to change the analysis than the requirements in the regulation." Politics complicates the role of OIRA, which has the dual mission of reviewing cost-benefit analyses and implementing the preferences of the President and White House staff (Arbuckle 2011). OIRA's presence places cost-benefit analysis in a more political context than other forms of comprehensive-rational analysis, which have no comparable institution supervising their implementation.

Heads of agencies responsible for safety (consumer safety, transportation safety, worker safety) seemed particularly likely to be adamant about a regulation coming out in the wake of a highly publicized accident. Under pressure from victims and families of victims, as well as Congressional committees, a significant accident often leads to a regulation that economic analysis suggests is ill-advised. One economist described the dynamic this way, "The way the incentive structure works is that there is an accident and you have to respond. As an economist all you are asked to do is add up numbers later to make someone's idea for a solution work."

Bureaucratic structure was also cited as an impediment to cost-benefit analysis. Specifically, when economists were located within the program office responsible for drafting a regulation, they had less influence on regulatory decisions. "As long as program people write performance appraisals of economists, they will get the results they want. They don't have to say they want a particular outcome but people aren't stupid. The lack of independence at the agencies, I know people all over government

and they have the same problem," was how one interview subject described it.

Above, I discussed the timing of the involvement of economists in regulatory decisions. This interacts with the bureaucratic location of the economists in numerous ways. On the one hand economists within a program office will be more likely to be in meetings where a regulation is discussed within that office but their input may not be paid attention to. Economists located elsewhere at the agency or department will provide a more neutral perspective but they need to be actively invited to participate in the decision-making process.

Somewhat related to the structural issues are the limitations on resources devoted to economic analysis. Numerous interview subjects highlighted the oxymoronic nature of political leaders who support economic analysis and also support the defunding of the offices that conduct such analysis. I was told that the "number of analysts in government is decreasing," and that "there were too many projects for too few economists."

One other issue was mentioned by numerous interviewees, and it likely underlies a number of the other limitations on the use of economic analysis. Numerous economists acknowledged that their discipline is not one that is designed to give the clear answers that decision-makers in a political context often desire. As one economist put it, "The reason is the information is ambiguous. You can argue both sides." As described in the literature on cost-benefit analysis, economics is a social science, and as such it provides answers that are necessarily couched in uncertainty. This uncertainty leaves room for political or bureaucratic actors with a particular agenda to question economic analyses that point in a different direction from their preferred solutions. Interview subjects also described how uncertainty magnified the role of personality described above. Some economists are better at presenting uncertain outcomes to agency leaders and some agency leaders are better at grappling with the implications of uncertainty.

The role of uncertainty is amplified by challenges to information that is used as inputs to the economic analysis. In policy areas where the goal of regulation is to reduce risks to the public, numerous economists complained about the information on risks that they received from agency scientists. This subject will be discussed in much more detail in the next chapter. It does serve to highlight, however, that science itself is rooted with uncertainty, and the problems that uncertainty presents in a political context are even greater for a social science like economics.

Concluding Observations from the Interviews

The reforms suggested by the economists I spoke with generally flowed naturally from the comments above. Statutes that give agencies more discretion in agency choices were uniformly desired, as often economists felt that economically efficient choices were precluded by statutory prescription. Ironically the discretion given to regulatory agencies has often been blamed for the increasing costs of the regulatory state. The interview subjects indicate that Congress is little better at making economically sound decisions than the agencies they often blame for regulatory costs.

Of course discretion to agencies will only result in a greater role for cost-benefit analysis (and more generally comprehensive-rational analysis) if the analysts are well positioned within the agency to have an influence. From the perspective of the economists, independence from the program office within the agency was critically important. Many also emphasized that such independence was only effective if a representative of the independent office was in the room very early in the decision-making process. If analysts (economic or otherwise) were absent when the agency makes its initial selection of policy alternatives, they will inevitably be asked to produce an analysis that justifies the pre-selected choice. The best that can be hoped for in that case, is to nibble around the edges and make marginal improvements to that choice.

Economists come to the question of the role of cost-benefit analysis with an obvious bias. They clearly would like to see analysis play more of a role. Still, I found that the interview subjects had a relatively nuanced view about the role they played. They often realized the reasons for limitations on their power and many of them acknowledged that decision-making in a democratic system of government required a balancing of values including economic efficiency. In the next section, I detail three brief case studies of cost-benefit analysis in the regulatory process. My hope in presenting these cases is to illustrate with concrete examples when comprehensive-rational analysis affects agency policy-making and when it doesn't.

CASE STUDIES

Case 1: Aircraft Repair Station Security: Major Revisions due to Reaction to a Cost-Benefit Analysis

On December 12, 2003, Congress passed the "Vision 100: Century of Aviation Reauthorization Act" revamping a number of aspects of the

regulation of the aviation industry.[8] Section 611 of the statute required an assessment of the state of aircraft repair stations and 611(f) stated, "Not later than 240 days after the date of enactment of this section, the Under Secretary, in consultation with the Administrator, shall issue final regulations to ensure the security of foreign and domestic aircraft repair stations."

The 240 day deadline was not met. The Transportation Security Administration (TSA) issued a proposed rule entitled, "Aircraft Repair Station Security" on November 18, 2009. The TSA described repair stations as, "those facilities certificated by the FAA to perform maintenance, repair, overhaul, or alterations on U.S. aircraft or aircraft components, including engines, hydraulics, avionics, safety equipment, airframes, and interiors," and noted that there were 4227 domestic repair stations and 694 foreign repair stations (TSA 2009a).

The proposed regulation required these stations to, "adopt and carry out a standard security program." The bulk of the regulation specified the components required in such a security program. The TSA summarized the requirements as follows,

> describe the specific measures the repair station has implemented to identify individuals authorized access to the repair station, aircraft, and aircraft components; control access to the repair station, aircraft, and aircraft components; challenge individuals who are not authorized access and use escort measures for authorized visitors; provide security awareness training to all employees; verify employee background information; designate a security coordinator; and establish a contingency plan.

The regulation also delineated the authority of the TSA to conduct inspections of the repair stations.

The economic benefit of the regulation was a decreased likelihood of terrorist attacks via sabotage of an aircraft via a repair station. Because the probability of such an attack is necessarily speculative, an accounting of the benefits is impossible. Instead, the TSA carried out a break-even analysis. A break-even analysis answers the question, "How many adverse events must be prevented for the benefits of the regulation to exceed the costs?" In this case, the TSA argued that if the regulation prevented one "minimal attack"[9] every 1.1 years, one "target attack"[10] every 32.1 years, or a "severe attack"[11] once every 92.7 years, then the benefits of the regulation would exceed the costs.

While the benefits of the aircraft repair station rule were necessarily speculative, the costs were quite detailed. The TSA went through the individual security program requirements, assumed the costs of those requirements and multiplied the sum by the number of stations affected.

The range of ten-year costs was calculated at US$241–296 million. The TSA considered two alternatives to the proposed rule. Each one involved background checks on employees at aircraft repair stations, and the TSA calculated the cost of each alternative as being higher than the agency proposal.

The TSA received 177 comments on the proposed rule. Many of the commenters complained that the costs of the rule were high, and that the likelihood of achieving the benefits was remote. Numerous commenters accused the TSA of not recognizing the diverse nature of aircraft repair stations and the resultant diverse security risks associated with them. Owners of smaller stations in particular were concerned that they would have to shut their doors if forced to develop a security program as envisioned by the TSA.

The final regulation was very different than the proposed rule (TSA 2014). The TSA abandoned the idea of requiring all stations to adopt a security program. The scope of the regulation was limited to those stations on or near certain airports. Also, these stations no longer needed to implement a full program but rather had to meet the following requirements,

> (1) designate a point of contact(s) to carry out specified responsibilities; (2) prevent the unauthorized operation of large aircraft capable of flight that are left unattended; and (3) verify background information of those individuals who are designated as the TSA point(s) of contact and those who have access to any keys or other means used to prevent the unauthorized operation of large aircraft capable of flight that are left unattended.

The inspection provisions of the proposed rule were left largely unchanged. The costs of the final rule were dramatically lower than those of the proposed rules. The range of the ten-year costs was now US$16–19 million. The break-even analysis showed that a severe attack resulting from a security breach at an aircraft repair station would now have to be prevented only once every 9000 years in order for the benefits of the regulation to exceed the costs.

This regulation is an example of the interaction between cost-benefit analysis and public comment. The highlighting of the costs associated with the proposed rule gave small business owners a clear picture of the burdens that the regulation would impose. Would the TSA have modified the proposed rule, without a cost-benefit analysis? The answer is uncertain but the individuals that I spoke with pointed to the analysis as a significant factor in driving the TSA toward a much more lenient final regulation.

Case 2: Dietary Supplements: Ignoring the Marginal (and Total) Costs and the Benefits[12]

The FDA issued a proposed rule requiring good manufacturing practices at facilities that manufacture dietary supplements on March 13, 2003. The FDA stated that the primary purpose of the regulation was to protect public health. They noted that the dietary supplement industry was growing quickly and there was a lack of FDA regulation. This had resulted, according to the FDA, in "the adulteration and misbranding of dietary ingredients and dietary supplements by contaminants or because manufacturers do not set and meet specifications for their products, including specifications for identity, purity, quality, strength, and composition" (FDA 2003).

The regulation had seven sets of requirements for manufacturers of dietary supplements. Manufacturers had to ensure training of personnel, manage the plant environment, keep equipment and utensils clean, implement production and process controls, ensure the safety of the holding and distribution of products, have a consumer complaint process, and keep records on all of the above. In the preamble to the proposed rule the FDA said it would consider exempting products that manufacturers could prove were safe (FDA 2003) but an interview subject told me that within the agency they planned on never following through with this.

The economic analysis accompanying the proposed rule identified three categories of benefits from the proposed rule. These were: a reduced number of illnesses, fewer product recalls, and greater assurance of product quality for consumers. The last of these results in lower search times for consumers of dietary supplements. The total benefit was estimated at US$218 million, with half of this coming from US$109 million in reduced search costs. Annual costs were estimated at US$86 million. At one point in the RIA, the FDA says, "Most provisions did not have costs attached to them, mainly because they were either descriptive or the costs were included elsewhere." The FDA also assumed that tests of products (one of the most costly provisions) would cost US$50/test despite finding that some tests cost as much as US$300. They note, "Changing our assumption about the midpoint of testing costs would change our estimate of the cost of the rule. If the cost of testing each batch is actually significantly higher, then the impact to those firms that incur the cost and to society will have been understated" (FDA 2003).

The FDA also estimated the costs and benefits of five alternatives to the proposed rule (see Table 3.1):

Table 3.1 Annual benefits and costs of regulatory options (in US$ millions)

Regulatory option	Annual benefits	Annual costs
Proposed rule	218	86
Fewer requirements for vitamins and minerals	109	69
Stricter Good Manufacturing Practices	218	178
Hazard Analysis and Critical Control Points only	42	38
Testing only (unable to estimate)		32
High risk products only (unable to estimate)		(\1\)

Note: \1\ Less than US$86 million.

Source: FDA 2003.

The FDA also outlined the areas of uncertainty in their estimates and highlighted their most questionable assumptions. They made clear that they assumed that the regulation would eliminate product recalls, and that there were currently 100 unreported illnesses for every illness reported. Finally, the FDA assumed that the regulation would reduce the time consumers spend searching for products by 33 percent. They also note – and this is critical – that they do not estimate the benefits and costs of individual provisions, making it impossible for readers to evaluate the wisdom of the specific requirements in the rule.

The FDA received more than 400 comments on the proposed rule. While the dietary supplement industry filed comments that suggested many changes, many of the larger manufacturers and trade associations were broadly supportive of the rule. For example, the American Herbal Products Association (2003) said,

> AHPA and its members support the establishment of cGMP that are specific to dietary supplements. AHPA's support for new rules stems from a belief that, although full enforcement of the current cGMP for foods, to which all dietary supplement manufacturers are bound, already protect the public health, new rules can more accurately reflect practices that are more representative of current industry practices and can more fully implement current

> industry thinking as to what constitutes good manufacturing practice for this diverse and important class of goods.

Small businesses were more critical. Ortkho Medical Products filed a comment saying, "The proposed GMPs are, in fact, not GMPs at all" (McGinley 2003). Most commenters were critical of the economic analysis in the proposed rule.

The FDA published the final rule on June 25, 2007. Despite the four-year gap between the proposed and final rules, there were not many significant changes between the two iterations of the regulation. The most important change was a wording change that instructed dietary manufacturers that they were required to maintain product quality rather than prevent adulteration and defined quality as "consistently meets the established specifications for identity, purity, strength, and composition and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the Federal Food, Drug, and Cosmetic Act." It is not clear whether the wording change will have any concrete impacts. On a more substantive level, some of the recordkeeping and testing requirements were reduced in response to public comments (including comments on the economic analysis) (FDA 2007).

While the regulation itself did not change much, the cost-benefit analysis was quite different. The estimated costs of the regulation now outnumbered the benefits by US$164 million to US$44 million. The FDA said that many of the possible benefits of the regulation were unquantifiable but that they were proceeding because these benefits justify the costs of the rule. The reduced benefits appear to come from two significant changes to the analysis. After receiving several comments on the subject, the FDA removed from its baseline analysis an outbreak of "Eosinophilia-Myalgia Syndrome." This incident was included in the baseline of illnesses in the proposed rule but not in the final rule, reducing the estimate of the number and severity of illnesses likely to be prevented. Also, the FDA eliminated the benefits from reduced search costs saying, "Although we do not agree with the comments on the applicability of the search model as a measure of benefits, the empirical difficulties associated with quantifying those benefits have led us to replace the search model with a qualitative description" (FDA 2007).

The changes to the cost estimate largely arose from using different numbers for some of the assumed parameters. The FDA admits that there was a technical error when it estimated the number of batches of product manufactured, and this was increased in the final analysis. The FDA also modified assumptions about the number of tests, and the costs per

worker. While these changes increased the cost estimate, the reduced testing requirements led to overall lower costs (by as much as US$118 million). The FDA also broke out the costs (but not the benefits) by provision of the regulation. However, the analysis of regulatory alternatives that was present in the proposed rule was not in the final analysis (FDA 2007).

The Dietary Supplement CGMP regulatory analysis illustrates a number of the points brought out in the interviews. The FDA did change some provisions between proposal and finalization that reduced the cost of the rule, specifically testing and recordkeeping requirements. The cost-benefit analysis may have played a role in these changes but they also may have occurred simply due to public comment. In addition, the interaction between public comment and analysis was clear as public comments led to significant changes in the estimates of the costs and the benefits of the regulation.

But, at the end of the day, the FDA moved forward on a regulation where the costs significantly outweighed the benefits. They did not show the benefits and costs of alternatives in the final economic analysis, possibly because doing so would have demonstrated that other more economically efficient possibilities existed. They did not attribute the benefits of the regulation to particular provisions (an admittedly difficult task), possibly because doing so would have led to calls to scale back certain provisions. Economic analysis was largely ignored in the decision to move forward with this regulation (and several interview subjects confirmed this).

Why? This was a rare regulation that had support within the agency, from the public health community, and from a portion of the regulated industry.[13] According to one interview subject, larger established firms saw the regulation as a way of discouraging "fly by night" dietary supplement manufacturers from entering the industry and providing competition.[14] Indeed, the three meetings that industry conducted with the OMB,[15] while the final regulation and analysis were being reviewed, were all with the purpose of attempting to persuade the OMB to conclude its review and allow the FDA to issue the regulation.[16]

Case 3: EPA's Cooling Water Intake Structure Rule: A Seesaw with Analysis in the Middle

Cooling water intake structures are used by industrial facilities to take in water from lakes and other bodies of water to cool their facilities. In doing so, these structures kill thousands of fish by heat, physical stress, and chemicals used to clean the structure.[17] The EPA is required under

section 316(b) of the Clean Water Act to issue technology based standards when regulating these structures. In 1995, the EPA entered into a consent decree with Riverkeeper, an environmental advocacy group, to produce regulations (Harrington et al. 2009). What followed has been two decades of regulatory efforts and court cases.

The EPA initially promulgated final rules on cooling water intake structures in three phases during the George W. Bush Administration. The EPA covered new facilities in Phase I, large steam electric plants in Phase II, and the remainder of existing facilities in Phase III. In various court cases, parts of all three standards were remanded to the EPA. Cost-benefit analysis was at the center of these decisions as the Phase II standards were initially ruled invalid because the EPA impermissibly used cost-benefit analysis to construct them.[18] The Supreme Court overturned this decision, ruling that the EPA was permitted to consider costs and benefits in promulgating rules under the Clean Water Act, even if it was required to base these standards on technology.[19]

Because the other standards were remanded, the Obama Administration revisited the entire question of cooling water intake structures, proposing a regulation in 2009 (EPA 2009) and finalizing one in 2014 (EPA 2014). To recount the details of each of the iterations of these regulations and the costs and the benefits is beyond the scope of this study (for an excellent summary of the initial Bush Administration standards see chapters 8–10 of Harrington et al. 2009).

At the first stage of the rule-making, there is considerable agreement that the cost-benefit analysis played a significant role. While some economists and critics of the rule found fault with the analysis (Farrow, in Harrington et al. 2009; Sinden 2014), critics and the courts adjudicating the Phase II standards both made it clear that they blamed or credited analysis for the form that the standard took (the Phase II standards were quite different than many other technology based standards in the Clean Water Act) (Sinden 2014). Clearly there were legal questions (decided by the Supreme Court) over whether analysis could play a role under this statute.

Agreement is not as prevalent about the role of analysis in the Obama Administration revisions of the standards. Sinden (2014) argues that despite encouragement from the Supreme Court to engage in an informal or simple analysis of the trade-offs between ecological benefits and costs to factories with cooling water towers, the EPA spent years on a survey trying to pin a monetary value on saving the fish. They then discarded the results (under pressure from industry) when the results were inconclusive. The net result was a benefits analysis that the EPA acknowledged vastly understated the probable benefits of the regulation. It appears from

the outside, thus, that the analysis must have had a minimal impact on the revised rule.

In speaking with EPA officials, one gets a different but equally inconclusive story. One interview subject claimed that the analysis was critical. Detailed work by economists showed that cooling water intake structures were located on a wide variety of bodies of water. Some of these bodies of water were teeming with fish, others contained few fish. Therefore, as a result of the analysis, the EPA concluded that the standard could not be a "one size fits all" approach and developed the new standards, which give a great deal of discretion to state regulators. However, another interview subject indicated that a key factor in the EPA decision was the desire at the agency (and at the White House) to appease the nuclear power industry whose support was crucial in debates over climate change.

No agency has as long and controversial a history with cost-benefit analysis as the EPA. The various iterations of the cooling water intake rule are far from atypical in the EPA's history. Cases 1 and 2 above (the FDA's dietary supplement regulation and the DHS's regulation on aircraft repair stations) are comparatively simple. Economic analysis helped prevent a policy with high costs and likely negligible benefits in one case, and was largely ignored in the other. The cooling water intake regulation fits into neither category.

CONCLUSIONS

At the outset of the chapter, I described cost-benefit analysis as the form of regulatory analysis closest to an epitome of comprehensive-rational analysis. As such, it makes an excellent case study for determining whether the hopes and fears associated with an increased analytical presence in policy-making have been realized. Indeed, the literature on cost-benefit analysis in the regulatory process echoes the hopes and fears in the broader literature on comprehensive-rational analysis.

As might be expected, neither the extreme hopes nor the extreme fears have been realized. Cost-benefit analysis clearly does not trump all other inputs into the decision-making process. Its adoption as part of the regulatory process has not replaced a democratic system of governance with a purely technocratic one. Government decisions are not made on the sole grounds of economic efficiency. The dietary supplement case and the experience of numerous economists across the government both make this clear.

None of that means that cost-benefit analysis has been useless, however. Both the interviews and the case of the aircraft repair stations indicate that it has played a significant role in ensuring that the "worst" regulatory decisions made by government have been avoided. This "worst" is most plainly stated in terms of economic efficiency (decisions where the costs are very high and the benefits are negligible), but these same decisions may also be ones that never would have survived the scrutiny of a well-informed public. It is also clear that many of the impacts of cost-benefit analysis are invisible and occur before proposals become public.

There is also a clear relationship between the use of analysis and the transparency of the public comment period. In both cases brought up by agency economists, and in the aircraft repair station rule, a delineation of the costs and benefits led to public comments that then led to either changes or abandonment of regulations. It is important to note that this benefit of analysis is quite dependent on the comprehensibility of the analytical document. If analysis is not understandable to the informed commenters, if it exhibits the false formality described by Sinden (2014), then it will not provide useful information and may deter affected parties from delivering input to agencies rather than encourage them. The analysis for the aircraft repair station rule for example, was quite simple and clear.

Excessive formality (false or true) is one barrier that inhibits cost-benefit analysis from playing more of a role in agency regulatory decisions. Politics is another. As discussed in Chapter 1, the relationship between analysis and politics is complicated, and in a democratic society one could be heartened to see that political forces serve as a consistent brake on technocratic preferences. I will return to this issue in Chapter 7, but suffice to say that the tension between politics and analysis described earlier plays out in regulatory issue after regulatory issue. It plays out in some cases where political factors attempt to influence the results of the analysis. In others, economists are allowed to conduct their analyses but then the results are trumped by political concerns.

The role of economists within the bureaucracy also was a constant theme throughout the interviews with economists. Whether it was the question of when economists are brought into the agency decision-making process, the independence of economists within the agency, or the role of OIRA, it was clear that organizational culture and structure could enhance or inhibit analytical input to regulatory decisions.

Several economists touched on a variable that is impossible to operationalize: personality matters too. The ability for economists to be heard depends not just on the personality of the economists (although that

clearly matters) but also on the personality of the key decision-makers at the agency. An openness to analysis is a critical factor in whether advocates of analysis can get heard. Training economists in how to function in a bureaucratic environment could help in this regards (Meltsner 1976).

Finally, the epistemological limit of economics was also a theme in the interviews. Agency economists acknowledged that there were questions they could not answer. They also acknowledged that even with many questions they could answer, they had to couch their conclusions in uncertainty. Often this uncertainty was sufficient to allow decision-makers to justify their pre-existing preferences. It allows political actors to claim that the economic analysis supports their decisions when, in reality, it is not so clear. Interestingly, this problem is not limited to a social science like economics but also comes up repeatedly when discussing the science behind risk assessments and environmental impact statements described in the next two chapters.

NOTES

1. Pub. L. 74-738.
2. See also Hammond (1966).
3. OMB Guidance, otherwise known as Circular A-4 can be found at: http://www.whitehouse.gov/omb/circulars_a004_a-4/ (last accessed December 1, 2014).
4. Congress authorized the review of economic analysis within the Government and Accountability Office (GAO) in the "Truth in Regulating Act" P.L. 106-312 but never authorized the appropriations for the GAO office to conduct this function.
5. Sinden (2014) calls this "false formality" and argues that it plagues the analytical process.
6. The subject of risk analysis in the regulatory process is covered in the next chapter of this book. This Morgenstern and Landy conclusion, however, highlights the connection between risk assessment and economic analysis.
7. An exception is Nelson (1987, p. 84): "Moreover the greatest contribution may not be to make a proposal that is adopted; rather as another former CEA staffer, Robert Tollison put it, 'the role of the economist there is a stop gap – keep them from doing something completely dumb, just completely dumb.'"
8. Pub. L. 108-176.
9. The TSA describes this scenario as a missile being stolen from a repair station and used to attack a lightly populated area.
10. This would involve the placement of a bomb on an airline killing 132 people.
11. This involves stealing a large plane and attacking a populated area killing 250 people and wounding 750 others.
12. For a similar story see the description of the "Hazard Analysis and Critical Control Points" regulation by the FDA in Richard Williams (2008).
13. This conclusion is drawn both from a perusal of the public comments and from interviews with those involved with the rule-making.
14. The use of the regulations as a "barrier to entry" for new firms was also voiced in a public comment by Rep. Chris Cannon: "In developing regulations, it is important that the Agency not allow rent seekers from one side or another to use the power of the Agency to raise barriers to entry or expansion against new products, companies, and processes."

15. Industry held three meetings with OIRA. They were on November 16, 2006, October 4, 2006, and November 29, 2005. See http://www.whitehouse.gov/omb/oira_0910_meetings/
16. As an indication that the OMB itself was not happy with the rule or the supporting analysis, the regulation was under review at OIRA from October 2005 until May 2007. Numerous interview subjects confirmed this impression.
17. See http://water.epa.gov/lawsregs/lawsguidance/cwa/316b/ (last accessed January 9, 2015).
18. Riverkeeper Inc. v. USEPA, 475 F. 3d 83 – Court of Appeals, 2nd Circuit 2007.
19. Entergy Corp. v. Riverkeeper Inc. 556 U.S. 208 U.S. Supreme Court 2009.

4. Risk assessment and the regulatory process

On the surface, risk assessment and its role in the regulatory process may seem quite different than cost-benefit analysis and other forms of comprehensive-rational analysis. Risk assessment occurs before cost-benefit analysis in the regulatory process, and more clearly plays a role in priority setting. Rather than relying on social science, it is grounded in "hard" science. As such its practice and its use have been closely examined by the National Academy of Science in multiple reports over the past three decades. It has had its own professional society and journal for much longer than cost-benefit analysis.[1] The academic literature on risk assessment is significantly larger than the literature on cost-benefit analysis.[2]

Despite these differences, there are a number of critical similarities between debates over the use and effectiveness of cost-benefit analysis and risk assessment. In both fields, there is concern about the ethics of the practice, the possibility of overly technocratic analysis subverting democratic preferences, and biases inherent in the analytical technique. Meanwhile, advocates of both cost-benefit analysis and risk assessment bemoan the influence in the opposite direction – the interference of political preferences on the practices of their disciplines. Within the regulatory process, both cost-benefit analysis and risk assessment must fit within a pre-existing legal and bureaucratic structure that inevitably affects whether or not they will influence policy decisions.

In addition, many of the criticisms of risk assessments mirror those of comprehensive-rational analysis in general, and cost-benefit analysis in particular. Advocates of regulation have complained that risk assessment delays the promulgation of regulations designed to protect public health. Opponents of regulation argue that risk assessments have been manipulated by pro-regulatory scientists within agencies to better justify the case for regulation. As one author put it, "Risk assessment, however, is almost always used to produce estimates that defy objective verification" (Shere 1995, p. 412).

Just as cost-benefit analysis is criticized as being impossible because one cannot monetize everything, risk assessment is criticized for a narrow

conception of "risk." According to leaders in the field of risk perception, risk assessors view risk as consisting only of risk to life or perhaps to health. The public at large implicitly includes factors such as dread in their assessments of risks (Slovic 1999). By ignoring these other factors, risk assessors systematically mis-estimate risks, and produce analyses for decision-makers that are potentially inappropriate in a democratic system of governance.

The use and the successes and failures of risk assessment therefore have much to tell us about analysis in the policy process. In this chapter I follow a similar pattern to the previous one. First, I give a brief overview of the history of risk assessment in the United States, particularly as it pertains to the regulatory process. I also review a subsection of the relatively vast literature on risk assessment. In particular, I discuss both frustrations from those inside the risk assessment field about how risk assessment is used in decision-making, and concerns from outside the field about problems with risk assessment that make it less useful to decision-makers.

Then, I share the results of interviews I conducted with more than a dozen people with risk assessment experience in the federal government. Risk assessors with current or past experience in the EPA make up the majority of these interviewees, just as discussions about environmental policy dominate the literature on risk assessment. I then focus on two areas of environmental policy where the sentiment regarding the role of risk assessment is quite different. First I discuss the Integrated Risk Information System (IRIS) which has been plagued with delays and controversy virtually since its inception. Then, I turn to evaluations of new pesticides, where EPA risk assessors are widely praised for their contribution. Finally, I offer concluding thoughts on lessons from risk assessment for comprehensive-rational analysis in general.

HISTORY AND LITERATURE REVIEW

As described in Chapter 2, risk assessment has its origins in concerns about exposure to nuclear radiation and statutory requirements on food safety. The EPA and OSHA, prompted in part by executive order, and in part by the Supreme Court, began to institutionalize risk assessment in the regulatory process. The practice of risk assessment evolved rapidly in the 1970s in response to the same statutes that prompted the arrival of cost-benefit analysis. The vast trove of statutes designed to protect public health had varying standards for when the new regulatory agencies had to act. Under the Clean Water Act, the EPA had to prevent "reasonably

anticipated adverse effects,"[3] while under the Clean Air Act it had to "protect public health with an adequate margin of safety."[4] These and many other statutes left agencies with the task of figuring out whether the risks of a particular chemical merited regulation (National Research Council (NRC) 2009).

Concerns about the conduct of risk assessment, still early in its evolution, led to a landmark National Academy of Sciences (NAS) study on how it should be conducted, and its relationship to policy-making. Known as the "Red Book," the NAS study provided a definition of risk assessment, "the characterization of the potential adverse health effects of human exposure to environmental hazards" (NRC 1983). The report also explained that risk assessment is supposed to proceed in four stages (NRC 1983). The first is hazard identification, which involves determining whether a chemical poses a risk to humans. The second is assessing the relationship between the magnitude of exposure and the likelihood of developing an illness. The third is assessing the exposure of humans to the chemical. The fourth combines the previous two stages to develop a characterization of the risk (NRC 1983).

The Red Book focused considerably on the line between science and policy as it pertained to risk assessment.[5] The authors discuss the question of separating risk assessment (the four steps described above) from risk management (the economic and policy choices of what to do about a risk). While they argue for some degree of separation, they acknowledge that because risk assessment involves choices regarding assumptions and approaches, there exists such a thing as risk assessment policy. The basis of these choices cannot, in the views of the authors, be made on solely scientific grounds. Examples of such choices abound, including whether to assume a threshold for risk exists, and translating between studies of high doses of a chemical to animals and the risk of much lower but prolonged exposure to humans.[6] "Risk assessment is an analytic process that is firmly based on scientific considerations, but it also requires judgments to be made when the available information is incomplete" (NRC 1983). In the years following the publication of the Red Book, many focused on the separation between risk assessment and risk management, and overlooked the more subtle points about the policy decisions inherent in risk assessment.[7] Indeed the authors of the Red Book "lamented the bureaucratic separation of assessment and management" (Hassenzahl and Finkel 2008).

Prior to the 1990 amendments to the Clean Air Act, the EPA, acting pursuant to the D.C. Circuit Court of Appeals,[8] adopted a general policy that a lifetime risk of 1 in 10 000 to the most exposed person would be considered acceptable (NRC 1994). The 1990 amendments altered the

requirements for the EPA, and directed the NAS to report on and recommend risk assessment practices as a follow up to the Red Book. The ensuing report identified many challenges for risk assessors and made a multitude of recommendations. Relevant to the question of how risk assessment informs decision-makers were recommendations that the EPA should communicate "uncertainty (e.g. for models and for data sets) as it occurs into each step in the risk assessment process," and that risk managers should "be given characterizations of risk that are both qualitative and quantitative," in order to demonstrate the problems inherent in presenting a single number or even a range of numbers (NRC 1994). The 1994 report also said,

> EPA should increase institutional and intellectual linkages between risk assessment and risk management so as to create better harmony between the science policy components of risk assessment and the broader policy objectives of risk management. This must be done in a way that fully protects the accuracy, objectivity, and integrity of its risk assessments – but the committee does not see these two aims as incompatible. (NRC 1994, p. 267)

The EPA has regularly gauged its process in meeting the recommendations of the NAS reports. In a 2004 staff paper, the EPA noted three concerns that it had received from the public about its risk assessment process as part of an OMB solicitation of public comment. The first was that the EPA overly relied upon unwarranted conservative assumptions when conducting risk assessments. The second was that the EPA did not sufficiently disclose uncertainty in its risk estimates. And the third was the long debated intermingling of policy concerns with scientific questions (EPA 2004). The staff paper largely attempts to answer these questions. It repeatedly invokes the EPA's statutory mandate to be protective of human health. It also discusses what it called the necessary interactions between risk assessors and policy makers (EPA 2004).

The Government Accountability Office (GAO) has provided some independent assessments of the EPA response to the NAS panels. In a 2005 report, the GAO reported that the EPA has made significant strides in complying with the NAS and other recommendations. Most of the GAO's conclusions were based on interviews with EPA employees who cited the production of EPA guidance in areas such as default assumptions and uncertainty as evidence that the EPA has responded to the recommendations. When interviewing outsiders, the GAO found that there were still some areas in which the EPA needed to improve, although these outsiders did describe the improvements at the EPA as "beneficial", particularly in the involvement of stakeholders, transparency, and training for risk assessors. These outside experts also noted

organizational culture as a source of concern, "that EPA has a general reluctance to deviate from using methods and assumptions it has used in the past" (GAO 2006).

In 2006, the Office of Information and Regulatory Affairs (OIRA) issued a proposed set of guidelines on risk assessment that would apply throughout the federal government (Office of Management and Budget (OMB) 2006). The guidelines delineated three "tiers" of risk assessment, with the tiers varying with the anticipated influence of the risk assessment. More stringent requirements were placed on more influential risk assessments. The proposed guidelines were widely criticized for imposing excessive procedures on agencies conducting risk assessment and politicization of the risk assessment process (S.A. Shapiro 2007). Particularly damning was a report from the NAS (NRC 2007) which concluded,

> The committee, however, is concerned that the bulletin is inconsistent with previous recommendations in a number of ways, including its presentation of a new definition of risk assessment, its omission of discussion of the important role of default assumptions and clear criteria to modify or depart from defaults, its proposal of risk *assessment* standards related to activities traditionally regarded as risk *management* activities, and its requirement for formal analyses of uncertainty and presentation of "central" or "expected" risk estimates. In several respects, the bulletin attempts to move standards for risk assessment into territory that is beyond what previous reports have recommended and beyond the current state of the science. Such departures from expert studies are of serious concern, because any attempt to advance the practice of risk assessment that does not reflect the state of the science is likely to produce the opposite effect.

Others condemned the guidelines as a "politicization of risk assessment" (S.A. Shapiro 2007). The OMB subsequently withdrew the guidelines.

The National Academy returned to the question of risk assessment at the EPA in a 2009 report *Science and Decisions* (NRC 2009). The 2009 report argued that the line between risk assessment and risk management was much more complicated than it had been portrayed by many who interpreted the Red Book as recommending a strict separation.[9] In particular the NRC argued that risk managers/policy-makers should be instrumental in formulating the questions that risk assessors examine. Only by involving risk managers at this stage can risk assessors properly scope their studies so they maximize their usefulness to decision-makers (NRC 2009). Others have built on this concept to propose "solution focused risk assessment" (Finkel 2011).

It also identified several other impediments that pertain to the use of risk assessments including,

1. "Are the decision contexts in which risk assessments are to be developed well defined in advance?"
2. What is the right level of detail for a risk assessment?
3. Are the criteria for selecting the defaults necessary to complete risk assessments and for departing from them fully specified and set forth in agency guidelines?" [Elsewhere the NRC argues that they have not been sufficiently specified by the EPA. In part this may be because "it has proved difficult to achieve scientific consensus on judgments regarding the adequacy of scientific evidence to justify in specific cases, departures from one or more defaults"] (NRC 2009, p. 25).

The NAS committee acknowledged the fear that the blurring of the line between risk assessment and risk management would open the door for political interference in risk assessment but thought that this fear could be mitigated,

> That the framework allows assessors to see the choices facing the decision-maker does not imply that they would be involved in risk management, nor does it imply that the decision-makers would have license or opportunity to impose their will on the analysis. The framework empowers risk assessment to drive the engine that determines which options perform best in the presence of uncertainty, variability, and public preferences, but it does not empower risk assessors to impose their preferences on the analysis. (NRC 2009, p. 255)

The report also noted that several of the recommendations in previous reports had not been fully implemented,

> Although EPA has a 20 year history of issuing guidelines and other reports designed to implement recommendations for improvement offered by the National Research Council and other advisory bodies, moving from policy to practice has in some cases been incomplete or only partially effective (as to provisions put into practice), and in others uneven (as to use for all assessments in all parts of the agency where applicable). (NRC 2009, p. 57)

While the EPA is the focus of the NAS panels, much of the literature on risk assessment, and occasional proposed legislation in Congress, other agencies have also struggled with the questions surrounding risk assessment. As one example, the FDA's office for food safety (the Center for Food Safety and Applied Nutrition (CFSAN)) recently looked at its risk assessment practices and made dozens of recommendations on scientific practice, collaboration, and communication (FDA 2014).

The scholarly literature on risk assessment is greatly informed by the NAS reports. A quote from *Science and Decisions* describes many of the critical issues that others have also focused on:

> Many decision-making situations involving public health and environmental risk have five common elements: the desire to use the best scientific methods and evidence in informing decisions, uncertainty that limits the ability to characterize both the magnitude of the problem and the corresponding benefits of proposed interventions, a need for timeliness in decision-making that precludes resolving important uncertainties before decisions are required, the presence of some sort of tradeoff among disparate adverse outcomes … and the reality that because of the inherent complexity of the systems being managed and the long-term implications of many decisions … there will be little or no short-term feedback as to whether the desired outcome has been achieved by the decisions. (NRC 2009, p. 66)

In short, it is hard to figure out whether risk assessment has done a good job from a policy perspective? Have regulatory agencies focused on the right risks? Have they taken the appropriate level of precaution of dealing with these risks? How do we know?

Renn (2008) describes a series of concerns with risk assessment that lead to skepticism that these questions can be answered positively. Many of Renn's criticisms focus on the fact that risks are perceived by people in ways that are different than they are calculated by scientists. Furthermore, organizational and other dynamics affect these perceptions. The weighting of risks and the treatment of uncertainty is also a considerable source of concern (Renn 2008).

There are numerous other debates in the literature on risk assessment. Perhaps most prominent is the concern about the "science charade." To some degree this inverts the concern about political influence on scientific decisions. Instead it expresses the political tendency to hide behind science to mask decisions made on policy grounds. The term, coined by Wendy Wagner, refers to when "agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions" (Wagner 1995, p. 1617). The science charade is a particular danger on questions that "appear to outside observers to be resolvable by contemporary science and thus are often mistaken for straightforward scientific questions" (Wagner 1995, p. 1627).

Others have noted the science charade in various contexts. Coglianese and Marchant (2004) describe the 1997 EPA particulate matter and ozone National Ambient Air Quality Standards (NAAQS), and point out repeated places where the EPA cited science and risk assessment as the

reason for their policy choice when the risk assessment itself made it clear that tighter standards would save more lives.

> Throughout the PM rulemaking, EPA invoked uncertainty as a wild card in an effort to defend its regulatory decisions. The Agency dismissed sometimes large uncertainties in the estimates it used to support its regulatory actions but it then cited uncertainty as a barrier to adopting regulations that it was not otherwise inclined to adopt. (Coglianese and Marchant 2004, p. 1306)

Another observer says, "In public policy debates, the confounding of knowledge and discretion provides many opportunities for both government officials and nongovernmental advocates to obscure arguments actually based on ideology or interest behind the more respectable veil of science" (Greenwood 1984, p. 2).

The science charade is a particular concern in the role of risk assessment in priority setting, a role that cost-benefit analysis aspires to play but never really has. Some may view agency decisions about which problems to address (which chemicals to regulate in the case of the EPA, which threats to address in the case of homeland security agencies, etc.) as one based on an assessment of the risk. However, Wagner notes, "Many of the observers of toxics regulation believe that the agencies assign priority to the worst risks first. A careful examination of the standard-setting record reveals however that this is not the case" (Wagner 1995, p. 1681). Greenwood (1984) also argues that risk assessment can never fully lead to a technocratic ordering of priorities.

The relationship between politics and risk assessment therefore has many dimensions. Some worry about political interference in scientific decisions. Others worry about public preferences being subsumed to those of technocrats (Green Center Scholars 1995). These debates are reflections of the broader tension between democracy and expertise discussed in Chapter 1. Risk assessment (as a subset of science generally[10]) also has raised the concern of giving political leaders the ability to hide their policy preferences with calls to the authority of science. "The model of an uncertain science interacting with values is one that is very very new to our culture. We are still groping to try and understand it" (Green Center Scholars 1995).

Other issues about the use of risk assessment in policy-making raised in the literature include echoes of the debate on cost-benefit analysis. Like cost-benefit analysis, risk assessment has been accused of being used to delay regulations that protect public health. Risk assessments for dioxin, Tri-Chloro Ethylene (TCE), and formaldehyde took (or continue to take) decades (NRC 2009). The interaction between participation by

outside parties in the regulatory process and risk assessment has also been a source of hope and frustration.[11] The NAS reports trumpet the potential for a mutually beneficial interaction between participation and risk assessment. However, the 2009 report acknowledges that the potential has not been reached. "In recent years, a number of federal agencies have raised concerns about EPA risk assessments of contaminants, and are now playing a more formal role in risk policy-making at the federal level … Those agencies and other public and private stakeholders often assert that they are inadequately involved in EPA processes" (NRC 2009, p. 17).

As with cost-benefit analysis, the empirical examination of the role of risk assessment in actual regulatory decisions is very limited. The most notable example is a book by Graham et al. (1991), *In Search of Safety*, which examines the decisions by various agencies in the 1970s and early 1980s to regulate or not regulate benzene and formaldehyde exposures.

For formaldehyde, scientific data at the time showed that the chemical caused cancer in animals but human data was limited. Formaldehyde was an irritant to humans but its carcinogenicity was not determined. The Consumer Product Safety Commission (CPSC) banned its use in particleboard building materials, but the ban was overturned by the courts. OSHA, after much controversy, regulated exposure to workers for formaldehyde. The EPA declared formaldehyde a priority substance under section 4(f) of the Toxic Substance Control Act but never established exposure limits.[12] Graham et al. (1991) argued that because the science was the same for all three agencies, differences in regulatory approaches had to be chalked up to personnel and organizational differences at the CPSC and political circumstances at OSHA and the EPA.

Benzene had a different scientific basis for regulation than formaldehyde. It was established as a human carcinogen in the 1970s, but the level at which exposure to benzene was dangerous was not clear. OSHA strove to regulate benzene and its efforts were initially overturned in an important Supreme Court case.[13] The case required OSHA to conduct quantitative risk assessments in order to regulate substances harmful to worker health. OSHA eventually complied with the requirement and established maximum exposure limits nine years after initially proposing to do so. The EPA regulated fugitive emissions of benzene and coke oven by-product recovery plants which covered 60–70 percent of benzene emissions (Graham et al. 1991).

Graham and his co-authors concluded that much work needed to be done on risk assessment. The questions that agencies like the EPA and OSHA were asking were difficult ones and, "the available scientific data seldom allow scientists to answer such questions" (Graham et al. 1991,

p. 179). In the 24 years since Graham's work, the questions have not gotten any easier although the recognition of the difficulty may have improved (Hassenzahl and Finkel 2008).[14] And, as the interviews and cases that I describe in the next sections illustrate, many of the questions that surrounded risk assessment early in its history still remain. And those questions bear more than a passing resemblance to the issues surrounding other examples of comprehensive-rational analysis.

As with the previous chapter, the goal of both the interviews and the case studies is to gain a greater understanding of the role of risk assessment in the regulatory process. When does it play something close to the stylized role we might imagine for a form of comprehensive-rational analysis grounded in the physical sciences? And when do the fears described above about the relationship between politics and risk assessment emerge?

INTERVIEWS

I used the same method for identifying risk assessors in federal agencies as I did for finding practitioners of cost-benefit analysis. I began with personal contacts and members of the Society of Risk Analysis. From here I asked interview subjects for the names of other people who would be able to provide me with insights regarding risk assessment in rule-making. All interview subjects were promised confidentiality in order to ensure that they felt comfortable speaking freely. The interview protocol can be found in the Appendix.

I spoke with 16 individuals with experience in conducting or reviewing risk assessments used in regulatory decision-making. Collectively they have worked on more than 1000 risk assessments. Because of the emphasis in the literature on the EPA, ten of my interview subjects were current or former employees of this agency. I felt that this emphasis was necessary in order to connect my conversations with the NAS reports and the academic literature. However, I did not want to ignore risk assessment in other regulatory agencies, so I also spoke with officials in the Departments of Agriculture, Health and Human Services, Homeland Security, and Labor.

I found a somewhat more diverse set of opinions on the actual role of risk assessment than I did with cost-benefit analysis. Perhaps relatedly, my interview subjects were more clearly familiar with the academic literature and the NAS reports than their economist colleagues. Several brought up the "Red Book" and "Silver Book" (the common names for the 1983 and 2009 NAS reports respectively), and one mentioned the

"Science Charade." All of this was without my prompting. At the EPA in particular, there was a sense that following the recommendations in the NAS reports was an important value at the agency but a few dissenters argued that there was still a significant gap between its practice and the NAS recommendations.

Despite the varied views of my respondents, it is possible to assemble a picture of how risk assessment is used. Risk assessors are clearly aware of the context of their work and largely feel that knowing this context helps them scope out their analysis. Explicit political interference in how risk assessment is conducted from policy-makers, or "risk managers" as they have been called since the Red Book was published, is largely non-existent (respondents collectively could come up with only one or two examples). As with cost-benefit analysis, while politics is important, the legal framework, bureaucratic structure, and individual personalities all play a role in how risk assessment fits into decisions.

How does Risk Assessment Fit in the Regulatory Process?

Similarly to cost-benefit analysis, there is considerable variation in the functional role of risk assessment across agencies, and even across programs within the EPA. One commonality, however, is that the decision of what risks to study came from other parts of the agency. As one agency representative said when asked about the role of politics, "it [politics] affects what we work on, not how we work on it." Risk assessment plays a priority setting role in the sense that the findings can then drive decisions about whether an agency should use regulation as a policy tool to mitigate a risk.

Once an agency has identified the need for a risk assessment, the next questions involve the scoping of the risk assessment (a topic that gets considerable attention in the 2009 NAS report). While some said that there was a wall between risk managers and risk assessors at their agencies, others said there was not, and that it would be detrimental to have one. One EPA scientist said, "in order to focus our resources most effectively we have to talk with risk managers around the scoping of the assessment, what chemical uses should we look at, what information do we have that will result in an assessment that is useful for decision making?" A scientist from another agency told me, "We meet regularly to make sure we know risk management questions and which projects need risk assessment. So there is a distance but we interact regularly."

But does the decision to regulate depend on the findings of the risk assessors? The answer to this question varied considerably between agencies. In some cases, like the pesticide approval process described

below, risk assessment has a pre-defined role in the decision whether to approve the use of a product. In these cases, it is clear that the risk assessment precedes the decision to regulate. In another section of the EPA, one scientist was firm, "I am adamantly opposed to the regulatory decision being made before the risk assessment is completed and used to inform the decision." This respondent said that this preference was respected within the agency.

In contrast, other interview subjects came up with instances (not from the same program as the individual quoted above) where decisions preceded the findings of a risk assessment. One interview subject said, "Everyone would like to think that we do the risk assessment and that drives the decision to regulate but really the decision to regulate may come first." Another, describing the interaction between risk assessment, cost-benefit analysis, and the writing of a regulation, commented, "You can't just tell risk assessors I want a risk assessment, it doesn't work well. If that's the way it is handled, then risk assessment, cost-benefit analysis, and the rulemaking are inconsistent."

One consistent criticism came from several respondents who argued that the presentation of risk assessments to decision-makers compromises their usefulness. As one respondent put it, "I believe that the risk assessments have to change. They have to quantitatively reflect the uncertainty in what science is telling us. Then the agency has to explain why it is making policy decision within the legitimate range that the science provides." Another said, "We as assessors give them information that is not as helpful as it can be. It doesn't reflect underlying imprecision of biology… The fault is on the assessor's side. Managers are happy with any answer. They can't be expected to ask the right questions. In retrospect, it really is the assessors because the managers don't know." This concern about the portrayal of uncertainty was the most prevalent concern in the presentation of risk assessment. Little consensus existed on the best way to present uncertain outcomes, however, and interview subjects noted that different agency leaders react differently to presentations of uncertainty.

Risk Assessment Working Well

Many of the cases where risk assessment works well according to my interview subjects have a number of common qualities. The case of EPA approval of pesticides described below embodies many of these qualities, and I will elaborate on that below. Here I will merely discuss examples other than the pesticide program (or observations from people doing risk assessment in other contexts).

The first of these qualities is that risk assessment is more successfully incorporated into decisions when the policy choice is whether the government should approve something rather than reject it. In cases where risk assessments are used to justify the banning of a substance or restrictions on its existing use, there is much more dispute about the risk assessments. This is natural in that it is politically harder to tell an individual or firm that they cannot do something they have been doing for years than to tell them they can't do something new.

In addition to pesticides, interview respondents described to me cases of successfully incorporating risk assessment into decisions to approve agricultural products for import to the United States, and evaluation of new chemicals as part of the Toxic Substances Control Act (TSCA) program in the EPA. One interview subject said "We knew we were facing people opposed to it so we needed a strong document to back up a decision to do so," and then described a risk assessment that was done carefully with a great deal of external expert input that played a major role in the decision in question. Within the TSCA, interview subjects described the greater ease of conducting risk assessment for approval of new chemicals than for the use of existing chemicals.

Many of the programs where risk assessment is used to approve a new product also share the quality of having a deadline for the completion of the risk assessment. While some programs (see the discussion of IRIS below) are repeatedly criticized for decisions that stretch out over decades, deadlines were routinely cited by interview subjects as helpful in ensuring that risk assessments were both completed and used by decision-makers. The TSCA, for example, requires determinations from the agency on new chemicals within 90 days. According to one official, this gives officials leverage in negotiations with industry, "If we think there might be a risk concern, we can negotiate risk management for the company like personal protective equipment, or have a consent agreement where we specify the volume while you try to prove the chemical is safe."

While OIRA does not have the formal role in risk assessment that it does in cost-benefit analysis, it has often concerned itself with risk assessment. Since risk assessment feeds into the calculations of benefits in cost-benefit analysis, OIRA has naturally asked questions about risk assessments to agencies. John Graham, OIRA Administrator under President George W. Bush, made it a priority for OIRA to strengthen its capacity for involvement in scientific issues. Agency risk assessors told me that Graham's emphasis was helpful to them within the agencies, "There was a big commitment to doing risk assessment."

Finally, I want to reiterate the relatively universal consensus that explicit political interference in the conduct of risk assessment by policy officials or risk managers is virtually unheard of. None of my interview subjects could recall instances where they were told to come up with particular findings, and a number of them reacted strongly when I asked about it. The question of implicit pressure is harder to determine (finding particular results because you know that is what your employers want), but as far as I could tell, this phenomenon was extremely limited as well. The closest I came was one respondent who said that after presenting a completed result of a risk assessment, he might be asked, "'Is your exposure number refined enough? Can you push the number lower so we can be more sure?' I would look at the number and see if any improvements can be made." He went on to say, however, that if these "improvements" were not possible, policy officials were always understanding and willing to work with what he gave them.

Challenges in the Use of Risk Assessment

While political interference does not come from the outside, numerous interview subjects acknowledged that the preferences of those conducting the risk assessment could affect the risk assessments. One respondent said, "So we build in assumptions for the worst case. The assumptions all err in the same direction which we call conservative. We are conservative in relation to safety." This making of assumptions within the analysis is largely hidden from the outside observer. One experienced observer of risk assessments said risk assessors make decisions like, "We are going to pick the lowest number in the literature, we are not going to let a negative study or three negate a positive study, we are going to do something on page 562 of this thousand-page document that protects against the 99th percentile instead of the 90th percentile."

These types of decisions have their origins in a variety of places. Most of my respondents believed that they largely originated in the personal policy preferences of the scientists conducting the risk assessments. However, the bureaucratic culture inside risk assessment offices within agencies, sometimes in response to legal mandates to look at risks in a particular way, may also be a root cause of these preferences. One risk assessor said: "They do reflect policies we have had for many years. We assume that individuals are exposed for their entire working life. That comes from a policy decision that comes from our statute regarding chemical exposure." Another person I spoke with pointed out that just because assumptions are based on policy preferences, that doesn't mean they are wrong.

In addition to bureaucratic culture, bureaucratic structure clearly also plays a part in determining the role of risk assessment in agency decision-making. The EPA has gone through a variety of structures over the years, with risk assessors placed within program offices (each of which regulates risks in a particular media, such as air or water) and risk assessors located in a central office. Often there have been combinations of centrally located scientists and program scientists weighing in on risk assessments. One scientist summed up the trade-off associated with the decision about how to structure risk assessment as follows, "Restructuring the program office (by increasing the number of risk assessors) so they had sufficient technical capacity for risk assessment helps risk assessors be involved with the actual decisions. The counter-argument is if you separate scientists by media you will have different things done with the same data." I did not find a clear consensus on which of these systems is best.

Several respondents bemoaned the training of risk assessors. One respondent said, "The lead person [in that program] has a PhD in physics, you need one in toxicology with ten years in risk assessment." Another individual echoed that sentiment saying, "You have to ensure that the staff is well trained, and then you have to keep that training up."

Finally the interplay between participation that was a significant strength in the use of cost-benefit analysis does not seem to work as well in risk assessment. That may be a natural outgrowth of the technical nature of risk assessment, but there was an overall sense from the people I spoke with that there was a general lack of transparency in risk assessments that was a barrier even to those with significant scientific training. "We need to have a transparent deliberative process to discuss all forms of analysis and to allow everyone to understand why an approach is used," said one respondent. For all the problems with the density of cost-benefit analyses, most subjects seemed to think they were much more accessible and open to input than risk assessments. One person also noted that there may be a limit to how transparent a risk assessment can be given the highly technical nature of the subject matter, and hence transparency can only be purchased at the expense of accuracy.

Concluding Observations on Interviews

As with cost-benefit analysis, the role of risk assessment in regulatory decision-making is a nuanced one. In certain contexts, good risk assessments clearly make a difference in regulatory decisions. These contexts seem highly dependent on the legal setting in which risk assessment takes place. If a risk assessment is required in order to secure government

approval of a particular action (approval of a product, allowing an import into the country) and there is a deadline for the conclusion of the risk assessment, then risk assessment seems to play a significant role in policy-making. It is also encouraging to hear that political interference, as it is commonly perceived (telling scientists to make certain assumptions), does not seem to play a role in risk assessments.

However, politics of a different sort does seem to play a significant role in risk assessments. The assumptions that go into risk assessments are critical to their final outputs. These assumptions are often made by scientists who are guided by either personal preferences or legal guidance. The assumptions are often difficult to detect in scientific documents that are not easily accessible to the lay reader. Hence the assumptions can play a role in policy-making that is invisible to outsiders. We should be aware, however, that disclosure of the assumptions will not eliminate values from the process of risk assessment; it will just make them clearer. Elimination of the values is likely impossible (Finkel 1989).

If these assumptions are appropriate reactions to statutory language that is intended to push agency decisions in a particular direction, then this is simply democratically expressed preferences influencing policy decisions – a good thing. If, however, it is an overreaction by agency scientists to these standards, and no one is aware of these assumptions, then decisions that appear to be grounded in science are instead grounded in the policy preferences of unelected officials. Unfortunately, because of the challenges of penetrating risk assessments it is impossible to know which of these scenarios prevail. The more comprehensive and rational the analyses attempt to be, the less we will know whether the decisions that spring from them are grounded in the analysis or the assumptions that go into the analysis.

The interviews also highlight the roles of individuals and of bureaucratic structure in the interplay between analysis and decisions. As with economists, the decision to place risk assessors in a central office, as opposed to within programs, was often cited as critical. However, it was not as clear as with the case of economists which structure is better from a policy-making perspective. The training of individuals was also cited as an important factor in the effectiveness of risk assessments in influencing policy. I now turn to two cases that highlight many of these issues.

CASE STUDIES

Case 1: Integrated Risk Information System (IRIS)

"EPA created the IRIS program in 1985 to provide information on human health effects that could arise from chronic exposures to environmental contaminants. A primary goal of IRIS is to increase the consistency of risk assessments being conducted throughout the agency" (NRC 2014). The 1994 and 2009 NRC reports discussed above dealt with risk assessment generally but were motivated in part by concerns with IRIS. Conducting risk assessments in IRIS has always been an extremely time-consuming process. In 2008 the GAO concluded, "The IRIS database is at serious risk of becoming obsolete because EPA has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments" (GAO 2008). The GAO also noted that completed reviews were becoming out of date, and the EPA had not even begun to analyze chemicals requested by IRIS users.

Timeliness is not the only criticism that has been leveled at the IRIS program. In examinations of IRIS assessments of formaldehyde, dioxin, and TCE, the NRC found significant issues with the EPA's weighing of evidence and treatment of studies that found no relationship between these chemicals and cancer risks. Subsequent to the issuance of the formaldehyde report, the EPA pledged[15] to improve the IRIS process in response to the NRC recommendations.[16] These recommendations dealt with the transparency of risk assessments, their clarity, and the development of a more coherent analytical approach (NRC 2014).

NRC (2014) reviewed the EPA's progress in responding to its recommendations. On participation, the NRC found that the EPA had increased transparency but that in response, participation in IRIS reviews was uneven. Industry participated much more often than public interest groups and was able to contribute much more to the scientific debate underlying risk assessments. The NRC suggested that the EPA should perhaps provide technical assistance to underfunded groups in order to facilitate their more effective participation and increase their attendance at professional meetings. The NRC also praised improvement in IRIS quality and the production of an agency-wide guidance document, but notes, "Although the draft handbook provides guidance that is generally informative and useful, it fails to define specific procedures for estimating and evaluating the reliability and validity of processes that are central to the hazard-identification part of the process, such as identifying,

selecting, and evaluating evidence" (NRC 2014, pp. 23–24). The NRC also noted that gains in efficiency for the IRIS process were not yet realized.[17]

Perspectives on the need for IRIS improvements are not uniform. At a 2012 meeting with stakeholders, the American Chemistry Council (ACC) (representing industry) and the Environmental Defense Fund (EDF) (a group that advocates on behalf of the environment) provided starkly different visions of the needs for change in IRIS.[18] The ACC argued that greater opportunities for participation were needed in IRIS assessments and applauded EPA movements in this direction. The EDF on the other hand said that calls for increased participation were essentially smoke-screens for delay, and that the chief problem with IRIS was that it made decisions too slowly. The varying perspectives of the ACC and the EDF also give us an idea of the challenging political climate in which IRIS operates.

The criticisms in the literature and in public comments of IRIS tend to fall into three categories. There are concerns with the accuracy of the risk assessments on specific chemicals[19] as detailed in the NRC reports referenced above, and often cited by the producers of these chemicals or their representatives. There are concerns with the transparency of the process for the risk assessments, also a feature of NRC reports and industrial critics. Finally, there are concerns with the timeliness of IRIS assessments as voiced by environmental advocates, as well as the NRC and GAO reports. There is an inherent tension between the steps to address the timeliness and transparency. Increasing participation slows down assessments. It may or may not improve the accuracy of assessments.

Why is IRIS in this particular box regarding risk assessments? Several of my interview subjects were experts in the IRIS program, and I discussed this with them. The culprits that they cited were familiar ones both to those who have read the risk assessment literature cited above and to those who have studied cost-benefit analysis. These culprits largely fall into five categories: the politics surrounding IRIS, the legal structure for IRIS, the bureaucratic organization of risk assessment, the inherent uncertainty in the science behind IRIS, and personalities.

As discussed in the broader summary of my interviews above, politics comes in two forms. First, IRIS decisions have inevitably high stakes and therefore they receive intense attention from powerful interest groups. One EPA employee said of the chemicals examined in IRIS, "They are typically chemicals where the stakes are high. They've been out for a long time or there are big legacy contamination issues and applying the IRIS value would imply lots of money and remediation. There is a huge

incentive to push back." Because IRIS values are used by other parts of the EPA to justify regulations of often widely used chemicals, the producers of those chemicals have tremendous incentives to fight the conclusions of risk assessments.

Then there is the politics of personal policy preferences within the EPA. IRIS is a "hazard assessment," it does not take into account the exposure of the chemicals. That is left to the program offices within the EPA using the IRIS numbers. As one critic of IRIS said to me, "They don't even frame their questions in exposure contexts. Without the appropriate exposure context, the public will assume that there are exposures or risks that are relevant when in fact there may not be." The assumptions embedded in IRIS evaluations (a criticism also voiced by the NRC) are invisible to those who will be affected by IRIS decisions.

A close cousin to the political issues is the legal setting for IRIS risk assessments. Few analyses have deadlines and as one EPA employee said, "we are processed out," meaning that the procedural requirements for IRIS reviews are extensive, and a source of the delays in decisions that many complain about.[20] One interview subject made an interesting differentiation for integrated assessments of chemicals for the NAAQS. As this employee described them, "We've had real successes come with integrated assessments. There are court mandated deadlines. Those get done … There is a statutory process." In other words when the law mandates results, the types of risk assessments done in IRIS can affect policy decisions. When it doesn't, the current problems exist.

Interview subjects also cited the bureaucratic structure of IRIS within the EPA as a problem. Interestingly, these critics made the opposite point made in the previous chapter about the location of economists conducting cost-benefit analysis. There, several interview subjects responded that the greater the degree of independence for economists, the more influence they were likely to have. With IRIS, I heard the opposite concern. "I think the agency made a great mistake when Superfund and RCRA came along and they didn't staff their programs with their own scientists … I have said publicly that NCEA [National Center of Environmental Assessment – the office within the EPA that conducts the IRIS assessments] should be dismantled and the staff sent back to the program offices," said one subject.

Without taking a view on whether this assessment is correct, the varying perspective could have to do with the different times in which cost-benefit analysis and risk assessment are brought into regulatory decisions. Cost-benefit analysis often comes in after the decision to regulate (which is also a concern); hence independence may be needed to fight the already entrenched bureaucratic and political preferences of the

agency. Risk assessment plays more of a role in priority setting. As *Science and Decisions* noted, this may mean that risk assessors need to talk to policy-makers in order to better understand the questions they need to answer.[21] The emphasis on problem formulation in the book has found its way into the EPA (several interview subjects described the agency emphasis on this), so perhaps this will improve in the near future.

Several interview subjects voiced criticisms of leadership at IRIS. Some of these criticisms focused on decisions made long ago to separate IRIS from the media offices at the EPA, "IRIS was once supposed to be that, it originally envisioned to be a collaborative exercise and then someone decided it would no longer be." There were also criticisms of more recent leadership, "EPA started IRIS in 1986, and had 500 chemicals on system by 1990. Even if it is ten times harder we would be doing 50 in five years. To me it is not the statutory deadline; it is not more amorphous stuff. It goes down to the leadership in IRIS."

Finally, it is important to remember that risk assessment is hard. Graham (2006) points out that over the years the questions that IRIS has looked at have gotten increasingly difficult. Like economics, the results of risk assessments are inherently uncertain and the presentation of that uncertainty can be mischaracterized by those with vested interests. To a much greater extent than in the case of economics, the lay public often treats scientific findings (like those in risk assessments) as hard cold facts. Politicians and interest groups take advantage of this tendency to engage in the "science charade" described by Wagner (1995). As one EPA employee succinctly summed this up, "There is uncertainty in everything."

EPA Pesticide Registration

As I was conducting my interviews, risk assessment in the pesticide registration process was repeatedly mentioned as a contrast to risk assessment in the IRIS program. This happened often enough that it became clear that the pesticide program was an appropriate case study for risk assessment "working" in the regulatory process. The EPA's website explains the program:

> Before manufacturers can sell pesticides in the United States, EPA must evaluate the pesticides thoroughly to ensure that they meet federal safety standards to protect human health and the environment. We grant a "registration" or license that permits a pesticide's distribution, sale, and use only after the company meets the scientific and regulatory requirements. These data requirements apply to anyone or any company that registers pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) or seeks a

> tolerance or tolerance exemption for a pesticide under the Federal Food, Drug, and Cosmetic Act (FFDCA).[22]

And the role of risk assessment:

> EPA conducts ecological risk assessments to determine what risks are posed by a pesticide and whether changes to the use or proposed use are necessary to protect the environment. Many plant and wildlife species can be found near or in cities, agricultural fields, and recreational areas. Before allowing a pesticide product to be sold on the market, we ensure that the pesticide will not pose any unreasonable risks to plants, wildlife and the environment. We do this by evaluating data submitted in support of registration regarding the potential hazard that a pesticide may present to non-target plants, fish, and wildlife species. In addition, EPA reviews studies available in the open literature.[23]

The most important feature distinguishing risk assessment in the pesticide program from the IRIS program is that pesticide manufacturers want to see a decision made. The longer the risk assessment takes, the longer before they can market their product. Hence pesticide manufacturers have no incentives to delay the decision-making process.[24] Even if they are not satisfied with a particular decision by the EPA, they would not want to see wholesale changes which would slow down EPA review of their applications to market new pesticides.

Perhaps because of this political climate, the Pesticide Registration Improvement Act (PRIA) was passed in 2003 (and has been renewed twice since, in 2007 and 2012) requiring expeditious review of applications to use new pesticides.[25] EPA has since promulgated specific deadlines for different types of pesticide applications (new products, new uses, new active ingredients, etc.).[26] These deadlines serve as a further assurance that the risk assessments that are a critical part of the process will not be prolonged.

The combination of the political climate for pesticide risk assessments and the legal deadlines have in part resulted in a program that is well perceived. One interview subject said, "In the pesticide program, risk assessment is front and center because there is a formal requirement for data gathering and assessment and the work of risk assessors is a significant part of the decision-making." Someone outside the program said, "They work with industry to get things on the market. Everyone else is trying to stop something."

Others pointed to other sources of the success of the pesticide risk assessors. One factor cited by several people that I spoke with was the fact that the risk assessors were in the program office rather than

centrally located like the IRIS risk assessors (or like the more successful economists in the previous chapter). One EPA employee said, "The pesticide program was self-contained. There is a continuous dialogue between managers and risk assessors so risk assessors have a far better understanding of the context in which their work finds itself." Another former EPA employee cited the training of the risk assessment staff, "The pesticide office works well. They have good people, good biologists at senior level making decisions."

The pesticide program is not without its critics. Over the years the GAO has issued several reports about concerns with pesticide approvals. Several of these reports have focused on insufficient protection of farmworkers and their children (GAO 2000). The GAO has also discussed the problem of follow-through on conditional registrations (wherein the EPA approves a pesticide but places conditions on their approval – but there is rarely follow up on whether those conditions are met (GAO 2013)). However, these particular concerns are a sharp contrast with the repeated reports by the NAS and by the GAO that characterize the debates over the IRIS program.

CONCLUSIONS

In the spectrum of types of analysis, risk assessment may not be comprehensive but it is certainly perceived as rational. With the veneer of science surrounding it, proponents of risk assessment have long trumpeted its potential value in setting priorities for regulatory agencies deciding which threats to public health are worth their time and energy. The criticisms of risk assessment have significant parallels in the more general criticisms of comprehensive-rational analysis. It takes too long. It cannot produce the answers with the level of certainty that decision-makers hope for. In a political environment, it will either give cover to politicians making decisions for other reasons (the science charade) or inevitably it will be corrupted by the preferences of political leaders or the risk assessors themselves.

As with cost-benefit analysis, all of these concerns have merit. Yet, also as with cost-benefit analysis, sometimes risk assessment works. It works much better in the political environment of the pesticide program then that of the IRIS program. It works better in certain organizational structures (particularly those where risk assessors and risk managers interact as envisioned in *Science and Decisions*) than in others. It works better when the scope of the risk assessment is constrained either by deadlines or by other factors.

After looking at two forms of comprehensive-rational analysis, certain patterns are emerging. The roles of certain institutions highlighted by the literature play out on a day-to-day basis in the world of policy analysis. Pre-eminent among these institutions is politics both writ large and writ small. There is less room for analysis to maneuver on issues where the political temperature is high. Priorities are set (in the case of risk assessment) or policy choices are made (in the case of cost-benefit analysis) before the scientists or economists are invited into the room. In cases where the political climate is less intrusive, analysis has more room to influence decisions but also there is more room for the ideological preferences of the analyst to play a role.

Besides politics, bureaucratic organization and personality (of analysts and of their supervisors) are also clearly important. Interestingly, economists strove for independence from reporting to policy-makers while risk assessors craved more connection in order to better structure their research. This difference likely arises from the role of risk assessors in setting agency agendas as opposed to the role of economists in evaluating policy choices. It may also indicate that there is no one "best way" to structure analysis within a bureaucracy. The continual role of personality highlights the role of agency culture often discussed in the literature (Wilson 1989).

Finally the limits of cost-benefit analysis and of risk assessment are well recognized by their practitioners. But it is not clear that outside supporters and critics of these forms of analysis share this recognition. Decision-makers turn to analysts hoping for answers. If they get uncertainty instead, some may not turn to the analysts the next time. This puts pressure on analysts of all stripes to be very careful about how they portray uncertainty and perhaps to obscure it. Many outside critics of analysis (including some I spoke with) bemoaned the way uncertainty is portrayed by risk assessors. This may be an attempt to impose one's personal preferences on policy choices. But it may also be a rational response to a decision-making environment that is looking for more concrete answers than are feasible. The continual attempts to separate science from values may in the end be impossible (Finkel 1989).

We now turn to a form of comprehensive-rational analysis that is used both in the regulatory arena and in other policy choices. Environmental impact assessment has been required of federal agencies for longer than cost-benefit analysis or risk assessment. In the next chapter, I will explore how the factors that influence cost-benefit analysis and risk assessment influence environmental impact assessment and how assessors have responded to them.

NOTES

1. The Society of Risk Analysis began meeting annually in 1981, and the Society for Benefit Cost Analysis began in 2006. The journals *Risk Analysis* and *The Journal of Benefit-Cost Analysis* were each started with the founding of the professional societies.
2. It is not a perfect measure but a Google Scholar search of "risk assessment" returns 1.8 million results, nearly double the combined result for "cost-benefit analysis" and "benefit-cost analysis."
3. Clean Water Act 33 U.S.C. §§1345 (d)(2)(D).
4. Clean Air Act 42 U.S.C. §§7412 (c)(9).
5. The chemical industry had been arguing for more separation between science and policy at regulatory agencies (Jasanoff 1990).
6. For a discussion of the animal/human issue see Allen et al. (1988).
7. There were exceptions, "proceedings founded on the separatist principle frequently generate more conflict than those which seek, however imperfectly, to integrate scientific and political decision-making" (Jasanoff 1990, p. 231).
8. Natural Resources Defense Council v. EPA (824 F.2d 1146).
9. The EPA had presaged this discussion in some of the many reports it issued on risk assessment. For example in its 1994 report entitled, *Managing Ecological Risks at EPA*, one of its recommendations was for risk managers to play more of a role in scoping risk assessments so that risk assessors knew which questions they should address. In a 2004 staff paper the EPA (2004) noted the evolution of thinking, "EPA risk assessment practices have evolved over time along with this progression of thought, and in many cases helped drive the evolution of thinking on risk assessment."
10. But see Jasanoff (1990) on the difference between regulatory science and traditional science. Regulatory science is more focused on knowledge production, knowledge synthesis, and prediction than traditional science.
11. Graffy (2008) presents an interesting case study about the problems that arise when science is insulated from the public and an effort at the United States Geologic Survey to bridge the divide.
12. In 2010, Congress passed the "Formaldehyde Standards for Composite Wood Products Act" Pub. L. 111-199, which established limits for formaldehyde emissions from composite wood products: hardwood plywood, medium-density fiberboard, and particleboard.
13. Indus. Union Dept. v. Amer. Petroleum Inst. 448 U.S. 607 (1980).
14. "Moreover, an increasing number of practitioners and critics have come to understand that in large part, the range of plausible answers for risk-assessment questions reflects the real variation in risk estimates within affected populations, which no amount of research can reduce" (Hassenzahl and Finkel 2008, p. 592).
15. The EPA has issued a panoply of reports over the years regarding the improvement of risk assessment generally and IRIS in particular. Here I focus only on the most recent set of responses and the NRC's 2014 evaluation of them.
16. Many of the improvements that the EPA has committed to are outlined in a document issued by the agency in 2013, http://www.epa.gov/iris/pdfs/irisprocessfactsheet2013.pdf (last accessed April 28, 2015).
17. GAO (2012) reached similar conclusions to the NRC.
18. The presentations can be found at http://www.epa.gov/iris/publicmeeting/stakeholders-kickoff/publicmtg_speakers.htm (last accessed April 28, 2015).
19. See also for example this comment submitted to the EPA on outdated assessments in IRIS: http://www.regulations.gov/#!documentDetail;D=EPA-HQ-ORD-2014-0211-0019 (last accessed April 30, 2015).
20. See also Mills (2006), who is a former IRIS administrator.
21. Jasanoff (1990) describes several efforts at making risk assessment (and other science-related policy efforts) wholly independent of regulatory agencies. She details the experiences of the Health Effects Institute which has been quite successful and several efforts by the FDA which have had more mixed results.

22. See http://www2.epa.gov/pesticide-registration/data-requirements (last accessed March 20, 2015).
23. See http://www.epa.gov/pesticides/about/overview_risk_assess.htm (last accessed May 7, 2015).
24. This is in contrast to EPA regulation of existing pesticides whereby the EPA can pull pesticides in use off the market. This program is plagued by many of the same challenges as the IRIS program (Jasanoff 1990).
25. Pub. L. 108-199.
26. See http://www2.epa.gov/pria-fees/fy-201415-fee-schedule-registration-applications (last accessed May 7, 2015).

5. Environmental impact assessment

On the surface, environmental impact assessment seems narrower than comprehensive-rational assessment. After all, one is just looking at the environment. However, it was created right when faith in the ability to thoroughly analyze the consequences of a government action was at its peak. And its proponents thought of it as, well, comprehensive, "the environment is made up of both biophysical and socioeconomic elements which should be considered in environmental impact analysis" (Jain et al. 1981, p. 3) and, "The philosophy and principles of EIA can be traced back to a rationalist approach to decision-making that emerged in the 1960s" (Jay et al. 2007). Its chief legislative backer, Senator Henry "Scoop" Jackson was a significant proponent of rational decision-making (Lazarus 2011).

In some ways, it is also much broader than the other forms of comprehensive-rational analysis. Whereas cost-benefit analysis and risk assessment have played their largest roles in regulatory policy, environmental impact assessment (EIA) involves any project that the government funds in addition to regulatory issues.[1] As a result, a far wider range of agencies must undertake environmental impact analysis than the other forms of comprehensive-rational analysis covered in this book. Agencies must do an environmental analysis for projects as diverse as new railroad lines, changes in national parks, and the approval of the Keystone Pipeline.

Congress passed the National Environmental Policy Act (NEPA) in January of 1970. Coming amidst a wave of environmental statutes, the legislation was intended to upgrade the minimal environmental emphasis in federal decisions ranging from timber leasing, to dam building, to nuclear site approval (Clark and Canter 1997). NEPA required the production of environmental impact statements (EISs) for certain decisions. Section 102 of NEPA requires agencies to conduct an EIA. Section 102(2)(C) requires that this assessment cover:

(i) the environmental impact of the proposed action,
(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
(iii) alternatives to the proposed action,

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.[2]

According the website of the Council for Environmental Quality (CEQ), which is charged with overseeing NEPA:[3]

> Each Federal agency has its own agency NEPA implementing procedures which adapt the framework established by the CEQ regulations to address agency specific missions and decisionmaking authority. The NEPA process begins when an agency proposes to take an action (this can include proposals to adopt: rules and regulations; formal plans that direct future actions; program; and specific projects – see 40 C.F.R. § 1508.18). Once the proposal is conceptualized and any reasonable alternatives have been developed, the agency must determine if the action has the potential to affect the quality of the human environment. This process results in one of three levels of NEPA analysis. Agencies may:
>
> a. apply a Categorical Exclusion;
> b. prepare an Environmental Assessment (EA); or
> c. prepare an Environmental Impact Statement (EIS).
>
> The most rigorous level of NEPA compliance, an EIS has more regulatory requirements than an EA. First, the agency files a Notice of Intent in the Federal Register, informing the public of the upcoming environmental analysis and describing how they can become involved in EIS preparation.

The EIS is intended to be a comprehensive analysis of the environmental consequences of the agency decision. Hence it fits squarely within the description of comprehensive-rational analysis described by Lindblom. One important distinction though is that agencies can perform a less comprehensive analysis in order to demonstrate that a more comprehensive analysis is not necessary. In fact many more environmental assessments than EISs are performed.

EISs therefore affect a much broader class of federal government decisions than just regulations. The decision about whether to undertake an EIS must be taken for any government action. Arguably the debate over EISs has been most prominent in government projects such as dams built by the Army Corps of Engineers, oil leases granted by the Department of the Interior, and nuclear waste clean-ups by the Department of Energy. Regulations form merely a subset of the policy choices that NEPA was intended to impact.

Still, the experience with NEPA, in the regulatory context and elsewhere, holds many commonalities with the experiences of the other types

of analysis in the regulatory world. Some of the differences are instructive as well. This chapter proceeds much as the preceding ones have; I start with a review of the literature on EIA and then proceed to my empirical research before drawing conclusions.

LITERATURE ON ENVIRONMENTAL IMPACT ANALYSIS

Environmental impact analysis has been a part of the federal landscape since 1969. The journal *Environmental Impact Analysis Review* dates to 1980. The practice has spread to many state and local governments, and, to a degree not matched by other forms of comprehensive-rational analysis, across the globe. The international context in particular has led to a multifaceted and deep literature on EIA. I focus on works that specifically discuss the use of environmental impact analysis by U.S. agencies in order to facilitate the comparison to the other types of analysis discussed in this volume.

After the passage of NEPA, the EIS evolved quickly. Within two years, federal agencies had produced 3635 EISs (and produced innumerably more environmental assessments and determinations of categorical exclusions) and had been sued in 149 separate cases (Clark and Canter 1997). The process for conducting an EIS became more systematic with the issuance of regulations by the CEQ in 1978 (Clark and Canter 1997). NEPA has also evolved to have a strong component of public participation. Public comment was initially required by executive order but before long, courts also required agencies to solicit input on their analyses (Taylor 1984).

Taylor (1984) describes the evolution of litigation on EISs as follows. In the first stage agencies argued that they did not have to perform an EIS; the environmentalists sued the agencies and won. In the second stage, agencies tried to get away with overly simplistic EISs, and again environmentalists sued in court and again they won.[4] Then, agencies began to write dense and complicated EISs (thousands of pages long on occasion) that were impenetrable to outsiders. Again, environmentalists sued, but now they lost.

Taylor's (1984) three-stage description nicely captures the criticisms of the EIS process as it is currently practiced. The CEQ acknowledges that EISs are designed more to be "litigation proof" than to help inform decisions (CEQ 1997). The EISs are excessively detailed and this detail conveys the false impression of precision, while obscuring the ability of outsiders to evaluate the accuracy of the analysis. Courts have been

reluctant to overturn decisions based on these EISs, which contain so much information. Scholars hypothesize that courts understand the mass of the analysis to signal that the agency has comprehensively assessed the environmental impacts (Karkkainen 2002).

This has given agencies the incentive either to try to skip the EIS process altogether or to produce massive analyses that play little role in actual decision-making.

> NEPA ambitiously and naively demands the impossible: comprehensive synoptic rationality in the form of an exhaustive one shot set of ex-ante predictions of expected environmental impacts … As the critics point out, it places extreme demands on agency resources, often generates little useful information and produces a work product too late in the decision-making cycle to influence the agency's course of action. (Karkkanien 2002, p. 906)

Karrkanien is far from a lone voice. Caldwell (1991) describes the emphasis in EISs of "precision over relevance." Lindstrom (2000) argues that the intent of the framers of NEPA has been subverted. Some have noted that EIAs while not affecting decisions may serve to educate laypeople about environmental concerns (Cashmore et al. 2010). Sullivan et al. (1996) argue that even this effect is limited as laypeople could not understand an EIS for a flood control measure that would affect them. Only 31 percent of EISs contain adequate information as rated by the EPA, and this number has not improved over time (Tzoumis 2007). These criticisms sound remarkably similar to the criticisms of cost-benefit analyses described in Chapter 3.

Agencies have taken advantage of the ability to avoid carrying out EISs in certain circumstances. Karkkainen (2002) describes the appeal of the "mitigated FONSI (Finding of No Significant Impact)" approach where the agency announces some environmental improvements that will mitigate the effect of its decision and thereby eliminate the need for an EIS. Mitigated FONSIs have been accepted by the courts and have become an increasingly common agency practice (Mandelker 2010) although views are mixed on whether they are a positive or negative development for environmental protection.

Jay et al. contrast the rhetoric of NEPA with the argument that EISs inform decision-makers but do not force them to choose the environmentally preferred option. "Even if an EIA is presenting information satisfactorily … it is unlikely to succeed in its stated aim of ensuring that environmental considerations are fully incorporated into decision-making" (Jay et al. 2007, p. 293). They go on to argue, however, that EIAs may be having a more profound long-term effect by educating a broader population about environmental thinking.

Indeed, there is considerable emphasis on public participation within the EIS process, and within the literature. For cost-benefit analysis and risk assessment there has long been the hope that public comment and the analytical enterprise will work together. Advocates hope that the analysis will increase transparency about the impacts of agency actions, and the comments will (in addition to improving the underlying policy) improve the analysis by providing valuable information to analysts.

In the case of an EIS, this hope is written into the implementing regulations. Agencies are required to get public input on their EIS and academics have seized on the potential of this process. "An assumption of the law is that intra- and inter-agency analysis accompanied by input from private and public parties will shape better decisions" (Greenberg 2013, p. 4). Whether this hope has been realized is of course the subject of this chapter. However, some have contended that the participation/analysis partnership has had other impacts,

> they [the EISs] provided nongovernmental organizations with information on agency actions they never could have produced on their own. Based on that new information, environmentalists could determine what restrictions other environmental protection laws might impose on the proposed federal agency activity. (Lazarus 2011, pp. 1518–1519)

On the other hand public comment is a blunt tool for participation, and differences in risk perception between the public and experts may make meaningful individual participation impossible (Eckerd 2014). Some have asserted that citizen involvement through this process has been negligible (Walker 2014).

Public comment also gives leverage to the analysts within the agency. Knowing that the EIS will be subject to ridicule if it is done poorly, agency managers have the incentive to listen to analysts so as to avoid this outcome (Taylor 1984). This external environment is important. Outside groups such as the Sierra Club and Environmental Defense exist to pursue the same values in public policy that are embodied in the EIS requirement. No such groups explicitly exist to pursue economic efficiency or risk analysis. It is possible that the environmental groups have been able to grow in part because of NEPA and the EIS requirement; but it is also possible that their existence and power is independent of NEPA and the EIS requirement. In short, EISs take place in a different political environment than the other forms of comprehensive-rational analysis discussed in Chapters 3 and 4. This political environment is replicated in the discussion of SBREFA panels in Chapter 6.

Another difference between EISs and the analyses discussed in Chapters 3 and 4 is that, as described above, there is meaningful judicial review of EISs. NEPA's requirement for an EIS is more firmly grounded in statute than cost-benefit analysis and risk assessment. However, as described above, courts, after initially forcing agencies to write EISs and to make them substantive, have been reluctant to overturn agency decisions once a detailed EIS is done. Courts have avoided requests from plaintiffs to resolve technical disputes (Taylor 1984). Yost (1990) argues that the Supreme Court has interpreted the EIS requirement to be procedural in nature rather than substantive. The government has a perfect record in defending NEPA-based challenges before the Supreme Court over the past 40 years. The Court has also refused to hear challenges when EISs are upheld by lower courts (Lazarus 2011). The courts have largely ruled that as long as an agency follows the correct procedural steps, and produces a defensible assessment of the environmental impacts of its actions, it is not required to change its decisions about those actions (see also Taylor 1984). Yost echoes Lindstrom (2000) and argues that the intent of NEPA has been lost because of this interpretation.

A key provision of the implementation regulations of NEPA requires agencies to assess meaningful alternatives to their preferred policy option. As with economic analyses, the insufficiency of these alternatives is a frequent subject of criticism. Unlike in the case of cost-benefit analysis, agencies can be (and have been) sued for ignoring this requirement. Such lawsuits are not frequently successful, however, as one analysis found that agencies successfully defended themselves 89 percent of the time. In other words, the quality of the analysis of alternatives has not been a reason for courts to overturn agency actions (Smith 2007).

Are successful agency defenses of EISs in court evidence of a failure of the analytical requirement? Taylor (1984) argues that judicial review of EISs has given external environmental groups another tool of influence and in doing so has abetted the growth in power of environmentalists within agencies. So, judicial review may have important impacts that do not show up in overturned decisions due to EISs.[5] Also, in recent years, the Ninth Circuit Court of Appeals has shown signs of breathing substantive life into the EIS requirement overturning agency decisions on grazing (Western Watersheds Project v. Kraayenbrink)[6] and whaling (Metcalf v. Daley).[7] However, the Ninth Circuit also applied NEPA to a United States Department of Agriculture (USDA) decision to approve genetically modified crops and was overturned by the Supreme Court (Montana Co. Et. Al. v. Geertson Seed Farms).[8]

Some have also attributed an impact on agency culture to judicial review, despite its failure to affect many individual policy decisions. One author describes the "near miss effect" where conducting an EIS makes an agency aware of violations of other environmental statutes and the "tourniquet effect" of reducing environmental impact through mitigated FONSIs (Gerrard 2009). One study has shown that in Europe, many of the changes wrought by the EIS process occur before the EIS is completed (Barker and Wood 1999). A survey of agency NEPA personnel found that agency culture ranked second to senior management support as a factor in ensuring that environmental analysis gained attention within the agency (Lamb 2014). "The process of preparing EISs can itself change agency behavior. It is one thing to resist expending resources to acquire information about adverse environmental impacts. It is quite another to ignore such information once it is available and part of the decision-making record" (Lazarus 2011, p. 1519).

Despite these possible successes the limitations of the EIS process are echoes of the argument put forward by Lindblom. "As long ago as 1959, Charles Lindblom tried to explain to public administrators why rational-comprehensive analysis is impossible in highly politicized decisions … Nothing in the last two decades of environmental management has refuted Lindblom's argument" (Culhane 1990). And,

> Rather than enabling fully informed decision-making, the EIS has become a costly procedural bottleneck in agency decision-making, generating vast quantities of often low quality information too late in the decision-making cycle to make much of a difference in the outcome. Consequently agencies have largely shunned it. (Karkkainen 2002, p. 970)

While much of the literature on EISs focuses on their technical aspects, the interaction with the courts and with the public participation aspects of NEPA, there are very few works that contain case studies of how NEPA affected U.S. policy decisions. The two best works are nearly a generation apart. Serge Taylor (1984) used studies of the Army Corps of Engineers and the U.S. Forest Service to draw broader conclusions about the integrations of scientific analysis into public policy-making. Michael Greenberg (2013) carried out eight case studies of how EIS affected particular decisions.

Taylor's work has been quoted extensively throughout this volume because its coverage of NEPA touches directly on many of the themes present in all of our analytical enterprises. Regarding NEPA, he argues that three factors determine the effect of the EIS: 1) the political environment of sub-units; 2) the slack (e.g. if a project can easily

incorporate environmental improvements); and 3) epistemic constraints on knowledge. His overall assessment is that NEPA increased environmental consciousness in agencies but, "saying the managers are more environmentally aware does not tell us to what extent they will trade off other values they favor in order to gain more environmental protection" (Taylor 1984, p. 125). Also, "the 'average' project is better than before; this is because a portion of the environmentally worst projects has been clipped off the overall distribution of projects" (Taylor 1984, p. 150). As with cost-benefit analyses, we see that one impact of analysis is to eliminate the worst policy initiatives, and to shine light on the easiest decisions.

This finding is echoed by Greenberg (2013). "NEPA, say its proponents, has been instrumental in the cancellation or postponement of highways, dams, airports, nuclear waste disposal programs, outer continental shelf leases, and other proposals. More often, the scoping, presentation, and preparation of the results have caused changes in locations, designs and other changes to mitigate undesirable environmental effects" (Greenberg 2013, p. 12). On the other hand,

> Some contend that many actions with environmentally significant impacts are not accompanied by an EIS because agencies decide the actions are not 'major' or 'significant' or do not constitute an agency 'proposal' or 'action.' In addition, to avoid preparation of an EIS, or to make sure that one is not vulnerable to legal opposition, documents are infused with as much information as possible to protect the agency's position … This problem is especially evident in the discussion of alternatives. (Greenberg 2013, p. 14)

Greenberg (2013) conducted eight case studies of the effect of EISs and the results are mixed. They range from an instance of tribal nations and environmentalists using NEPA to challenge and eventually modify a project in the Four Corners area of the southwest (United States), to a case where an EIS played almost no role in determining the suitability of a chemical weapons disposal site. His cases also show long delays due to EISs, and other statutory constraints boxing in the usefulness of the EIS.

One of the key figures in the creation of the statutory requirement for environmental impact analysis sums up the literature well, "I conclude that EIA has only partially succeeded in its intended purpose. It has been instrumental in stopping some environmentally damaging proposals and in modifying many others. But EIA alone should not be expected to do more than it was designed to do" (Caldwell 1991, p. 90).

On the non-academic side, the GAO (2014) carried out an examination of agency practice regarding NEPA compliance. It reported that 95 percent of NEPA analyses were Categorical Exclusions, fewer than

5 percent were Environmental Assessments, and fewer than 1 percent were EISs. The applicability of NEPA is so wide that this still meant that there were 397 EISs in 2012. The EISs took an average of 4.6 years to complete, and the GAO says this may be an underestimate. As for the benefits of performing an EIS as reported by the agencies:

> According to studies and agency officials, some of the qualitative benefits of NEPA include its role as a tool for encouraging transparency and public participation and in discovering and addressing the potential effects of a proposal in the early design stages to avoid problems that could end up taking more time and being more costly in the long run.

Interestingly the reported benefits do not include a cleaner environment (GAO 2014).

The literature on the EIS is vast. In it, there are echoes of the experience many of the other forms of comprehensive-rational analysis. Supporters of the EIS are frustrated by projects and policies that move ahead despite deleterious impacts on the environment. Critics cite interminable delays in projects, even with projects that eventually get approved. The literature also emphasizes several institutional factors more than we have seen with other forms of analysis. Judicial review is central to the EIS story. Participation, a factor in all forms of analysis, is held up as critical component of a successful EIS process. Finally, the use of mitigated FONSIs presents questions that may have implications for analysis generally. All of these played important roles in my interviews.

INTERVIEWS

Due both to the widespread presence of EISs across the federal government, and the limitations in my own network regarding EIS use (my own experiences prior to this research are much more involved with cost-benefit analysis and risk assessment), my methodology of finding interview subjects for this chapter differed a little from the previous two chapters. In addition to relying on colleagues who did have experience in this field, I posted invitations on a LinkedIn group for EIA and contacted several professional organizations which publicized my interview requests. I spoke with 16 individuals who had experience working at or contracting with nine agencies (several interview subjects had experience in more than one agency). Their experience included work with the Environmental Protection Agency (EPA),[9] the Nuclear Regulatory Commission (NRC), the National Oceanic and Atmospheric Administration

(NOAA), the Departments of Transportation, Interior, Agriculture, and Homeland Security, and several branches of the military. As with the other forms of analysis, collectively the people I spoke with had worked on or reviewed more than 1000 analyses.

I also added two questions to my interview protocol, and reduced by one the number of examples I asked respondents for. The modifications are shown in Appendix A. The two additional questions included one on the effect of judicial review and one on the impact of public participation. These two subjects were so important in the literature on the use of EISs that I felt it critical to get on-the-ground assessments of their roles. Besides this modification, the interviews largely paralleled those used for economists and risk assessors.

The experiences of the people I spoke with varied widely. All had more than 20 years in the field of EIA and had many experiences upon which to draw. Just as the type of government actions that EISs affect is much broader than the other forms of comprehensive-rational analysis, so were the experiences of my interview subjects. I heard perspectives on everything from a decision to build a childcare center on a military base to the Keystone Pipeline. Because of the tiered nature of NEPA, every project must be analyzed and categorized as either meeting the criteria for a categorical exclusion, requiring an Environmental Assessment (EA), or an EIS. So the need for an environmental assessment is both not limited to regulations and has no threshold effect (although only projects with a significant impact on the environment get the full comprehensive analysis).

Despite the varying experience, as will be shown below, several trends emerge. Many of these trends echo the findings in the risk assessment and cost-benefit chapters as well as the literature described above. Even more so than these other forms of analysis, EISs are plagued by length and complexity. The interaction between the analysis and public participation is even more crucial in the EIS context (perhaps because such participation is required by statute, but also because there are organized interests monitoring the EIS process). Some factors not present in the previous chapters also emerge: the role of judicial review, and the extensive use of contractors to conduct EIS. The ability of an agency to avoid conducting an EIS by mitigating the effect on the environment is another crucial difference. And like cost-benefit analysis and risk assessment, sometimes the EIS works well, and other times it is ignored or leads to unnecessary delays in decision-making.

How does Environmental Impact Assessment Fit in the Decision-making Process?

As with the other forms of analysis, timing is an essential variable in the use of EIA. Done at an early stage, as part of a project or policy planning process, environmental assessment and EIS can have important impacts on government decisions. Conducted later, after key decisions are made, it is obviously nearly impossible for environmental assessments to have an impact; at this stage they play more of a role in justifying decisions already reached than influencing them.

Some interview subjects praised their agencies for making environmental impact a key part of the planning process. Several mentioned the U.S. Forest Service as particularly strong in this area (although one commented, "The Forest Service is very into planning. So much so they don't get much done."). One consultant noted a positive trend, "In the late 1980s it was more common to justify decisions already made. Today there seems to be more interest in seeing impacts early on, to make small changes while there is time." At another agency, someone said, "Our leadership is very plugged in and informed by NEPA analysis."

However, others recalled the opposite experience. Someone who had carried out work with the Department of Energy said, "The myths you hear over and over that decision is made and the NEPA analysis justifies it is not a myth," and "How could anyone put NEPA at front when it is the engineers who make the decisions that already have calculated the need for the project?" It is clear that in some situations, environmental impact analysis is a "check the box" exercise that is conducted because it is legally required. This was not the prevalent view among my interview subjects but it occurred often enough that it bears noting.

What is the difference between those agencies which systematically empower environmental analysts and those which do not? Many of the answers to this question are similar to the answers I heard from scientists and particularly economists. The location of the analysts within the agency, the culture of the agency, and particularly the receptiveness of key decision-makers to hearing analytical conclusions that may disagree with their prior preferences all were cited by interview subjects. As one well-placed analyst put it, "It's not just the staff but they have to have the standing in the agency. My boss values my input. You need the combination of the skill set and the standing."

As for agency culture, it clearly also plays a role. As noted above, the planning culture in the Forest Service has likely facilitated the permeation of environmental impact analysis into agency decision-making. Fear of being overturned on judicial review also plays a role in affecting

agency culture (particularly if an agency has lost a case before). However, some agencies react to the NEPA requirement and its legal implications as a hurdle to be cleared. One analyst said, "It is pigeonholed into this document creating process but it should be more of an integrating process."

A number of my interview subjects were consultants who authored EISs and environmental assessments on contract for government agencies. While contracting out analysis occurs to some degree with cost-benefit analysis, its use in the EIA process is much more widespread. One former agency employee said that at his agency, "Environmental assessments were done in house but EIS would be contracted out." The Nuclear Regulatory Commission does no environmental impact analysis itself, but rather requires it of applicants for permits, making the analysis an entirely private enterprise.

As with risk assessment, no one came up with examples of being asked to change assumptions or the analysis itself. Analysts may have been asked to justify pre-made decisions but the conduct of the analysis was done by agency experts or their contractors. In fact, the environmental impact assessors I spoke with seemed further removed from political leaders than either the economists or scientists I interviewed.[10]

Environmental Impact Assessment Working Well

The two clearest areas in which the NEPA process works well are in encouraging participation among potentially affected parties (although that also comes with its downsides), and through the mitigation of environmental harms early in the project or policy planning process.

Mitigation

Agencies have embraced the concept of the mitigated FONSI. If, by preventing some environmental harms, they can get out of the process of doing a full-blown EIS the deal is often too good to pass up. Examples of this abounded. From a former project manager in the military, "I've always found it beneficial to learn what the critical issues were upfront and then do everything you can to avoid impacts. One of the first NEPA projects I worked on, neighbors told us there would be a historical cemetery site where we were planning on building. We found it and avoided impacts by fencing it off." And, "Due to ongoing work with the affected tribes, we eventually modified the flight plans ultimately selected to coexist with the traditional ceremonies and locations. By working with Tribal elders and their council we determined that particular sites were of significance only at certain times of year and day. We

worked out an arrangement with the Tribe to ensure a 'no fly' area of several miles during the specified times/days provided to us."

Civilian agencies also used mitigated FONSIs to reduce the environmental footprint of their projects and avoid months or years of paperwork. Some agency personnel weren't necessarily happy about this, "Adverse consequences are mitigated in order to claim that environmental impact is mitigated. Agencies are encouraged to adopt every damn measure known to humankind (to within an inch of the project's life)." But the same person noted that he had seen thousands of examples of this agency behavior.

The mitigated FONSI is an interesting creation which has no real parallel in the other forms of analysis. In no other cases can agencies avoid an analytical requirement by reducing the impact of their action. An agency may reduce costs on business as a result of doing a cost-benefit analysis, but the analysis still has to be done. While some scholars have criticized the use of the mitigated FONSI as a way of short-circuiting the NEPA process (Ensminger and McLean 1993), many environmental improvements have occurred through its usage. If the purpose of NEPA is to improve the environment, mitigated FONSIs accomplish this goal. They may do so at some expense to the agency. They may not be the comprehensive improvements envisioned by the statute's advocates. But collectively their impact is clearly considerable.

Participation

My interview subjects had a mixed set of experiences with participation but on balance they viewed it as an important part of the process of analyzing environmental impacts. The most negative response that I heard when discussing public input was, "Does it bring people in? Yes. Does the government use it? No, it gets junk. Ninety-nine percent of participation is junk. The project goes out with a draft analysis. We get 50 000 postcards, that's not useful. It's not democratic and it didn't become democratic. The myth that is perpetrated is that we crave your input. But then we ignore your input." Another subject said, "Meaningful participation is an elusive goal. People who come into meetings who look at the map, look for the road and ask is it near their house? If not, they leave." One consultant said that the public misunderstood the NEPA process, "When you talk to the public about the NEPA process they are always upset that there is no process for public to change the design of a project."

Most of the hostility toward participation came from experiences with organized interest groups who were protesting government projects. In a sense, it is not surprising that people who worked on projects were upset

by organized campaigns to derail the project. In addition, most of the instances where there was organized opposition led to project delays but not project cancellations. This produced the sense that the time spent interacting with and countering the concerns of the outside groups was merely a legal exercise and a waste of time. It lead to few meaningful changes. The case of the Mexican truckers described below shares this characteristic.

But there were many examples of useful participation as well. A NOAA employee noted that they sought out participation even when it was not required, "Even in the EA process where we are not required to have public comment, we still provide that opportunity so the people in that community have some say." A consultant noted, "There is a lot of information out there that the public has that is not yet in the public record and that's not in the federal state databases, and that [finding out what the public knows] is why you are asking for comment."

An EPA official provided insights on the differences between how agencies manage participation. "I've seen agencies very open to it, they hold good meetings and engage with the public and they are genuinely interested in the public information. I've seen other agencies that treat it as a formality, check the box. I've seen the meetings handled well and handled badly and only one perspective gets to be heard." This openness to participation is likely a key factor in whether public comment plays a role in eventual decisions.

Agencies can be required to solicit participation on their analyses, but with the exception of blithely dismissing this participation in an "arbitrary and capricious" manner they cannot be forced to take heed of the public comments they receive. Agencies thus have a choice, they can "check the box," have the required participation and move on. If a decision is firm, because of organizational or political forces, this is the approach that the agency is likely to pursue. If, in addition, organized interests oppose the decision, then this may be a recipe for a long drawn out process that eventually ends up in court.

Or agencies can see participation as a way of improving their analyses and engage the public. When there is truly room for changing the policy decision this seems like it has clear benefits for the agency and for the public. Agencies do not hold monopolies on the information about a project, no matter how expert laden they are, and soliciting opinions from the public can only increase the information available. And there are other benefits. One interview subject said that participation "also helps the acceptance of a decision." Another noted long-term impacts, "It helped us form public partnerships with groups that work in the area. Twenty years later, we are still partnering with those groups."

One person I spoke with from the U.S. Forest Service (USFS) pointed me toward the preamble of the USFS NEPA regulations revised in 2007 (USFS 2007),

> There continues to be focus on preparing NEPA documents such as an EIS or environmental assessment (EA) for litigation rather than to facilitate an informed decision process. The proposed NEPA documentation requirements are intended to enable interested parties to engage more effectively in the decision-making process rather than merely as commenters on proposals and documents. Rather than a document to be used only for a final Agency decision, the EIS could evolve as the decision evolves incrementally and be useful throughout the process. The EIS would then be used as a tool to foster a collaborative and incremental decision-making process rather than an end in itself.

The USFS representative talked about how the agency was working toward this goal and that the interplay between analysis and public participation was more critical than the specific requirements of the EIS itself.

Environmental Impact Assessment Working Poorly

The most frequently cited problem with the EIS is their length. One respondent said, "Many federal agencies go very overboard documenting issues that they don't need to and create documents with multiple thousands of pages that go against CEQ guidance." Another said, "I would require much shorter EIS documents." The length of the documents is a problem for a variety of reasons. It makes the documents less transparent. It makes them less useful to decision-makers. And the perceived need to cover every aspect of a decision in painstaking detail contributes to a process which stretches on for years.

Numerous factors were cited as being causes for the impenetrable analyses. Some subjects cited the fear of eventual judicial review, but others said that the possibility of ending up in court had a minimal impact on their analyses. One person believed that the prevalence of contractors conducting EISs was a factor as contractors behaved as though, "they were being paid by the word." Finally, one person recommended better training for agency staff that perform EISs. His contention was that if analysts weren't so afraid of making the wrong decision, they would not feel the necessity to produce analyses that were thousands of pages long.

As with cost-benefit analysis, interview subjects could cite occasional examples of cases where their work was largely ignored. In a case of land

being withdrawn for military use, one analyst said, "I determined that a portion of the land that was being considered for exclusion from the withdrawal should undergo an additional and separate analysis, based on whether the final decision included this exclusion. My recommendation was not accepted. The land was subsequently excluded with no further analysis."

However, many analysts struggled to come up with examples of the EIS process having no impact on the eventual project or policy decision. As described above, there were numerous examples of decisions being delayed for years by litigation pushed by organized interests that did little to change the original policy choice. The case of the Mexican truckers below is an example of this being the only impact of an environmental impact analysis. But in most contexts the use of an EIS at least led to some mitigations of possible environmental harms.

The Question of Judicial Review

Responses to my question on whether judicial review affected the conduct of analysis and its eventual use were tremendously varied. As noted above, some respondents blamed the presence of the courts for documents that stretched into the thousands of pages. While the literature often portrays this as a strategic choice designed to make it hard for judges to deem agencies as arbitrary in their analytical choices, interview subjects described it more as risk aversion: being sure to include everything so as to maximize the chance that the analysis is litigation proof. Regardless of the motivation, however, the effect is the same. There is likely a relationship between the presence of judicial review and the length and lack of transparency of EIS documents.

Other respondents simply noted that the specter of judicial review was ever present as they were conducting their EISs. One respondent said, "You are writing it to be legally sufficient, not to solve the problem." Another described the consequences of an agency losing a case in court (even though the loss was eventually overturned). When the agency then conducted environmental analyses of decisions similar to the one that ran into trouble at court, "There was not a lack of analysis but rather an expansion of analysis greater than their authority in an area that has nothing to do with their decision." The strongest comment I heard was, "It is the threat of adverse litigation that forces managers to pay attention. My job would be impossible otherwise."

Some analysts minimized the effect of judicial review – "I didn't think it had a major impact on the decision-makers. They knew it was out there. People were trying to be responsive. They weren't driven by

judicial review. They were more driven by how can I put the best technical document together," was how one respondent put it. A former Forest Service employee was more blunt, "A ranger once said to me 'I have 16 projects for next year, if I lose one or two I still have a dozen left over.' So he is not concerned about the courts."

In all likelihood the effect of judicial review, like that of public participation, probably varies with the nature of the project. There is every reason to believe that, as they begin their work on an EIS, analysts (and their employers) know whether they are working on a highly contentious issue. If they are, then the probability of litigation is high, and risk-averse behavior is more likely. If the issue has a lower profile then analysts may be more focused on putting "the best technical document together" that they can.

Concluding Observations on the Interviews

With both participation and judicial review, the effects largely vary by context. Large projects (for example the approval of genetically modified crops) with well-publicized impacts are going to be opposed by powerful interest groups. This means that participation may be dominated by letter writing campaigns, and comments that provide a small amount of useful information. It also means that the EIS will likely end up in court and therefore analysts will be very careful and produce documents that are extremely detailed and long. On the other hand, projects which still may be controversial but which are carried out away from the glare of national interests are going to produce a different set of behaviors. Agencies may (depending on the agency) encourage participation and, as a result, get useful feedback. They will not be as worried about being sued in court and will conduct the analysis accordingly.

NEPA has the longest history of any of the forms of comprehensive-rational analysis and a number of the people I spoke with had careers dating to its inception in 1970. They could recall the early days when agencies were fumbling around trying to figure out what NEPA required. Those days are long gone now and a clear process, for better or for worse, has been established. This process varies by agency and by the context of the individual decisions at hand, however. It does appear that the higher the salience of the decision, the less of a role that the environmental analysis plays in the decision, as agencies dig in to avoid altering politically preferred decisions. The first case below focus on this phenomenon.

But that shouldn't obscure the fact that thousands of environmental mitigations have occurred as a result of NEPA. Communities around the

country have been engaged in decisions that affect their local environments. As one of the people I spoke with put it, "NEPA is a beautiful thing. It works well if you do it as intended. But people also make a career of doing it and making it as complicated as possible."

CASE STUDIES

Case 1: Allowing Mexican Trucks into the United States

Congress first restricted the entry of motor carriers from Canada and Mexico in 1982,[11] making the restriction permanent in 1995.[12] The restriction allowed for the President to make an exception if required by treaty, but President Clinton declined to do so in the wake of the North American Free Trade Agreement (NAFTA). This decision was ordered to be reversed by a NAFTA arbitration panel in 2001.[13] Despite opposition from Congress as well as labor and environmental groups, President George W. Bush began to use the regulatory process to comply with the order from the arbitrator (Bhargava 2004).

The Federal Motor Carrier Safety Administration (FMCSA), an agency within the Department of Transportation, issued a proposed rule allowing Mexican carriers to apply to have their trucks enter the United States beyond the previously permitted border zone on May 3, 2001 (FMCSA 2001). The proposed rule included a revised safety monitoring system for trucks coming into the United States from Mexico. The FMCSA declared in the preamble to the rule that the regulation would have no environmental impact and hence an environmental assessment was not necessary.

Several environmental groups expressed a different point of view. In a comment submitted jointly by the Friends of the Earth, the Natural Resources Defense Council, the Sierra Club, and the Center for International Environmental Law, FMCSA was told, "DOT must comply with NEPA before finalizing these proposed rules that would allow Mexican-owned trucks to drive throughout the United States resulting in increased air pollution and other environmental hazards." The groups cited NEPA and the implementing regulations from the CEQ as requiring the FMCSA to do an environmental assessment and possibly an EIS (Friends of Earth et al. 2001).

In response to the comments, the FMCSA conducted an environmental assessment in January 2002. The document, 142 pages long, included descriptions of the proposed action, the affected environment, environmental consequences and the potential mitigation strategies. The only alternatives that the FMCSA considered were the baseline (no action),

the proposed rule, and the proposed rule without a safety monitoring system. The FMCSA concluded that the effects on safety, air emissions, and noise would be minor, and that the proposed rule was more protective than allowing the trucks into the country without the revised safety procedures. The agency contended that it would be required to allow the trucks in regardless of the regulation because of the arbitration decision. In the final rule, issued in 2002, the FMCSA said that as a result of the environmental assessment, they were concluding that there was no significant environmental impact of the regulation (FMCSA 2002a).

The environmental groups sued the FMCSA for violating NEPA. The FMCSA argued that the effect on of the regulation on national emissions was minimal. They also maintained that because of the arbitration decision, Mexican trucks were going to be allowed into the country, and the regulation was not responsible for any possible environmental impacts. The Ninth Circuit agreed with the plaintiffs saying that NEPA still applied to the regulations, and that the FMCSA had erred by considering only national impacts rather than including local ones (Bhargava 2004).[14]

The case then went to the Supreme Court. The court unanimously overturned the decision of the Ninth Circuit. The court's opinion agreed with the Administration contention that the regulation itself did not have environmental impacts, and the FMCSA had no authority to prohibit Mexican trucks from entering the country.[15] The FMCSA had begun the process of conducting an EIS, holding numerous public meetings on the subject[16] after the Ninth Circuit decision. This process appears to have been stopped after the Supreme Court decision and I could find no record of a final EIS.

The Mexican truck case is not a stellar moment in the history of NEPA. As one scholar put it, "There is no question that *Public Citizen* was a significant loss for NEPA plaintiffs" (Lazarus 2011, p. 52). The case also illustrates some of the perceptions of participation and judicial review described in the interviews above. Organized groups championed the opposition to the regulation and, in doing so, did little to affect the eventual outcome. They managed to delay the effective date of the regulation by a couple of years through the use of the courts. But this was a hollow triumph.

On the other hand, the FMCSA was forced to produce an environmental assessment and had begun the process of holding public hearings with the goal of conducting an EIS. The courts specifically agreed that the environmental groups had standing to sue (Lazarus 2011). These actions show that NEPA is sufficiently strong for outside interests to get

the attention of government agencies, even when the agency is hostile toward doing the analysis. In this case, the substantive impact of the environmental assessment was non-existent. But outside interests don't even have this ability to be heard when they object to a cost-benefit analysis.

Case 2: Prohibiting the Import of Beluga Whales

Under the Marine Mammals Protection Act,[17] zoos and aquariums are allowed to apply to NOAA to import marine mammals for public display. In 2012, the Georgia Aquarium applied to import 18 beluga whales from the Utrish Marine Mammal Research Station in Russia. U.S. populations of the whale are considered endangered under the Endangered Species Act, and the worldwide population is a source of international concern.

NOAA conducted an environmental assessment under NEPA for the decision to grant a permit to the Georgia Aquarium (NOAA 2012). The agency published the environmental assessment for public comment in August 2012 and held a public hearing on October 12, 2012. The environmental assessment was a mere 19 pages and considered only two alternatives, granting the permit and refusing it. The whales were already in captivity so the immediate impact on the environment was limited. The environmental assessment discussed the stress the transfer would place on the whales themselves, but did not meaningfully address the question of whether approving the import would increase incentives in Russia to capture additional members of this endangered species.

The public response was overwhelming. NOAA received more than 9000 comments and they were overwhelmingly against the approval of the permit. Many of the letters were from individuals and provided little additional information. However, major environmental organizations also commented. One letter from 64 non-governmental organizations cited the tremendous stress that would be placed on the whales, and also more broadly discussed the long-term impacts of the decision, "We are concerned that any international trade in these animals, including the proposed import of belugas by the Georgia Aquarium, will increase demand by the public display industry, with a resultant impact on wild populations targeted by live capture operations" (Animals Asia Foundation et al. 2012).

In 2013, NOAA announced that it was denying the permit, citing the long-term impacts on whale populations of granting the permit. If NOAA approved the permit, it would possibly create incentives for over-harvesting the whale stock. In the period while considering the NEPA comments, NOAA also discovered that five of the whales were young

enough still to be nursing. This is a violation of the Marine Mammal Protection Act.

The NEPA process had a clear impact on the NOAA decision regarding the Georgia Aquarium permit. The requirement to conduct an environmental assessment and the decision by NOAA to seek public comment on it (comment is required for an EIS but not for an environmental assessment) performed two important functions. It elicited an outpouring of public input including credible arguments that NOAA had neglected when it compiled the environmental assessment (the incentive on future whaling would be increased by an approval). It also delayed the decision, providing time for NOAA to figure out that the import of at least some of the whales violated another environmental law. These functions illustrate some of the less appreciated powers of NEPA and the requirement for an environmental analysis.

CONCLUSIONS

One of the findings in Chapter 3 was that many of the more important effects of cost-benefit analysis were invisible to the general public. My research of EISs echoes that conclusion. The higher profile cases of EIS use generally show virtually no impact of the environmental assessment. These cases, which attract the attention of the national media and powerful interest groups on each side, generally end up in the courts where the record of environmental plaintiffs has been poor. It is little wonder that many of the academic discussions of EIA have focused on these failures.

But there is another side to the story as well. Hundreds of EISs are carried out each year. These are in turn dwarfed by the numbers of environmental assessments. And many of these assessments are accompanied by mitigations that agencies conduct to protect the environment, and to avoid doing an EIS and possibly ending up in court. "NEPA appears to be trapped in uncommon partisan politics, on a path that accepts small patches rather than the kind of comprehensive adjustment that would benefit from a massive infusion of science driven analysis" (Greenberg 2013, p. 195).

However, maybe these small patches add up to a major accomplishment. Cumulatively, these mitigations have done a great deal to improve the natural environment over the past 40 years. While the goals of NEPA were indeed broader, the small improvements are important too. The environmental assessments and the EISs are also accompanied by a process of public participation that contains both a component of kabuki

theatre and the genuine exchange of information between government agencies and affected communities.

The failures and the successes are both parts of the story of environmental impact analysis under NEPA. They contain lessons regarding institutional factors such as judicial review and public participation that are far from simple. Bringing in the courts to the analytical process results in both incentives to produce inscrutable analyses and also to take steps early in the decision-making process that further the goals of the analytical requirement. Requiring public participation opens the door to letter writing campaigns that do little to affect agency decisions and that take up a lot of time. However, the participation requirements empower local communities.

The participation requirements also empower more organized and therefore powerful interests. This was likely one goal of NEPA when it was passed – the empowerment of environmental groups. When an analytical requirement is used to empower a particular constituency it acquires a power that both differs from and exceeds the neutral type of analysis that is most often discussed and debated. Certainly it makes an EIA different from cost-benefit analysis and risk assessment. I explore this theme further in the next chapter when I look at other impact assessments, all of which are geared toward particular constituencies. Most of them do not work as well as EISs but one – geared toward small businesses – has had clear impacts on agency decisions.

NOTES

1. Although most EPA actions, the types of regulatory actions that are such a focus of debates over cost-benefit analysis and risk assessment are largely exempt from NEPA.
2. Pub. L. 91-190 Statutes at Large, 83 Stat. 852 (1969).
3. See https://ceq.doe.gov/welcome.html (last accessed April 14, 2015).
4. See for example Kleppe v. Sierra Club 427 U.S. 390 (1976).
5. Lazarus (2012, p. 1586) echoes this point. "Even in ruling against environmental plaintiffs, the Supreme Court has promoted a view of NEPA that, in important respects, is likely far greater than its drafters envisioned at the time."
6. See http://www.endangeredspecieslawandpolicy.com/uploads/file/Western%20Watersheds.pdf (last accessed July 22, 2015).
7. See http://www.elawreview.org/summaries/environmental_quality/nepa/metcalf_v_daley.html (last accessed July 22, 2015).
8. See http://www.supremecourt.gov/opinions/09pdf/09-475.pdf (last accessed July 22, 2015).
9. The EPA conducts few EISs but reviews all of them for the federal government.
10. I hesitate to make too much of this conclusion though as the sample sizes in each group are clearly small and the methodology of finding interview subjects was different for environmental impact assessors.
11. Bus Regulatory Reform Act of 1982, Pub. L. No. 97-261, § 6(g), 96 Stat. 1102, 1107-08 (1982) (codified as amended in scattered sections of 49 U.S.C.).
12. 49 U.S.C. § 13902(c) (2000).

13. Cross-Border Trucking Services and Investment (U.S. v. Mex.), NAFTA Arbitral Panel, USA-MEX-98-2008-01 (February 6, 2001).
14. *Public Citizen I*, 316 F.3d at 1022.
15. *Public Citizen 11*, 124 S. Ct. at 2214-15.
16. For meeting transcripts see http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;s=environmental;dct=SR%252BO;D=FMCSA-1998-3299 (last accessed July 2, 2015).
17. Pub. L. 86, Stat. 1027.

6. Impact analysis and the regulatory process

Impact analyses make less of a claim of being comprehensive than the other forms of comprehensive-rational analysis discussed in this book. By their very name, they indicate that the intention of the analysis is not to look at the comprehensive impact of a policy or regulation, but rather the particular impact on a subset of the affected universe. Like Environmental Impact Statements (EISs), they focus on one policy aspect of a regulatory decision but on a more manageable scale then the "environment." Like cost-benefit analyses they are focused on the economic impacts of the regulation, but just on a relevant population, not as part of an attempt to measure changes in social welfare. In some sense then, impact analyses are smaller than the other analyses.

Impact analyses have a political appeal that in some ways exceeds that of other forms of analysis. When political actors support a requirement to look at the impact of government policy on a particular group, they are signaling a value for that constituency. If a constituency is upset about a particular regulation, or regulations in general, one way to assuage those potential voters/donors is to require agencies to pay particular attention to that constituency in future regulatory decisions. That constituency will then be a reliable supporter of the impact analysis enacted in their behalf.

Impact analyses have also been studied less than the other forms of analysis in this book. Those studies that have been conducted, however, are largely critical of their role. Most scholars assert that impact statements have had a minimal role in regulatory decision-making. One former practitioner put it particularly colorfully,

> Old impact statement requirements meet a lonely and doleful demise – their once proud aspirations dulled and forgotten; their exaggerated promise relegated to the impact analysis dust bin; their sad fall from glory giving rise to a mild and vaguely embarrassing schadenfreude in us all. They stumble into their dotage in the *Federal Register* on the concluding pages of rules as humiliated, featureless, grey boilerplate.[1]

But the antecedents and growth of impact analyses are the same as the other forms of comprehensive-rational analysis. Impact analyses began to

sprout up in the late 1970s with the passage of the Regulatory Flexibility Act[2] and the Paperwork Reduction Act.[3] States have adopted a wide range of impact analyses requirements with a particular fondness for fiscal impact statements which measure the impact of regulations on state budgets (Shapiro and Borie-Holtz 2013). At the federal level, the original statutes requiring impact analysis have been supplemented by both laws and executive orders that require agencies to analyze the impact of their regulations on state and local governments, families, environmental justice, and the nation's energy supply.

In addition to having a common set of roots and producing a common set of frustrations to the more comprehensive forms of analysis, the particular failures and successes of impact analysis hold lessons for analysis generally. In this chapter, I review the large-scale failures of impact analysis and a potential area of success. This success, SBREFA panels, which involve small businesses early in the regulatory decision-making process, holds possible lessons for better integrating all kinds of analysis into policy-making. It also holds cautions because of its fundamentally political nature.

This chapter proceeds as follows. In the next section I review the history of requirements for impact statements and the limited literature on the subject. The following section reviews claims made by advocates on either side of the issue regarding the role of the largest of the impact statement requirements, the Regulatory Flexibility Act's requirement that agencies analyze the impacts of their regulations on small businesses. I then examine panels required under the Small Business Regulatory Enforcement Fairness Act (SBREFA[4]) and report on one particular panel for a regulation considered by the Occupational Safety and Health Administration. I offer concluding thoughts in the final section.

THE HISTORY OF IMPACT STATEMENTS

Impact statements are hardly limited to the regulatory process. Jenkins-Smith (1990) provides a detailed recounting of the debate over banning oil exports in the 1980s. He concludes that the results of the analyses, which looked at impacts on the oil sector, on consumers, and on international trade, varied considerably depending on who was conducting the analysis. Supporters of the ban argued that it would help the domestic oil producers considerably and would not hurt consumers, while opponents of the ban found the opposite impacts.

Currently, impact statements are expanding to policy sectors beyond the regulatory arena. Health impact assessments (HIAs) have gained

popularity in Europe as a way to elevate the impact of projects or policies on public health as a decision criterion (Kemm et al. 2004). There have been calls to increase the use of HIAs in the United States as well (Dannenberg et al. 2006). Equity impact analyses are used by metropolitan planning organizations to comply with federal civil rights laws when seeking federal funding for transportation projects. One study has found that these analyses "lack specificity and are rarely enforceable" (Karner and Niemeier 2013).

Within the regulatory process, the grandfather of all sector-based impact statements is the Regulatory Flexibility Analysis. This analysis was first required in the eponymous Regulatory Flexibility Act (RFA), signed by President Carter on September 19, 1980. The debate over the Act spread over several sessions of Congress and reflected widespread concern about the burden that regulations, issued pursuant to the wave of public health statutes passed in the late 1960s and early 1970s, placed on small businesses. Hearings demonstrated widespread dissatisfaction and frustration with regulatory and reporting requirements, emphasizing the disparate differences between entities of smaller size and larger businesses, and the inability of individuals to have their opinions heard on the issue (Shapiro and Moran 2016, forthcoming).

The resulting bill required that when an agency determined that one of its regulations would have a "significant impact on a substantial number of small entities," the agency would need to conduct a Regulatory Flexibility Analysis. The purpose of this analysis would be to assess the impact of the regulation on small businesses and to consider (and solicit public comment on) ways to reduce that impact. The agency was instructed in the RFA to consider alternatives to its preferred policy choice.

Critics of the RFA worried that the impact analysis would stifle agency regulation. Throughout the years of debate on the issue, this concern was repeatedly voiced. The legislative history of the RFA is rife with examples of assurances that the RFA and the analysis requirement would not have this effect (Shapiro and Moran 2016, forthcoming). In response to these concerns, a report by the Senate Judiciary Committee asserted that the bill would not alter regulatory goals and carefully stipulated that agencies can only consider alternatives to a proposed rule that are in accordance with the objectives of underlying statutes authorizing rule-making for that agency. Proponents of the Act argued that in the event that an agency could not consider alternative regulatory rules without compromising the legally mandated goals of the statute underlying rule-making, they could summarize this in the regulatory analyses as a

reason for rejecting alternatives (U.S. Congress Senate Committee on Judiciary 1980).

The RFA was passed by a bipartisan Congress and signed by a Democratic President. Hence, the assurances that the Act would not disrupt regulatory agencies charged with protecting public health were not trivial. They were essential to securing the bill's passage (Shapiro and Moran 2016, forthcoming). Particularly significant was the discretion given to agencies to determine whether the Act, and its requirement for an analysis of the impact of regulations on small businesses, applied to the agency's regulation. Further, the stipulation that agencies could avoid considering alternatives to its preferred policy in the Regulatory Flexibility Analysis turned out to be an important loophole.

The ability of an agency to avoid the strictures of the analytical requirement has often been cited as a failure of the RFA. The Government Accountability Office (GAO) has repeatedly studied the RFA and repeatedly reached the same conclusion. The GAO said in 1994 that "agencies' compliance with the Act varies widely" (GAO 1994). In 2001, reporting on the RFA and on subsequent amendments, the GAO said that, "their full promise has not been realized" (GAO 2001). In particular, the GAO identified the terms "significant economic impact" and "substantial number of small entities" to be of issue, leading agencies to construct their own definitions and interpretations.

Academic analyses of the RFA and the role of the impact analysis contained therein are limited but largely reach the same conclusion. Several studies hone in on the ability of agencies to determine the Act's applicability to their own regulations (Shive 2006; Raso 2015), and note that courts have deferred to these determinations (See 2006; Raso 2015, forthcoming). Bird and Brown (2010) say that evidence that the Act has not worked lies in the fact that, "Small businesses continue to suffer disproportionately from the cost of regulations" (Bird and Brown, 2010, p. 4). Throughout this limited literature, it is clear that even the presence of the courts as an enforcement mechanism for the RFA has not served as a way of ensuring that agencies minimize the impact of their regulations on small businesses.

The continual demand for strengthening the RFA is further evidence that the regulatory flexibility analysis has not had its intended effects (Phelps 2001). There has been one significant modification to the RFA. In 1996, Congress passed SBREFA.[5] SBREFA strengthened the provisions regarding the regulatory flexibility analysis but failed to curb agency discretion in the key areas described above. One innovative provision in SBREFA is the creation of the small business panel process. The panel requirements apply to the Environmental Protection Agency

(EPA), the Occupational Safety and Health Administration (OSHA), and the Consumer Financial Protection Bureau (CFPB).[6] These agencies must convene small business panels to review regulations prior to the proposal of regulations that will have a significant impact on small businesses. The panels operate under the joint supervision of the Office of Information and Regulatory Affairs (OIRA), the Office of Advocacy within the SBA, and the regulating agency.

While the impact on small businesses has been the most prominent cause to merit its own analysis, it is far from the only one. The Unfunded Mandates Reform Act (UMRA) of 1995 was one of the first bills passed by the Republican Congress which took office in the 1994 elections. It was passed by the Senate on January 27, 1995, and passed by the House, with amendment, on February 1, 1995. Conferences in both the House and the Senate took place to resolve debates before UMRA was subsequently signed into law by President Bill Clinton on March 22, 1995.[7]

UMRA was intended to force agencies to consider the impact of their regulatory activities on state, local, and tribal governments. These sub-governments had grown increasingly vocal about statutes such as the Clean Air Act and the Americans With Disabilities Act, and the costs to state governments of enforcing (and complying with) the regulations promulgated under these statutes (Shapiro and Moran 2016, forthcoming). For regulations with a cost of more than US$100 million (adjusted annually for inflation) UMRA required an analysis of the economic impacts on these sub-governments, as well as on the private sector.

The impact analysis in UMRA is particularly tricky to evaluate because of the overlap with the Regulatory Impact Analysis requirements under Executive Order 12866 described in Chapter 3. These requirements had been in place for 14 years when Congress passed UMRA in 1995. There has been no discernible difference in the quality of regulatory impact analyses between those regulations where analysis has been required under UMRA and Executive Order 12866 compared to being merely required under the Executive Order (Shapiro and Morrall 2012).

There are no academic articles analyzing the impact of UMRA. As with the RFA, there are several reports by government watchdog agencies. A report released by the GAO in 1998 found that UMRA had limited impact on agency rule-making actions. Much as the vague definition of "significant impact" in the RFA was a source of agency discretion, the term "economically significant" in UMRA was largely left open to interpretation by individual agencies. Critics of the Act noted that the vague definition allowed agencies to evade assessments and cost

benefit analyses by determining that rules did not qualify as economically significant (Shapiro and Moran 2016, forthcoming). The GAO (1998) supported this criticism stating that the Act gave agencies too much discretion in how they could comply with requirements. More recently the Congressional Service (CRS) has reported dissatisfaction with UMRA, noting that state and local governments have consistently called for an expansion of the authority and scope of the Act (U.S. Congressional Research Service 2014).

There have also been numerous requirements for impact analyses in executive orders. These include an analysis of government "takings" (Executive Order 12630), an analysis of the impact of a regulation on children's health and safety (Executive Order 13045), and an analysis of any adverse impact of a regulation on the nation's "energy supply, distribution, or use" (Executive Order 13211). These analyses are usually pro forma at best. Wagner (in Harrington et al. 2009) gives a particularly striking example of an EPA air-pollution regulation in which two of these executive orders (No. 12898 on environmental justice, and No. 13045 on children's health) are deemed inapplicable, even in a case where they clearly should have applied. These analyses are likely what Arbuckle had in mind when he described impact analyses as "humiliated, featureless, grey boilerplate."[8]

THE IMPACT OF IMPACT ANALYSES

The limited work by academics and the somewhat more expansive work by the GAO and the CRS all point to the same conclusion. Impact analyses are largely inconsequential in the agency decision-making process. There is one source that disagrees vehemently with this conclusion. The Office of Advocacy at the Small Business Administration (SBA) is charged with the oversight of the implementation of the RFA. The office puts out annual reports on the RFA assessing the impact of the statute.[9]

These reports regularly assert that billions of dollars of cost savings to small businesses are the result of the work of the Office of Advocacy and the RFA. For example, in the Fiscal Year 2014 report (SBA 2014), the Office of Advocacy calculates that small businesses saved US$4.8 billion as a result of SBA efforts under the RFA. Of the US$4.8 billion, US$4.6 billion comes from an EPA decision to not implement a numeric limitation on the level of turbidity in water discharges from construction sites. A numeric limitation had been put in place in a 2009 final regulation issued by the EPA (EPA 2014).

The preamble to the final regulation issued by the EPA in 2014 outlines the history and the rationale for the decision to rescind the numerical limitation. Upon promulgation of the 2009 regulation, the EPA was sued by a number of parties including the National Association of Home Builders (NAHB). After the filing of the suit, the SBA provided the EPA with information indicating that the basis for the numeric limitation was flawed. The NAHB petitioned the EPA to reconsider the limitation citing the SBA data. The EPA settled the lawsuit with the NAHB and others and agreed to eliminate the provision in question (EPA 2014).

The attribution of US$4.6 billion in savings to small businesses as a result of the RFA is questionable for a number of reasons. First, in the 2009 regulation the EPA asserted under the RFA that, "EPA does not consider the selected option to have the potential to cause a significant economic impact on a substantial number of small entities." Second, in that final rule, the EPA estimates the total cost of the regulation as US$1 billion, and these costs include provisions besides the numeric limitation. Finally, even if the cost savings estimate is correct, attributing it entirely to the RFA is dubious: a lawsuit – that clearly the EPA considered somewhat threatening – also played a key role. Surely the Office of Advocacy's citation of the flaws in the original EPA analysis was important in the timely resolution of the lawsuit. Was it necessary? That question is unanswerable. Yet, the SBA gives the public an unambiguous answer of yes.

The seeming exaggeration of the impacts of the RFA is not particular to the 2014 report. Each year the Office of Advocacy reports a very high value for the dollar impact of agency activities under the RFA. Each year these values are highly questionable (Shapiro and Moran 2016, forthcoming). In part this is not surprising. Just as regulatory agencies have incentives to exaggerate the benefits of their regulations and claim that costs are minimal, the Office of Advocacy has tremendous reason to do the same with their activities. Much of the Office of Advocacy's power comes from the RFA. An admission that the RFA is not working is tantamount to asking for enhanced Congressional oversight of the agency, or perhaps even its defunding. In fact, the Office of Advocacy will occasionally corroborate the general impression that the RFA is not strong enough to achieve its goals. In its list of priorities for the 112th Congress, the Office of Advocacy said, "The Office of Advocacy's top legislative priority is to give small businesses a voice in the regulatory process."[10] One has to infer from this that the RFA as currently written and implemented does not achieve this goal. Certainly this is the consensus in the academic literature and the GAO reports cited above.

Other impact statements do not have an agency charged with their evaluation. But if the impact statement with the highest profile, with the potential for judicial review of the impact analysis, and with an individual agency that spearheads its implementation has had a minimal effect on agency decisions, then it is unlikely that the other impact statements have had any effect. Again the academic literature and independent reports (limited though they may be) reinforce this conclusion.

Because of the rough consensus on the impact of impact statements, and because it is notoriously difficult to isolate their effects, I chose not to conduct interviews on this subject. Instead, I decided to focus on what I see as the most innovative piece of the requirements for impact statements – the small business panels required in the amendments to the RFA passed in 1996. These panels are particularly interesting because, while they do focus on one particular constituency, they incorporate some of the lessons for an increased role for analysis discussed in Chapters 3–5, particularly the interaction between participation and analysis. In the next section, I present a case study of SBREFA panels in action to further illuminate the findings on the more comprehensive forms of comprehensive-rational analysis.

SBREFA PANELS AND OSHA REGULATION OF INFECTIOUS DISEASE EXPOSURE

As described above, SBREFA panels are coordinated by three agencies. They are operationally managed by the regulating agencies (three agencies are required to conduct these panels – the EPA, OSHA, and the CFPB) while OIRA and the Office of Advocacy also play roles in organizing and supervising the panels. They take place before the proposed rule stage of the regulatory process. A group of small business owners likely be affected by the rule is assembled. The regulating agency sends them materials on the need for a regulation, possible provisions in the regulation, and the expected impacts of the regulation on small businesses.

After receiving this material from the regulating agency the small business owners have a series of meetings (also attended by representatives of the regulatory agency, OIRA, and the Office of Advocacy) during which the business owners provide feedback on the agency proposals. The three government agencies then take that information and provide a report to the agency administrator with recommendations for the eventual proposed rule (these recommendations may include considering alternatives to regulation).

There have been few studies of the SBREFA process but several of its qualities attempt to correct the problems with analytical requirements described in the previous three chapters. The SBREFA panels occur early in the rule-making process. They are designed to encourage public participation in the decision-making process and to inform the analysis with the input from affected parties. That said, there are also potential flaws in the process.

One recent study of the SBREFA process highlighted these flaws. The Center for Effective Government (CEG) (a group that generally supports public health regulation and opposes analytical requirements in the regulatory process) looked at the SBREFA process and cast doubt on its impartiality.[11] The CEG interviewed staff members at the Office of Advocacy, used Freedom of Information Act (FOIA) requests to get information on panels, and looked at the impact of the recommendations of the panels. They found that some of the small business owners who took part in the panels were "representatives, board members, lawyers, or consultants for trade associations and did not own or operate a small entity likely to be affected by the rule under development." They also found that the Office of Advocacy briefed the small business representatives prior to the panel meetings prepping them to raise particular concerns.

Keeping in mind both the potential advantages of the panel structure and the biases described in the CEG report, I observed the operation of a SBREFA panel for a potential proposed regulation by OSHA. I listened in on the panel meetings, reviewed the documentation given to the small entity representatives, and read the final report. The issue involved was the regulation of the transmission of infectious diseases in the workplace, primarily in healthcare facilities.

The rationale for the possible regulation considered by the SBREFA panel is outlined in a background document[12] supplied to small business owners at the onset of the panel process. OSHA already has a "Bloodborne Pathogens" standard[13] which is intended to protect health care workers from diseases transmitted via bloodborne routes. The standard does not protect such workers from illnesses transmitted via contact, droplet, or via breathing. Unions representing health care workers were concerned that the bloodborne pathogen standard was insufficient for protecting their members and, "in 2009, AFSCME petitioned OSHA for a rule addressing occupational exposure to infectious diseases."

The Centers for Disease Control and Prevention (CDC) (2007) has guidance for workers potentially exposed to infectious diseases. This guidance is non-binding but came up repeatedly in the small business

panel discussions. OSHA stated in its background document that the CDC guidelines would not be mandatory but that workplaces would have to "take these kinds of guidelines into consideration in developing and implementing their own infection control programs."

In justifying the potential need for a standard, OSHA cited data that showed that there were more than 99 000 patient deaths per year due to exposure to infectious diseases in hospitals. It went on to say,

> Preventing the spread of infectious diseases in healthcare and related settings benefits workers, as well as patients, given that there is a well-recognized link between patient safety and healthcare worker safety and that integration of patient and worker safety initiatives has been shown to improve both patient outcomes and worker protection.

OSHA also surveyed the academic literature on infectious disease exposure in workplaces and concluded that such illnesses were vastly under-reported. The lack of mandatory guidelines on this subject may have led to a significant risk for workers, leading to the potential need for OSHA regulation. OSHA also argues that the bloodborne pathogen standard has successfully reduced risk to health care workers, signaling the potential effectiveness of a regulatory approach.

OSHA also supplied to small business representatives a "framework" for a potential regulation.[14] The framework, according to OSHA,

> represent(s) all of the provisions the Agency believes, at this point, would constitute the best, most protective rule while providing the most flexibility and minimizing the burden on affected entities. While this framework represents OSHA's initial thinking, the Agency is still considering a number of alternatives and options.

The core of the framework is a requirement that affected workplaces develop a "Workplace Infection Control Plan (WICP)," which contains a number of required elements. Other parts of the framework included requirements that: employers have standard operating procedures for 11 different areas as part of their infection control plan, train their workers, conduct medical surveillance, and keep records of their compliance with the standard.

One requirement that would prove particularly controversial in the framework was the "Medical Removal Protection" provision. This provision, also present in a number of other OSHA standards, would require employers to ensure that workers who were forced to miss work due to infectious disease exposure would not lose their wages for the time that was missed. Employers would have to continue compensating

the workers while they recovered. The purpose of this provision is to ensure that workers feel comfortable reporting illnesses because they do not fear losing pay as a result of coming forward.

Fifty small entity representatives (SERs) were chosen to participate in the discussions with the SBREFA panel. The SERs came from a variety of businesses including hospitals, doctors' and dentists' offices, ambulance services and funeral parlors. The SERs represented businesses of various sizes and (as detailed in the CEG report) some were representatives of trade associations that represented large businesses as well as small ones.

OSHA sent the SERs the background and framework documents as well as estimates of how much OSHA believed the standard would cost small businesses. The SBREFA panel held three conference calls with the SERs on November 12, 13, and 14, 2014. I was on the telephone for the entirety of the calls on the 12th and 14th, and for part of the call on the 13th. I remained silent throughout the call. The SBREFA panel promised the SERs that they would not be quoted on the calls and I will adhere to that promise. What follows is a general summary of the concerns (much of which is also reported in the final report of the SBREFA panel described below).

The small business owners repeatedly questioned the need for an infectious disease standard. Many said that they are already subject to numerous requirements that address the issues in the standard. They mentioned the OSHA bloodborne pathogen regulation, state regulations (Cal/OSHA the California agency was mentioned specifically), and the CDC guidelines. While the SERs acknowledged that the CDC guidelines were not mandatory at least five of the SERS argued that they were in compliance with the guidelines. The representative from the SBA regularly asked the SERs whether there were accrediting bodies within their specific industries that had requirements for protecting employees. Many of the SERs acknowledged that they were covered by accrediting bodies as well as the regulatory entities.

The two provisions that caused the most apprehension for the SERs were the vaccination and the Medical Removal Protection (MRP) provisions. The MRP in particular came in for a great deal of criticism. Many SERs argued that this provision alone could drive them out of business. They voiced the concern that if one employee in a small business became sick, and the business had to pay both that employee and their replacement, the cost would be prohibitive. They also wondered why MRP was necessary when their businesses were governed by state workers compensation laws.[15]

With regards to vaccinations, SERs were concerned that being required to vaccinate their employees would be costly. Many of the SERs maintained that if employees ask to be vaccinated the employers generally provide the vaccines. However, the OSHA requirement would shift the cost for vaccines from insurance companies to the employers and would lead to employers purchasing vaccines that would eventually go unused.

Finally, SERs disputed the cost estimates for the regulation provided by OSHA. This disagreement extended across multiple provisions of the regulation and some SERs even voiced their belief that the regulation would put them out of business. SERs also submitted written comments to the SBREFA panel. These written comments largely echoed the comments made during the telephone conferences. The comments are publicly available as part of the final report of the SBREFA panel.

This report was issued to the OSHA Administrator on December 22, 2014.[16] The report, jointly issued by the representatives of the three agencies, was filled with recommendations that OSHA reconsider the need for a standard and the scope of the standard. As reflected in the verbal and written comments of the SERs, the report's first recommendation was, "The panel recommends that OSHA not proceed with issuing a proposed rule until it assesses available data on risk to address the need for the rule for each potentially covered task and work setting."

The report goes on to suggest ways in which OSHA should limit the standard if it decides to proceed with regulating. The panel recommended that the agency consider limiting the scope of the standard to exclude businesses where the risk of catching an infectious disease is minimal (such as funeral parlors and laundromats – both businesses represented by SERs that argued that the standard should not apply to them). The panel also recommended that OSHA consider exempting certain businesses from certain portions of the standard and reassess the need for certain provisions (such as the MRP and vaccine provisions). Finally, the panel recommended that OSHA revisit its estimates of the costs of the standard.

The panel report reflected the views of the small business owners who participated in the SBREFA process. As this book went to press, OSHA had not yet issued a proposed rule on the transmission of infectious diseases. Therefore, the ultimate efficacy of the SBREFA panel in this case cannot be evaluated. However, it can be inferred. If OSHA does issue a regulation, it is reasonable to assume that the cost estimates will be higher and that the standard will be less strict than envisioned in the framework issued by OSHA. If this is not the case, OSHA will have

difficult questions to answer about why it ignored a report which its own staff had signed off on.

CONCLUSIONS

The SBREFA process holds several lessons for the use of impact analysis in particular, and possibly comprehensive-rational analysis in general. The timing of the SBREFA panel, early in the regulatory process, before the agency has publicly issued a proposed rule, allowed it to play more of a role than the cost-benefit analysis or the other impact analyses described in this chapter. In addition, the interaction between analysis and participation, discussed in earlier chapters, is clear here. By exposing estimates of the impacts of regulation to public scrutiny, the estimates are likely to be improved. Any bias that agencies introduce into their estimates are counteracted by the biases of other parties.

But impact analysis differs from the other forms of comprehensive-rational analysis in an important way. Impact analysis is specifically designed to look at the effect of regulatory policy on a particular constituency. This makes the politics of impact analysis different from the politics of other forms of analysis. Whereas cost-benefit analysis and risk assessment have no natural constituencies, these impact analyses do. This structure is somewhat like the less formal role of environmental groups in public comment on EISs. Political science has long taught us that when there is a concentrated and well-organized constituency that group will devote resources to achieving its goals (Wilson 1980).

But despite this, most impact analyses have largely been a failure. They have mostly become "humiliated featureless grey boilerplate." This is because they have generally taken one of two forms. They have been parts of statutes like the RFA and UMRA. In these cases, the statutes mandate impact analyses but leave key choices regarding their applicability and their policy implications in the hands of the agency issuing the regulation. Choices about whether the analysis is required for any particular regulation and the conclusions of the analysis are often solely within the purview of the regulatory agency. And it is not an accident that these statutes are structured in this way. In order to pass Congress and be signed by the President, sponsors of the statutes have needed to commit to preserving agency discretion (Shapiro and Moran 2016, forthcoming).

The other source of impact analysis requirements is executive orders. Responsibility for these requirements for analyses of impacts on families, the nation's energy supply, and environmental justice are also given to

agencies to carry out. With no enforcement mechanisms, and no institutions peopled with supporters of the requirements, it is little surprise that these impact statements have been even less effective than those placed in statutes.

The SBREFA panels are different. Placed early in the regulatory process, and given an institutional supporter in the Office of Advocacy, which has a voice in the management of the panels, the SBREFA panels have had impacts on policy. This is evidenced both by the experience with the infectious disease panel and by the panels detailed in the CEG (2014) report. But this impact is not on behalf of "better" regulation in the sense often envisioned by advocates of more comprehensive forms of analysis. Instead it is on behalf of a particular constituency, small businesses. Regulations that have gone through the SBREFA process are more accommodating of the needs of small businesses (and possibly larger businesses who appear to also have a voice in the process).

The SBREFA process has an analogy in the non-regulatory world. HIAs have been increasing in prominence in numerous contexts. Like SBREFA, HIAs emphasize timing and the participation of affected communities (Lock 2000). Unlike SBREFA, they are not focused on the needs of a particular constituency. While the jury is still out on the general success of HIAs some of their limited successes point to the same lessons as those of the SBREFA panel requirement.

Those lessons include the utility of early timing, simplicity, and the participatory nature of the analytical enterprise. Placing analysis earlier in the process allows it to play more of a role in decision-making. This came up in the discussion of cost-benefit analysis in Chapter 3. Making analytical products simpler will make it more likely that a wider audience will be able to access them and contribute to their improvement. The documents provided to the SERs were easy to understand by those who would be affected by the standard. Finally, the participatory nature of the SBREFA panels highlights a theme in the previous chapters. To play a role, analysis should be participatory in nature.

I will return to these themes in the next few chapters. But merely grafting on the SBREFA process to other types of analysis is not a simple enterprise. Can other forms of comprehensive analysis develop a constituency similar to the self-interested forms that populate the SBREFA process? This constituency is as vital to the influence of the SBREFA process as its timing, simplicity, and participatory nature.

NOTES

1. See http://www.regblog.org/2012/11/26/26-arbuckle-jobs/ (last accessed January 13, 2015).
2. Pub. L. 96-354 94, Stat. 1164 (1981).
3. Pub. L. 96-354 94, Stat. 1164 (1981).
4. Pub. L. 104-121 110, Stat. 857 (1996).
5. Pub. L. No. 104-121 110, Stat. 857 (1996).
6. The CFPB was not in existence when SBREFA was passed but it was made subject to the requirements of SBREFA upon its creation in 2010.
7. Pub. L. 104-4 109, Stat. 48 (1995).
8. See note 1.
9. The reports can be found at https://www.sba.gov/advocacy/regulatory-flexibility-act-annual-reports (last accessed January 22, 2015).
10. See https://www.sba.gov/sites/default/files/files/leg_priorities112th.pdf (last accessed January 28, 2015).
11. See http://www.foreffectivegov.org/files/regs/gaming-the-rules-small.pdf (last accessed February 13, 2015).
12. See http://www.regulations.gov/#!documentDetail;D=OSHA-2010-0003-0239 (last accessed March 10, 2015).
13. 29 CFR 1910.1030.
14. See http://www.regulations.gov/#!documentDetail;D=OSHA-2010-0003-0245 (last accessed March 10, 2015).
15. The MRP program is in a wide variety of OSHA regulations and the concerns voiced during these telephone calls are often voiced by industry in their public comments. OSHA maintains that because workers compensation does not make the worker whole, there is still a considerable incentive for under-reporting injuries or illnesses.
16. See http://www.regulations.gov/#!documentDetail;D=OSHA-2010-0003-0250 (last accessed March 26, 2015).

7. The use of analysis

The scientist and the social scientist always strive to find clear answers to the questions they are addressing. That is no less true of me than it is of the scientists, economists and environmental analysts I spoke with in researching this book. But those analysts realize that the questions with which they are grappling are riddled with uncertainty and complexity. Similarly, in addressing in this chapter the question of how and when analysis affects policy, I will attempt to pull together the disparate threads of the four previous chapters and paint a picture of the use of analysis within government and the myriad things that affect its use.

Throughout the more than 50 years in which academics and advocates have debated the role of analysis, much of the discussion has focused on normative questions. Comprehensive-rational analysis has been praised as a way both to lead to better public policy and to increase the transparency of decisions made within the bureaucracy, an unelected fourth branch of government. It has also been decried as a tool to delay or prevent decisions that would benefit the public, and as a replacement of a democratic form of governance with a technocratic one.

For those in either camp, the results of the previous several chapters present some good news and some bad news. On one side of the ledger, the various forms of comprehensive-rational analysis have influenced public policy decisions. The regulation requiring greater security at aircraft repair stations was modified in part because the costs were high and the benefits were dubious. Pesticide approval decisions regularly hinge on the risk assessments conducted to evaluate the potential harms of the pesticide in question. Myriad changes to agency projects have been made as a result of sharing environmental analyses with affected communities. SBREFA panels regularly lead agencies to modify their regulations to lower the burden on small businesses.

However, the argument that analysis is either ineffective or harmful also was common in the empirical work of the preceding four chapters. The Food and Drug Administration (FDA) issued its regulation for good manufacturing practices for dietary supplements despite high costs and questionable benefits and an inability (or unwillingness) to calculate the costs and benefits of particular provisions. Decisions on the risks

associated with certain chemicals take not years but decades, as the risk assessments under the Integrated Risk Information Systems (IRIS) program are continually contested. Judges have systematically backed agencies when they produce environmental impact statements (EISs) that are voluminous but not informative. The Regulatory Flexibility Analyses produced by agencies are often similarly detailed and similarly ignored.

This chapter proceeds as follows. In the next section, I briefly recap the findings of the previous four chapters. Following that, I discuss what the successful uses of analysis have in common and what the failed uses have in common. I then discuss aspects of analysis that are not so easy to classify, such as review by the courts and public participation. I then review the role of politics, bureaucracy, law, and the epistemic limits of science and social science, and how these institutions affect the role of analysis in policy-making.

A QUICK REVIEW OF WHERE WE HAVE BEEN

As described in Chapter 2, the process for making regulatory decisions in the United States is an excellent means by which to understand the interaction between analysis and governmental decision-making. Regulations have evolved from a backwater of policy-making to a tool that is a central element for presidents to enact their agendas (Eisner 2000). The first key step in this evolution was the passage of numerous statutes in the late 1960s and early 1970s creating agencies such as the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA), and empowering them with the ability to make policy by writing regulations.

Analysis became central to regulatory decision-making for a variety of reasons. Powerful interests were economically burdened by these regulations, and supported analytical requirements. There was concern about housing policy-making power in the executive branch and analysis was seen as a means of increasing the transparency of these decisions and a way of improving them. Finally, the demise of the Planning, Programming, and Budgeting System (PPBS) did not signal the death of analysis as a policy tool but rather signaled its birthing pains. The growth of policy schools around the country and the permeation of policy analysts throughout the government helped spur a growth in the affinity for analysis as a policy-making tool (Radin 2013). Given the politics surrounding regulation, the rule-making process was an ideal outlet for this affinity.

EISs were already a requirement for regulations that had an effect on the environment. The requirements for analyses of the impact of regulation on small businesses and on the burden of information collections followed at the end of the Carter Presidency. Cost-benefit analysis joined the party with the issuance of President Reagan's Executive Order 12291, and risk assessment followed as a tool to help measure the benefits required for cost-benefit analysis. More impact analysis requirements followed in the 1990s and even more are being considered today.

In Chapter 3, I reviewed the regulatory experience with cost-benefit analysis. This included case studies of when analysis clearly had an impact (the weakening of the Aircraft Repair Stations Security regulation), when it clearly did not (the FDA requirement for good manufacturing practices for dietary supplements), and a brief discussion of the EPA cooling tower regulation where the analytical impact was ambiguous. Economists agreed that some of the most important impacts of cost-benefit analysis were invisible to the outside observer. In particular, economists were proud of their ability (often used by invoking the boogeyman of the Office of Information and Regulatory Affairs (OIRA)) to stop those regulations that were the worst from an economic perspective.

This ability was voiced by several economists but there were several important categories of exceptions. Those regulations which had an important basis of political support were much harder for economists to stop or often even modify. As one economist said, some political leaders "had more of an inclination to change the analysis than the requirements in the regulation." The position of cost-benefit analysis in the regulatory process, where it is often used to evaluate options to solve something policy-makers have already decided is a problem, leaves it rather subject to political manipulation.

The legal and bureaucratic circumstances in which the particular regulatory decision is made are also very relevant in the minds of agency economists. Interview subjects cited the location of economists within the decision-making process both organizationally and temporally as being important. Economists who did not report to decision-makers were freer to voice independent opinions and influence decisions. Economists who were brought into the decision-making process earlier were also more able to wield influence. Sometimes these two tendencies worked against each other as economists outside the program office were less likely to be included early in the decisions made by that program. Finally, if solutions to a problem were detailed in statute, economists could do nothing to influence their promulgation in regulation.

I also found an important cross-current between cost-benefit analysis and participation. When analyses were carried out in a transparent manner, as in the case of the Aircraft Transfer Station Security regulation, commenters could weigh in and make objections to the policy decisions that carried weight with agency officials. The subject of analysis and participation is discussed often in the literature, but more often in the discussions of risk assessment (NRC 2009) and environmental impact assessment (Glucker et al. 2013) than with cost-benefit analysis.

Finally, critics of cost-benefit analysis might be surprised to know that economists are acutely aware of the limits of their analysis. On occasion, however, decision-makers seem less aware of these limits, putting economists in the position of having to make difficult decisions about how to present uncertainty and the limits of their work. While Harry Truman famously wanted a one-handed economist (so that they couldn't say "on the one hand" and "on the other hand"),[1] the real practice of economics means that he might have been served by an economist with three or four hands.

Economics is a social science and one might expect that these epistemic limits would be less of a concern when science (even if it is just "regulatory science" (Jasanoff 1990)) was informing regulatory decisions. Unfortunately, as the examination of risk assessment in Chapter 4 showed, this is not the case. In fact, the problems may be worse with risk assessment than with cost-benefit analysis, because the expectations are higher. Decision-makers (and the lay public) expect science to produce concrete answers. This expectation puts pressure on scientists, even greater than the pressure on economists, to paper over uncertainty as a feature of their analyses. As a result, the supposedly inadequate presentation of uncertainty in risk assessment has been an issue cited by researchers for decades (NRC 1994, 2009).

Risk assessment plays a different role than cost-benefit analysis. It is more often used for priority setting within the bureaucracy than for the selection of a policy alternative. The use of risk assessment for agenda setting has certain important implications. It partially immunizes risk assessment from one kind of political interference. Almost none of my interview subjects could come up with a case where their political chiefs tried to influence the results of their work. This was not the case with the economists or environmental analysts who were on occasion treated as if their job was to justify choices already made.

However, the earlier placement of risk assessment in the regulatory process raises the stakes of certain decisions. This was clearly the case with the IRIS program. These high stakes lead to intense interest from affected parties, particularly industry. As such, industry works hard to

delay determinations that chemicals they produce already are hazardous. The IRIS program is famously plagued by decisions that stretch out over decades, and while interview subjects and the literature (e.g. Graham 2006; Mills 2006) point to a variety of culprits for this, the underlying political context is at the root of many of these. Determinations on the risks of existing pesticides are also plagued by this environment (Jasnoff 1990).

Interestingly, when risk assessment plays more of an evaluative role than a priority setting role, as it does in the EPA's program for determining the approval of new pesticides, it is widely praised. Both applicants and the agency (in part because of legal deadlines for decisions) are interested in a quick resolution to the question at hand. The pesticide program is also blessed with certain aspects of its legal setting that facilitate scientific input into decision-making. These include the deadline on decisions and the need for industry to secure approval before marketing its products.

I saw a different relationship between risk assessment and bureaucratic independence than with cost-benefit analysis and its location in the bureaucracy. Risk assessors wanted to be closer to decision-makers so they could better understand the questions they were being asked, whereas economists craved independence. This may be a function of the timing of their inputs to decisions (risk assessors as priority setters, economists as policy evaluators) or it may be a function of a greater political propensity to interfere with economic decisions instead of scientific ones.

Finally, the literature on risk assessment praises the potential of participation in risk-related decision-making. Risk assessments, however, are even more impenetrable than cost-benefit analyses and the calls for more transparency in risk assessment continue unabated. Everyone wants more participation in risk assessment but it is not clear to me that anyone knows how to get it.

The desire for participation and the frustration at being unable to meaningfully achieve it is also present in debates over environmental impact assessment. Adnan et al. (quoted in Glucker et al. 2013) compare the desire for participation in EISs to a "magical incantation." Indeed, interview subjects with vast National Environmental Policy Act (NEPA) experience described a variety of experiences with public participation. Some had valuable experiences, and described changes to projects that led to acceptance from local communities. Others recalled instances of being overwhelmed by organized campaigns that were in opposition to the project or regulation in question. In these cases, such as the Mexican trucker regulation, agencies tended to dig in and make few or no changes

to their preferred policies. On the other hand, the case of the beluga whales shows a clear example of participation being a key component of using analysis to affect policy change.

EISs also bring the courts into the debate over analysis more directly than the other forms of comprehensive-rational analysis. The direct role of the courts is not encouraging when it comes to incorporating analysis into agency decisions. Opponents of the Federal Motor Carrier Safety Administration's (FMCSA) regulation allowing Mexican truckers to drive in the United States found a receptive audience in the Ninth Circuit Court but their hopes were quickly dashed by the Supreme Court. This is part of a well-known trend in the courts, particularly the Supreme Court (Lazarus 2011), to uphold agency analysis under NEPA.

Once agencies began to actually perform EISs (after courts had informed the agencies that EISs were legally required), courts began regularly turning down challenges to agency decisions by environmental groups who raised issues with the EISs. The analyses became impenetrable, because of their length and their technical complexity. One could easily argue that judicial review led to analyses that were less transparent, thereby subverting one important goal of analytical requirements. Other factors such as the use of contractors may also contribute to overly detailed, hard-to-understand EISs.

However, numerous scholars have praised judicial review more for its indirect effects than its direct effects. The two most important of these effects are the creation of a culture within agencies of environmental awareness and the empowering of outside interests. Because agencies fear having their decisions overturned in court, many have hired a bevy of environmental analysts (although some have relied heavily on outside contractors). Having these analysts as part of the organization changed the culture of the agency, and led to decisions that better incorporate environmental concerns (Taylor 1984; Cashmore et al. 2004). Judicial review has also empowered outside environmental groups. Armed with the weapon of a potential lawsuit, environmental groups find themselves in better bargaining positions with the agency. This, however, is a double-edged sword – the environmental groups can use EISs to better hold agencies accountable for protecting the environment, but often they have found themselves on the losing end of court cases that drag on for years.

The use of analytical requirements to empower outside groups was also present in the SBREFA panels in Chapter 6. Here, the connection is even more explicit than with EISs. There is little doubt that in fashioning a requirement that agencies both analyze the impact on small businesses of a possible regulation and share this analysis with small businesses

before proposing a regulation, Congress was hoping to increase the power of this particular constituency. Analysis plays an important role in the SBREFA process that has parallels to the EIS but it is even more direct in empowering a particular set of interests.

However, the other types of impact statements described in Chapter 6 appear to be much less relevant to policy decisions. Unlike SBREFA panels and EISs, these impact statements have no one to enforce them. EISs have given outside groups power to use the courts for enforcement of the idea that environmental impacts need to be a part of decisions. SBREFA has given small businesses the Office of Advocacy (within the Small Business Administration (SBA)) to help them use agency analysis to better understand the trade-offs inherent in regulatory decisions.

I spoke to almost 50 analysts in the federal government, relatively evenly divided between economists, scientists and experts in environmental impact assessment. Coupled with case studies in each area, I have seen the various offspring of comprehensive-rational analysis in a wide variety of contexts. While the differences between the experiences with analysis are instructive, I was most struck by the similarities. In the next two sections, I discuss these similarities between when analysis worked in different contexts and when it didn't.

THE SUCCESSES OF COMPREHENSIVE-RATIONAL ANALYSIS

Casting Light on the Easiest Decisions

Across the different types of analysis, one benefit was common to all the cases. Economists described how they were able to scuttle regulations that had high costs and little if any benefits long before the ideas saw the light of day. Even in a case where a regulation did see the light of day, we saw how cost-benefit analysis facilitated the scaling back of security requirements at aircraft repair stations that were likely to do very little to reduce the risk of a terrorist attack. The literature also discusses the role cost-benefit analysis played in the Reagan Administration's decision to phase out lead in gasoline (Morgenstern and Landy 1997). An administration that was fundamentally anti-regulation was convinced by benefits that dwarfed the costs. Getting the lead out was an "easy decision" from an economic perspective.

Risk assessment in the pesticide program works regularly to secure the rapid approval of new pesticides that are likely to be harmless and to put conditions (including prohibition) on chemicals that are likely to cause

risks to human health. In the arena of environmental impact analysis, projects that the public never finds out about are abandoned because of environmental impacts (Greenberg 2013). Mitigated Findings of No Significant Impact (FONSIs) are a mechanism by which negative environmental impacts are eliminated or lessened by agencies who wish to avoid the burden of producing an EIS. Numerous interview subjects described the environmental mitigations that take place through the mitigated FONSI process. Finally, the SBREFA panels have led to the elimination of provisions of regulations that will burden small businesses but may do little to achieve regulatory goals.

Advocates of comprehensive-rational analysis have long couched their advocacy in optimizing government policy decisions, getting the most "bang for the buck." But if analysis is helping us avoid the worst policy decisions and is facilitating the best ones, this is not a trivial accomplishment. If analysis allows us to save tax (and compliance) dollars, to protect the environment, and to avoid significant risks by casting light on and facilitating the "easy" decisions, then helping with the "hard" decisions is icing on the cake. By no means would I suggest that limiting analysis to the easy decisions is appropriate but we should at the very least appreciate this benefit of requiring analysis.

Inculcating a Culture of Analysis

EISs are the oldest of the analytical requirements studied in this book. They also apply to a much wider variety of decisions than the other forms of analysis. It is not surprising therefore that EISs have affected the culture of agencies in which their practice is widespread more than other impact analyses, cost-benefit analysis, and risk assessment. While no one would claim that the U.S. Forest Service or the Army Corps of Engineers (the two agencies studied by Taylor 1984) are now first and foremost guardians of the environment, there is enough evidence in the literature to suggest that small but significant changes in agency culture can occur through the requirement of analysis. While it is more difficult to get a feel for culture in individual interviews, I did hear things like "We want to do good work and what the law requires."

It is possible that EISs have permeated agency cultures better because they have been part of the policy-making landscape longer than cost-benefit analysis or risk assessment. However, it is also possible (probably even likely) that judicial review has played a key role in this regard. Numerous authors have made this point (Taylor 1984; Lazarus 2011). In the early days of NEPA, agencies thought they did not have to carry out EISs or that they could do a cursory job on them. Once the courts

(particularly in the *Calvert Cliffs* decision[2]) disabused agencies of this notion, they began hiring environmental analysts. To the extent that agency culture has pivoted toward environmentalism, judicial review has been a significant factor.

The effects of cost-benefit analysis and risk assessment are not entirely absent from regulatory agency cultures. The "science charade" (Wagner 1995) – that phenomenon whereby policy-makers claim scientific justification for decisions made on policy grounds – is evidence of the idea that risk assessment is important to constituents of agencies dedicated to protecting public health. Similarly, in recent years we have seen an increased prevalence of policy-makers including the costs and benefits of their decisions in their announcements of regulatory changes (as long as the benefits are much greater than the costs).

But this recognition of the appeal of economics and risk assessment does not yet signify a broader change in the culture of regulatory agencies. Whereas risk assessors and economists are still fighting for a seat at the table when decisions are made (sometimes successfully), decision-makers at the U.S. Navy and the Forest Service know that they have to complete an EIS and plan to do so from the earliest stages of their planning process. This doesn't mean that the EIS always affects the decision in question, but it's placement at the proverbial table gives it a leg up on the other forms of comprehensive-rational analysis. And I believe this placement has at its roots the legal standing of the EIS.

Analysis Partnering With Politics

The tension between analysis and politics is omnipresent throughout the literature, and was prevalent in my interviews. Politics was seen as trumping analysis on some occasions in discussions of cost-benefit analysis, risk assessment, and EISs. However, the SBREFA panels, and to a lesser degree some instances of EISs, show that analytical requirements can be crafted to take advantage of interest group politics. This approach does carry with it risks for the analytical enterprise, as well as rewards.

SBREFA requires agencies to provide an analysis of the impact of their potential regulations on small businesses to a panel of small businesses before formally publishing a regulatory proposal. These small business owners then provide input to a federal panel consisting of the regulating agency, OIRA, and the Office of Advocacy (within the SBA). One report by the Center for Effective Government (2014) documents numerous cases where this process has led agencies to reduce regulatory requirements on small businesses (and occasionally on larger businesses which may be inappropriately represented in the discussions).

These changes are unidirectional. Small businesses never argue for stricter regulations in order to protect vulnerable populations. There is no reason to believe that the changes always increase the economic efficiency of a regulation or make them better from any comprehensive-rational perspective (they may – but this is incidental rather than systematic). But this approach may point a way toward incorporation of analysis into decision-making.

As I discuss below, the relationship between participation and analysis is complicated, and not always as successful as envisioned in the literature (Glucker et al. 2013). But SBREFA panels do point to a possible way toward integrating analysis and participation. The format of SBREFA panels does not need to be limited to small businesses. EISs could be reviewed by environmental interest groups at an early stage of decisions (indeed the role of outside groups in EISs is clearly stronger than in cost-benefit analysis or risk assessment). Economists from the outside could be brought in to review cost-benefit analyses before a regulation is proposed. Other affected interests could be treated similarly to small businesses. I will explore this type of reform further in Chapter 8.

THE FAILURES OF COMPREHENSIVE-RATIONAL ANALYSIS

The Inexorable March toward Precision over Relevance

Cost-benefit analyses have consistently grown in length over the past several decades (Carrigan and Shapiro 2014). According to my interview subjects, risk assessments are often documents that bury assumptions behind large volumes of technical jargon. In part because of judicial review, agencies have the incentive to produce EISs that are impressive in their length and scientific complexity, but may do little to shed light on the trade-offs in mitigating environmental harms (CEQ 1997). This trend was repeatedly confirmed by interview subjects in the EIS world.

All of these trends come at a time when there have been calls for increasing the role of simplicity in public policy (Sunstein 2013) and in legal decisions (Posner 2013). Arguments in favor of comprehensive-rational analysis have long had as their key pillar the contention that they increase transparency. If even informed parties have trouble using the analysis to decipher the trade-offs in government decisions, the transparency argument falls apart (Rayner 2003).

Judicial review, which may play a role in both fostering the culture of analysis within the bureaucracy and in empowering outside groups to use analysis, may work against the usefulness of analysis in this context. It is often said that judges are not scientists (e.g. Leiter 1997). Nor are they economists nor environmental experts. While it is relatively easy for a non-expert judge to determine when an analysis is insufficient, it is much harder to determine when an overly detailed analysis sacrifices relevance for false precision. This "false formality" (Sinden 2014) of analysis is a growing problem and it makes all forms of comprehensive-rational analysis less useful.

The Time Spent on Analysis

Concern about analysis leading to infinite delays in decisions goes back to Lindblom (1959). It has been variously characterized as "ossification" of the rule-making process (McGarity 1992) and "paralysis by analysis" (Vladeck and McGarity 1995). The argument that all regulation has been slowed down or even stopped by analytical requirements has largely been rebuffed (Yackee and Yackee 2010). However, the idea remains that requirements for comprehensive-rational analysis can deter regulation in certain cases, particularly the most politically salient or costly regulations (Pierce 2011).

The IRIS case provides evidence that this is indeed the case. Delays in risk assessment in the IRIS program appear to have many causes. Various sources blamed the separation of IRIS from the EPA programs that use the risk assessments, the leadership of the IRIS program, the complexity of the issues that IRIS deals with, and the political climate in which IRIS operates. The National Academy of Sciences (NAS) and the Government Accountability Office have repeatedly been called in to examine the IRIS process both because of questions about its accuracy, and because the process of finalizing a risk assessment can take decades.

Further, policy decisions are awaiting the risk assessments that IRIS produces. Similarly, interview subjects told me about projects that were delayed for years while environmental impact assessments were completed and contested in the courts. The literature also recounts these delays in the EIS context (Greenberg 2013).

A former colleague of mine at OIRA once said that "a bad decision delayed is a good decision." But how do we know that the decisions which are delayed are the bad ones? Analysis tends to facilitate some of the best decisions and eliminate many of the worst ones while lengthening the times of the most difficult ones. These are decisions that are rife with uncertainty. While no one is suggesting that we should rush into

difficult decisions, there is little argument that spending decades and untold amounts of money analyzing these questions is good public policy. The successful use of deadlines in the pesticide registration process points to a possible solution that I will explore further in Chapter 8.

Ignoring Policy Analysis Altogether

In the case of the FDA requiring good manufacturing practices for manufacturers of dietary supplements, the cost-benefit analysis was clear. The costs were high and the benefits were entirely questionable. If there were any benefits, the analysis did not tell us which provisions in the lengthy regulation would produce them. Yet the FDA issued the regulation. As a side note, public health crises as the result of problems with dietary supplement consumption have continued unabated in the years since the regulation.[3]

There are numerous cases where an agency decides that NEPA or the Regulatory Flexibility Act (RFA) does not apply to a particular decision, and the lack of application of these impact analysis requirements seems highly questionable to outside observers. The case of not carrying out an EIS for the regulation allowing Mexican truckers to drive further into the United States is one such instance. Numerous instances of agencies dubiously deciding that the RFA does not apply to their regulations are documented in the literature (Shive 2006).

These are the cases that lead most directly to the concerns about politics subverting analysis. In the dietary supplement example, the regulation was supported both by public health groups and established dietary supplement companies (in the hope of creating a barrier to entry for new or smaller manufacturers). In the case of the Mexican truckers, the FMCSA was forced to conduct an environmental assessment but found no significant impact on the environment, not surprisingly the same conclusion it had reached before the assessment.

So, comprehensive-rational analysis clearly has its limits. On the one hand these cases show that the concerns about analysis subverting politics and a technocratic state predominating are ill-founded. On the other hand, these cases – along with those where political factors lead to interminable delays – show that analysis is open to manipulation and to being used to avoid decisions that impose heavy costs upon certain actors.

THE COMPLEXITIES OF COMPREHENSIVE-RATIONAL ANALYSIS

The preceding chapters highlighted a great deal about when analysis works and when it does not. However, there are also a number of institutional characteristics that have long had complicated relationships with comprehensive-rational analysis in both the literature and in practice. The cases served to cast light on the nature of these relationships.

Judicial Review and Comprehensive-Rational Analysis

Two of the forms of comprehensive-rational analysis examined here are explicitly judicially reviewable. NEPA requires agencies to conduct EISs when their environmental assessments reveal significant environmental impacts of government actions. The RFA stipulates that Regulatory Flexibility Analyses are judicially reviewable. In both of these cases, judicial review has not guaranteed agency fealty to the principles in these statutes.

Over the last 40 years agencies have had a perfect record before the Supreme Court in defending their decisions under NEPA (Lazarus 2011). While litigants have had some successes in lower courts, the general sense within the environmental community is frustration with judicial review of EISs (Cashmore et al. 2004). The Mexican trucker case in Chapter 5 highlights these frustrations. Similarly, agencies have managed to avoid carrying out regulatory flexibility analyses required under the RFA by arguing that their regulations do not meet the statutory threshold of having a significant impact on a substantial number of small entities (Shive 2006; Raso 2015, forthcoming).

However, NEPA has been successful in ways that cost-benefit analysis and risk assessment have not. Environmental scientists proliferate within agencies that have to frequently write EISs (Taylor 1984). "The process of preparing [an] EIS can itself change agency behavior. It is one thing to resist expending resources to acquire information about adverse environmental impacts. It is quite another to ignore such information once it is available and part of the decision-making record" (Lazarus 2011, p. 1519). Judicial review within NEPA has both disappointed its supporters and had real impacts in ensuring the integration of environmental analysis within agency cultures.

Judicial review of regulatory flexibility analyses under the RFA has not had a similar effect so one cannot simply conclude that judicial review ensures agency attention to analytical concerns or alters agency culture.

Judges have largely deferred to agency assertions that they are exempt from the RFA requirements. In the early days of NEPA judges made clear that they would grant no such deference.

Any argument as to why judicial rulings solidified the requirement of an EIS, and facilitated agency exemptions under the RFA, is necessarily speculation. One possible reason for this is the consequence of the analysis. Under NEPA, agencies don't have to take any action if their analysis shows environmental impact; they merely have to present the impacts and alternatives to the public and consider ways to mitigate them. Under the RFA, there is a heavier burden to explain why alternatives were not chosen (agencies must explain "why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected"[4]). It is plausible that judges are more likely to force agencies to take actions that are in the nature of increasing transparency than forcing decisions.

But the relationship between judicial review and transparency is also not necessarily straightforward. While all of the types of the analysis in this study have been plagued by trends toward complexity and density, the area where this trend is most pronounced has been in environmental impact analysis. The literature describes this trend extensively (e.g. Greenberg 2013). My interview subjects brought it up more often than the economists and scientists I interviewed about cost-benefit analysis and risk assessment. One reason why EISs are so plagued by density is that their authors know they may have to defend those conclusions in court. Judicial review may not be the only factor in decreasing the readability of analyses, but in the case of EISs it is clear that it has contributed to a worrisome trend away from understandable analysis.

In any case, the story of judicial review and analysis is one of ambiguity. Supporters of cost-benefit analysis have regularly championed making the analyses judicially reviewable (Hahn and Sunstein 2002). The examples here indicate that such an effort is unlikely to have major effects on particular decisions in the short term and may produce more impenetrable analyses in the long term (although some may argue that cost-benefit analysis and risk assessment are already well along that path (Carrigan and Shapiro 2014)). On the other hand, a carefully constructed judicial review requirement may inculcate a culture of cost-benefit analysis and risk assessment in agencies.

Participation and Comprehensive-Rational Analysis

In a sense, analysis and participation have long moved on parallel tracks in the regulatory process. Both have long histories. Requirements for

participation date back to the Administrative Procedure Act in 1946.[5] As we have seen, requirements for analysis date back to the passage of NEPA and reached their full flowering with the issuance of Executive Order 12291 in 1981.[6] More so than analysis, there have been numerous empirical scholarly studies of the role of public comment in agency decisions (e.g. West 2004; Yackee 2006) but the results of these studies have been mixed. They are also limited to the dominant form of participation in regulatory decision-making, notice and comment, which may not always be the best way to get meaningful participation (Eckerd 2014).

The interaction between analysis and participation in the rule-making process has received less attention. Certainly, in the case of each individual type of analysis examined here, there have long been calls for more participation in the analytical enterprise. The NAS reports on risk assessment, particularly *Science and Decisions* (NRC 2009), called for a more participatory approach to risk assessment. The literature on environmental impact assessment is rife with calls for greater participation and claims about the value of participation (Glucker et al. 2013).

In the interviews and cases on cost-benefit analysis, the value of a participatory analytical process was clear. Economists regularly cited the value of using cost-benefit analysis to make the impacts of agency decisions transparent, and the valuable input into assessing costs and benefits they had received from outside parties. The aircraft transfer station security case was a clear example of outside parties using the analysis as a wedge to make clear that the regulatory decisions being contemplated by the Department of Homeland Security were flawed. Outside parties pointed out gaps in the environmental assessment conducted by the National Oceanic and Atmospheric Administration (NOAA) regarding whether to approve a permit for the import of beluga whales. This information played a key role in the NOAA decision to reject the permit.

In the case of risk assessment, practitioners largely mirrored the scholars who praise participation. Everyone loved the idea of making their analyses more transparent and getting public input on them but there were few examples of this actually happening. For environmental impact assessments, the experience with participation was more mixed. Practitioners described instances of local communities engaged in the EIS process and providing valuable information to agencies. There were also cases of outside parties, often large organized interests, using the agency analyses either to make public cases against agency decisions, thereby delaying them (as in the case of risk assessments in the IRIS

program), or to serve as the grounds for potential lawsuits as in the case of the Mexican truckers.

As described above, the SBREFA panels give us an alternative model for participation in agency regulatory decisions. Unlike the more general participatory regimes that are intertwined with the other types of analysis, the SBREFA process seeks to engage only a particular constituency. In doing so, it has exhibited success in marshaling analysis to affect policy decisions. However, that marshaling occurs in one direction only (toward deregulation). Whether a SBREFA process can be expanded to other constituencies or to the broader public will be explored in the next chapter.

Partial Successes? Mitigated FONSIs

Much of the rhetoric surrounding different forms of comprehensive-rational analysis treats analysis as if it should lead to clear conclusions. Regulations written using cost-benefit analysis should maximize net benefits. Risk assessment should lead decision-makers to attack the worst risks first and ignore minimal risks. Environmental impact assessment should lead to wholesale changes that benefit our environment. Other impact assessments should ensure that the burdens of regulation on particular communities are minimized.

The use of mitigated FONSIs points out another possibility. Agencies are given a choice regarding the conduct of an EIS. If it is possible to mitigate the impact of agency actions on the environment, then perhaps an EIS is not necessary. Agencies have reacted to this incentive by the thousands (Karkkainen 2002) by doing mitigations that improve the environment. My interview subjects confirmed this tendency and spoke proudly of the EIS process leading to the protection of tribal rights and to not digging up cemeteries that they hadn't known existed.

The mitigated FONSI process raises important questions about the use of analysis. Is the half-a-loaf that these environmental protections represent enough of an accomplishment for an analytical process often sold as promising more comprehensive policy changes? Should we make it more difficult to avoid carrying out an EIS, and in the process possibly sacrifice these improvements? Or should we change the way we sell comprehensive-rational analysis and instead set our sights on using analysis to point the way to small policy changes that are clear improvements? I return to this subject in Chapter 8.

ROUND UP THE USUAL SUSPECTS: INSTITUTIONAL FACTORS THAT AFFECT THE USE OF ANALYSIS

The literature in Chapter 1 pointed out several institutional factors that play a part in the role of analysis in policy-making. These institutions came up repeatedly in Chapters 3–6. Here I present brief summaries of how politics, bureaucracy, law, and the characteristics of analysis itself influenced the relationship between analysis and policy-making in the cases and interviews presented in the previous four chapters.

Politics

> People want policy to be well informed and analyzed, perhaps even correct or scientific; yet they also want policymaking to be democratic and hence necessarily an exercise of power. (Lindblom and Woodhouse 1968, p. 7)

> Inspired by a vague sense that reason is clean and politics is dirty, Americans yearn to replace politics with rational decision-making. (Radin 2012, p. 127, quoting Stone)

As described in Chapter 1, the relationship between politics and policy analysis has long been a complicated one and has been debated since policy analysis in its modern form emerged in the 1960s. It is probably the most explored environmental component in studies of policy analysis. The demise of PPBS was laid at the feet of political actors by some critics (Jenkins-Smith 1990). Advocates of analysis have long bemoaned political interference. Politics has been blamed both for influencing the results of analysis and for ignoring these results altogether. Critics of analysis have long worried that analysis would allow technocratic experts to subvert democratically expressed preferences.

The cases presented in Chapters 3–6 reveal that the extreme arguments generally have not come to pass. Certainly there are cases where analytical conclusions are ignored (dietary supplements) and cases where analytical conclusions affect the political discussion of the regulatory decision (beluga whales). But, more commonly, there is an interplay between analytical efforts and political preferences. Occasionally this is a tug of war between opposing conclusions. It can also be a reinforcing relationship where analysis facilitates the political preferences of one side of the debate or another.

In my view, the case with the most damaging interplay between analysis and politics are the risk assessments that the EPA conducts through the IRIS program. These are high-stake analyses. They are largely risk assessments of chemicals currently in use, and if the EPA

concludes that the chemical is harmful the economic consequences for manufacturers and users of those chemicals are likely to be huge. As a result, IRIS results are always contested. Problems inherent to risk assessment (like all forms of comprehensive-rational analysis) – such as its dependence on initial assumptions, the inherent complexity of the questions being analyzed, and the necessary uncertainty of the results – always give opponents of the conclusions a lever with which to delay action (Rushefsky 1986). The result in the IRIS program has been assessments that drag on for years.[7]

The EIS cases also show examples of outside interests using analytical requirements to delay decisions that they don't like. However, in both cases of the George W. Bush Administration regulation allowing Mexican truckers to penetrate further into U.S. markets and others described to me by interview subjects, these attempts to derail policy decisions ultimately proved unsuccessful. The government has been able to argue that it had fulfilled its analytical obligations and that its decisions were justified.

And when political forces are all lined up behind a particular decision, analysts can do little to stand in the way. Numerous economists I spoke with noted that when a disaster occurs (for example, an airplane crash), the political demand for the government to "do something" often outweighs any analytical concerns that the "something" may not be helpful or even necessary. In the case of the regulation of dietary supplement manufacturing practices, large manufacturers and public health groups both wanted to see the regulation issued. This proved to be too much momentum to overcome for an analytical argument that the quality of dietary supplements would be unaffected by the regulation.

Politics can be seen as setting the boundaries within which comprehensive-rational analysis can operate. The higher the salience of the issue the less space available for analytical influence, and the more likely it is that powerful groups will use analysis as part of their efforts to achieve their policy aims. In lower salience issues such as the aircraft repair stations and the EPA pesticide registrations, analysis can play an important role. However, the line-up of political forces also affects the room for analytical concerns. When forces are more closely balanced, then it may be possible for analysis to tip the balance.

There may be the possibility that an analytical framework could be set up that takes advantage of political conditions. The SBREFA process (and to some degree the EIS requirements) uses analysis to empower a particular outside constituency. Small businesses use the data provided to them about the potential impact of the regulation to strengthen their arguments against the regulation.

Bureaucracy

If politics is suspect number one when analysis does not achieve its goals, bureaucracy is seen as its chief accomplice. This was the case when autopsies of the PPBS found the lack of centralized control in federal agencies and resistance by those agencies to be significant culprits. There is a rich literature on how bureaucracies zealously pursue their missions, guard their turf, and are resistant to change (see e.g. Downs 1967 and Wilson 1989). The requirement to perform an analysis of their preferred policy options (and especially also to analyze alternatives to their preferred choices) has the potential to impinge on these preferences.[8] Thus bureaucrats have the motive to subvert analysis.

But the analysts are also bureaucrats. Meltsner (1976) focused on the assimilation of analysts into federal agencies and worried that many analysts were not prepared to function in bureaucratic organizations, "While we can teach students analytical skills, we can only expose them to the bureaucracy to develop the skills and knowledge essential for effective policy analysis" (Meltsner 1976, p. 290). However, some analysts became "politicians" and figured out how to champion their analytical findings and best ensure that they got a hearing from decision-makers (Meltsner 1976). Radin (2013) found that over time, policy analysts in general became embedded in the bureaucracy, which enhanced their ability to function in some cases. However, sometimes this embedding was many levels removed from decision-makers, which harmed their ability to make a difference.

My interview subjects were current or former analysts in the federal bureaucracy. Hence they were also current or former bureaucrats. As such, they were acutely aware that they were a small piece of a much larger enterprise. Many of them cited the fact that their successes often came from understanding how to navigate their organizations, and noted that they had come across colleagues who had not mastered those skills and who were therefore less successful in influencing policy through analysis. The adjustments that Meltsner (1976) described the analysts as having to make are still made on a daily basis by modern scientists and economists.

One factor that came up repeatedly in the interviews was the location of analysts within the decision-making process and the agency organizational structures. Analysts of all stripes desired to be a part of the regulatory decisions at an early stage. Risk assessors tended to have the most success at accomplishing this goal while economists and environmental impact assessors had only sporadic success. Of course, this is largely due to the fact that risk assessment plays a role in priority setting

at the agencies. It attempts to answer the question "What are the public health risks that require our attention?" The other disciplines answer the question, "What policy choices do we make to address these concerns?"

This difference plays a key role in determining preferences for where to place analysts within the organization. Economists almost uniformly argued that they needed to be separated from the program office whose policy choices they were evaluating (while still being brought in on those discussions as early as possible). The concern that was repeatedly voiced was that it was impossible to criticize the policy choice of the head of the program office if you reported to that person. Or, it was impossible to do so and continue to function in the organization.

Risk assessors had a different preference. The misinterpretation of the "Red Book" (NRC 1983) as suggesting the separation of risk assessment and risk management led over the decades to the creation of separate offices that conduct risk assessment (such as is done in the IRIS program). More recent work has attempted to correct this misinterpretation and argued that risk assessors need to better understand the uses to which others will put their work in order to construct their research appropriately (NRC 2009). My interview subjects heartily agreed with this newer perspective as risk assessors from numerous different agencies voiced the desire to be more thoroughly integrated with those making policy decisions.

For environmental impact assessors the results were a mixed bag but were closer to those of the economists who had the similar function of evaluating policy choices for their agencies. Taylor (1984) found that environmental scientists preferred independence and my interview subjects largely agreed. He also noted the trade-off that was true for all analysts: "We do not want the analysts to be integrated and influential at the cost of being co-opted, nor do we want them to be so autonomous as to be irrelevant to policy decisions" (Taylor 1984, p. 94). The location of analysts is an important factor in their effectiveness, and the more we expect analysts to criticize policy choices within their organization, the more independence they should have.

Law

The structuring of legal requirements for analysis interacts with the performance and use of that analysis in various ways. On the most macro level, the U.S. legal system has been described as "adversarial." The system for choosing regulatory policies is an excellent example of this. "American regulatory law is more legalistic – that is more detailed prescriptive, and complex … American regulatory regimes often enforce

the law legalistically … relationships between regulators and regulated entities are much more often adversarial" (Kagan 2001, p. 187). This has particular implications for the use of comprehensive-rational analysis, "adversarial legalism means that decisions sometimes are shaped less by rational analysis than by a panicky scramble to avoid the risks, delays, and costs of extended legally unpredictable litigation" (Kagan 2001, p. 209).

The second level on which laws affect the use of analysis is through the creation of both analytical requirements and statutory mandates for agencies to write regulations. Various laws set the context for each type of comprehensive-rational analysis. In the case of NEPA and other forms of impact analysis, the requirement to conduct the analysis is in law itself, and in the cases of NEPA and the RFA the analyses are judicially reviewable. But regulatory decisions are also made pursuant to their own statutes. Decisions regulating the quality of the air are made under the Clean Air Act; food safety decisions under the Federal Food, Drug, and Cosmetic Act; homeland security decisions are made under a wide variety of statutes. Each of these laws set out standards that agencies must follow when making regulatory decisions. These standards may be more or less open to allowing agencies to use analysis as part of their decision-making process.[9] Economists that I spoke with specifically noted that some of the cases where they had the least influence were cases where their preferred policy options were precluded by statute.

The discussions above of judicial review and participation both further highlight the influence of legal strictures on the analytical enterprise. While it is not clear whether requirements for judicial review or participation have had the impacts their proponents had forecast, the preceding chapters make clear that they have affected the use of analysis. Both judicial review and participation requirements have empowered outside groups, environmentalists in the case of NEPA and small businesses in the case of SBREFA.

Coupling judicial review and participation with analytical requirements has also had effects on the internal dynamics of the organizations subject to the analytical requirements. One effect that NEPA has produced has been the employment of, and the contracting with, large numbers of environmental experts. Another less commented upon effect came out in numerous interviews. Legal requirements for agencies empower lawyers within the agencies. The dynamic that Kagan (2001) discussed is extremely relevant. This is the case even when the analytical requirements are not subject to judicial review. Economists bemoaned the influence of lawyers and the need both for being exceptionally thorough and for not opening doors for lawsuits by potential plaintiffs. The environmental engineers I spoke with voiced the same concern.

Proponents of analytical requirements hope to empower analysts within agencies. However, they also empower lawyers (who may not need any more power). The risk aversion characteristic of bureaucracies (Downs 1967) is often reflected in their legal departments. Some of the negative trends in analysis, particularly the tendency toward excessively lengthy documents impenetrable to even the well-informed outsider, are the result, according to interview subjects, of legal advice. The type of analysis where this trend is most commented on – EISs – is the one where analysis is judicially reviewable.

Laws can also facilitate analysis, however. At the most micro level, laws can create conditions particularly conducive to analytical inputs. The case of risk assessments in the pesticide approval process is an example of this. In particular, deadlines are something of an antidote to several pathologies associated with analysis. Most obviously, analyses cannot drag on for years when an enforceable deadline exists. The incentive to produce long, detailed analyses is also counteracted when there is only a limited time in which to compile the analysis. Deadlines are explored further in Chapter 8.

The Inherent Limits of Analysis

As discussed in Chapter 1, the term "comprehensive-rational analysis" is something of a straw-man. The case studies that I have presented in the preceding chapters make clear that analysis can never be comprehensive, and whether it is rational depends to some degree on the eye of the beholder. Proponents of analysis have long fallen into the trap of advocating for something that does not and cannot exist. As a result, the performance of analysis is often evaluated against a standard that is impossible to meet.

The limitations of analysis are often poorly understood by those outside the scientific and economic disciplines. This provides an opportunity for political actors to sell their policies as supported by analytical results when the actual analysis is often far more nuanced (the "science charade" described by Wagner (1995)). It also allows analytical practitioners to bury important assumptions and present the results of their analysis with a greater degree of certainty than those results actually reflect (although I note that I found this concern only on a few occasions in my interviews, it is a common criticism of analysts).

This problem has been most thoroughly explored in the fields of analysis that have a scientific pedigree but it occurs in economic analysis as well. Throughout my interviews across the disciplines, I found humility in policy analysts. They largely recognized the limitations

inherent in the type of work they produce. Also across the disciplines, they noted a challenge in communicating these limitations (often described as communicating uncertainty) to decision-makers.

In the next chapter I will make recommendations regarding the use of analysis in policy-making (particularly in regulatory decision-making). These recommendations are all presaged by the discussion above. However, none of these recommendations can correct the inherent limitations in policy analysis. I am not going to make the foolish recommendation that we should "reform science and social science so it gives us concrete answers." Recommendations about better presenting uncertainty to the public and to decision-makers have been made repeatedly, particularly in the field of risk assessment (NRC 1994, 2009), and I have no intention of repeating them. Uncertainty is also complex, however, and there are probably limitations in simplifying it.

All of the recommendations will be informed by an understanding that analysis has its limits. And analysts and their advocates should make it a priority to ensure that everyone, particularly those considering new analytical requirements, understands those limits. The arguments about the proper role of analysis will be much more coherent and relevant with such an understanding. Rather than arguing about whether analysis can provide comprehensive and rational answers to our policy questions (and whether it should) we could argue about how best to structure analysis so that it assists democratic decision-making. I return to this theme in Chapter 9.

NOTES

1. See http://www.famous-quotes.com/author.php?aid=7325 (last accessed June 5, 2015).
2. Calvert Cliffs Coordinating Committee v. Atomic Energy Commission 449 F.2d 1109.
3. See e.g. http://www.cnn.com/2013/04/15/health/fda-warning/ (last accessed June 12, 2015).
4. Pub. L. 94-354, Stat. 1164 604.a.6.
5. Pub. L. 79-404, 60, Stat. 237.
6. See http://www.presidency.ucsb.edu/ws/?pid=43424 (last accessed June 15, 2015).
7. As I note in Chapter 4, other factors such as the separation of IRIS analysts from program offices and the personalities involved play a role in the delays in the program. That said, in my view, the political factors are the largest ones.
8. "Economists also brought an approach to issues and a way of thinking – an implicit set of values – that was foreign to many agencies and to their supporters; this economic approach could even endanger the idealism and sense of purpose on which agency morale was largely based" (Nelson 1987, p. 77).
9. In the 2015 Supreme Court Decision, Michigan v. EPA the Supreme Court required the EPA to consider costs pursuant to a statute that required the agency to consider factors that were "appropriate and necessary."

8. Using analysis to further democracy, not technocracy

My hope in studying the use of various types of comprehensive-rational analysis was both to understand how analysis has affected decisions and to recommend reforms to make analysis more effective. In Chapter 7, I covered the first of these two aims. The record of comprehensive-rational analysis, in its various forms, affecting regulatory decisions is mixed but there are consistent patterns of both successes and failures. The political climate, organizational structure, and legal requirements for analysis all play important roles in supporting or restraining the advance of policy analysis.

In this chapter, I turn to the second of my two goals, what do the case studies presented in Chapters 3–6 tell us about possible reforms to the use of analysis? Before discussing possible reforms, however, I must make the goal of possible reforms clear. My goal is not to ensure that analysis drives all public policy decisions. While I do not think there is any danger of that, the fear of a technocratic state which ignores public preferences is a prevalent one (Jenkins-Smith 1990), and should not be ignored. Any reforms to the analytic process must fit within a broader structure of democratic decision-making.

In the interest of transparency, however, I began this project with the sentiment that good analysis leads to better public policy decisions. Twelve years of teaching public policy, including five years of running a public policy master's degree program, have nurtured that sentiment. The sentiment has been reinforced by conducting the research associated with this book. I have talked to nearly 50 policy analysts of varying backgrounds. These include economists, scientists, environmental engineers, and other "experts." While they have extraordinarily diverse views on what constitutes good public policy, they have, during their careers, brought valuable insights to public policy decisions. At times, they have been listened to and at times they have been ignored. Most of them understand that part of their job is to give advice and then let decision-makers use that advice as they see fit.

The reforms suggested in this chapter are largely designed to give these analysts more of an opportunity to be heard in the public policy

decision-making process. By all means, democratically elected decision-makers and their political appointees should weigh the results of analysis as one of many factors before making decisions. The final word rests with the elected officials responsible to the public. The reforms I suggest in this chapter are designed to add to this accountability rather than diminish it. They are intended to widen participation in decision-making rather than narrow it.

This chapter goes through a series of potential reforms to the use of analysis in the policy process. I divide the reforms according to which of the significant institutions that have been discussed throughout this book (politics, bureaucracy, law, analysis itself) their implementation will most clearly depend upon. This categorization is imperfect and several reforms may depend on multiple institutions. However, I suggest that this structure provides a useful tool for presenting my proposed reforms.

In the next section, I discuss lessons from how SBREFA panels (and Environmental Impact Statements (EISs)) use analysis to empower particular groups, and how this political use of analysis can hold lessons for different contexts. I then turn to bureaucratic factors in the use of analysis and reflect upon what we have learned about the placement of analysts within the bureaucracy and the timing of analytical input. The following section describes legal devices that can be used to influence the role of analysis, including deadlines and the double-edged sword of judicial review. Finally, I conclude with a discussion of the need for simplicity in analysis, despite the fact that the questions that government agencies analyze can be hopelessly complicated.

POLITICS AND ANALYSIS: LONG-TIME ENEMIES, POTENTIAL PARTNERS

Politics and different forms of policy analysis have long been portrayed as working at cross purposes. Advocates of analysis have been accused of subverting a democratic decision-making process and replacing it with the rule of technocrats (Jenkins-Smith 1990). According to some critics of analysis, these advocates care more about delaying adverse policy outcomes than advancing analysis (Vladeck and McGarity 1995). Meanwhile, politicians have been accused of distorting analysis either directly or by influencing analysts (Williams 1998), and of using the veneer of analysis to mask (and promote) decisions that are inherently based on values or political preferences (Wagner 1995).

All of these concerns have merit. All are grounded in examples where analysis and politics were in conflict with one another. And within the

case studies, particularly those involving economics, there were further examples of politics leading to analysis being ignored, or perhaps even manipulated. But politics is not going away. In a democratic society, elected officials are naturally going to be concerned about their next election (Mayhew 1974). As long as analysis is conducted under the supervision of a political branch of government, it is going to have to fit within this constraint. And there has been no appetite (nor would I suggest there should be) for outsourcing analysis to an entity wholly independent of political influence. Such an approach would also be of dubious constitutional merit.

The experience of SBREFA panels and EISs, however, may point to a way toward using politics to advance analytical goals. In each of these cases, analysis focuses on a particular concern of interest to a powerful constituency. In the SBREFA example, small businesses are given an early look at a possible regulation and estimates of its impact on small businesses. They then have an exclusive venue (although there have been accusations that big businesses use the process toward their own ends (Center for Effective Government (2014)) in which to voice concerns and possibly influence the regulatory decision. For EISs, agencies must publish for public comment an analysis of the environmental impacts of their projects or regulations. Environmental groups have used this disclosure to identify concerns with projects that may violate other environmental statutes, and to influence agencies toward mitigating environmental concerns (Lazarus 2011).

There are numerous examples of this type of interaction between analysis and participation being effective. The SBREFA panel on occupational exposure to infectious diseases detailed in Chapter 6 led to a report on the possible regulation that was quite negative, and will undoubtedly play a role in any eventual decision on whether to regulate in this area. This panel was not atypical according to the report from the Center for Effective Government (2014). Numerous regulations have been scaled back, particularly regarding their provisions applying to small businesses, throughout the history of SBREFA.

Similarly, interview subjects noted how environmental groups used the EIS process to prevent and delay projects they opposed. On lower-profile projects, this often led to the mitigation of hazards. On higher-profile projects, such as the approval of genetically modified plants (described by one interview subject), environmental groups were able to gain White House attention and delay the approvals. The decision to deny a permit for the import of beluga whales shows the power of having an interest group invested in commenting on an analysis. In the case of both

SBREFA and EISs, there are also notable instances of failing to influence eventual decisions. But there are enough successes to merit attention.

How could the lessons of SBREFA and the participation requirements of EISs be applied more broadly? I believe there are two important components to the answer to this question.

1. Make Analysis the Focus of Public Feedback

The nexus between analysis and participation is a theme that runs through both the literature and the case studies presented here. Economists universally hailed the symbiosis, noting both that public input made their analysis stronger and that analysis informed public input. The risk assessment literature almost uniformly calls for more transparency in the discipline but the formula for successfully doing so has largely eluded practitioners. As noted above, both the EIS process and the SBREFA panels utilize participation by particularly interested groups coupled with analysis to move policy outcomes.

Coupling analysis and participation in a useful way is tricky though. You need a group of well-informed outsiders to provide input.

> An impact statement system depends on outsiders, public and private, having sufficient resources to challenge the intertwined technical and value premises of the organizations preparing the impact analysis. Yet policy areas differ in the effective pluralism of interests normally represented … The EIS process benefitted enormously from the rise of legally and scientifically well-endowed environmental interest groups. (Taylor 1984, p. 309)

While calls for participation intertwined with analysis are prevalent in the literature, and the case studies bear out some of this potential, the term participation is vague. Glucker et al. (2013) note many different objectives of participation within three categories.

1. Normative
   - 1a. Participation should influence decisions.
   - 1b. Participation should enhance democratic capacity.
   - 1c. Participation should create social learning.
   - 1d. Participation should empower marginalized groups.
2. Substantive
   - 2a. Participation should harness local information and knowledge.
   - 2b. Participation should incorporate experimental and value-based knowledge.
   - 2c. Participation should test the validity of information from other sources.

3. Instrumental
   3a. Participation should generate legitimacy.
   3b. Participation should resolve conflict.

Glucker et al. (2013) go on to point out that how participation is structured should depend on which goal(s) it is intended to achieve.

In the cases of SBREFA and the EIS, the combination of analysis and participation achieved (sometimes) Glucker et al.'s goals 1a and 2a. It may have achieved other goals too, but since the focus of this book is whether analysis affects decisions, it is toward these two ends that I consider how best to have participation inform analysis. This is not intended as an aspersion on any of the other goals considered by Glucker et al. (2013). As new requirements for analysis are considered, or old ones are refined, public participation should be an important part of the process. Early versions of the analysis should be subject to public comment both for the benefit of the public and for the benefit of the analysis. It may even be more useful to have an early analysis of a policy decision made available for public comment than the decision itself.

One of the environmental experts I spoke with in the context of researching environmental impact analysis made the following astute observation,

> EIS is not linear. It is based on a 1950–1960s linear decision-making model. After you arrive at alternatives you make a decision. That is not the way decisions are made. Right at the beginning when you are deciding the need for a project, the public engagement can influence drastically how a problem is formulated as a proposal. That is a much different decision model than contemplated for NEPA.

The interweaving of analysis and participation may not have a set formula but it is clear that the interplay between these two procedures is important.

2. Use Smaller Panels to Provide Feedback on Analysis at an Early Stage in the Decision-making Process

It is easy to be cynical about the SBREFA process. A favored constituency (small businesses) is given a privileged seat at the table as important decisions are made. That constituency then uses the process to secure changes that are in its own interest. These changes are always in a deregulatory direction. Similarly, opponents of environmentalists complain about how organized environmental groups "hijack" (the word was used by one of my interview subjects who also called some such groups

"extremists") the EIS process in order to achieve their goals (which are likely to be somewhat less self-serving than those of business owners).

At the same time, however, these instances are examples of analyses, often good analyses, playing a role in changing policy outcomes. It is not that difficult to envisage other ways in which similar panels or organized interests could be brought to bear on regulatory decisions affecting particular constituencies. Why not have a labor panel consisting of workers or unions look at the effects of proposed regulations on the labor force? How about a panel of security experts reviewing the analysis of proposed Department of Homeland Security (DHS) regulations? Citizen juries, contemplated in other contexts, could be coupled with analytical requirements to make better use of analysis (Kendall and Coote 1994). Or, a group of scientific experts could review risk assessments for potential hazards?

This last example points out a challenge in generalizing this form of participation. The National Academy of Sciences (NAS) has been used in this fashion several times to review Environmental Protection Agency (EPA) risk assessments in the IRIS program. But the NAS reviews were carried out after the risk assessments were published as official documents. It is conceivable that the criticisms voiced by NAS panels could have saved the EPA considerable time if voiced earlier in the regulatory process. It is also conceivable that this system will not work in all contexts and its application should be chosen carefully. Science advisory boards have also been used with this purpose and experienced mixed success (Jasanoff 1990). Using panels of participants also provides an alternative to notice and comment as a means of managing participation. Notice and comment has had varying results and may not be appropriate for all situations (Eckerd 2014).

"Deliberation is not a panacea for all risk problems. If done improperly, it may increase overall risk levels, lead to inefficiencies, stabilize existing power distributions and make ignorance and incompetence the guiding principles for decision-making. Deliberation may also may prolong decision-making and immobilize institutions" (Renn 2008, p. 283). The construction of a partnership between analysis and participation will be a tricky one and must be handled with care. But given the clear ways in which these two procedural mechanisms can mutually reinforce each other and the successes seen in this volume, any effort to increase the role of analysis in policy-making should include a significant participatory component, and vice versa.

BUREAUCRACY AND ANALYSIS: FOCUSING ON THE WHERE AND WHEN OF ANALYSIS

Like politics, bureaucracies have long been seen as hostile toward the increase of analytical requirements. Lindblom (1959) specifically contrasted the bureaucratic way of making decisions (the branch method) with the analytical way (the root method). His contrast was grounded in the view of bureaucracies as organizations that made decisions via satisficing. If one accepts all of Lindblom's criticisms of comprehensive-rational analysis as a decision-making tool, then the branch method has undeniable appeal.

Bureaucrats have also been seen as obstacles to analysis for reasons more centered on their tendency to guard their turf (Downs 1967) and zealously pursue their missions (Wilson 1989). Requiring an agency dedicated to protecting the environment such as the EPA, or to defending the homeland such as the DHS, to use a competing set of norms grounded in economics or science to make decisions is bound to produce a hostile response. When this requirement is coupled with a demand to analyze alternatives to the preferred policy of the agency, the incentives for the agency to ignore or undermine the analytical requirement are considerable.

Nothing simple is going to change that. But giving the people at the agency charged with implementing the analytical requirement a considerable degree of independence can help. Economists and environmental analysts (but particularly economists) emphasized the importance of their reporting structures. Numerous examples were given to me of analysts who had reported to an official besides the program office proposing a particular policy who clearly felt they could say things that analysts within the program could not. Complete independence is impossible – even the independent economists still reported to the same cabinet official. However, giving analysts who have a responsibility for analyzing policy choices as much independence as possible is critical.

The role of the Office of Information and Regulatory Affairs (OIRA) in implementing economic analysis merits discussion here. OIRA is the one analytical force that is completely independent of the agencies setting policies. As such, it provides an important voice for cost-benefit analysis. The agency economists I spoke with, however, said that the most important role that OIRA plays is as a boogeyman that they can invoke with their program offices. They frequently tell programs which want to issue new regulations something like, "If you don't let me help you, this

will never get through OIRA." Several economists mentioned using this tactic to influence program offices to drop or change policies.

OIRA is independent of the agencies, but it is not independent of the President. As an office with the dual functions of enforcing the norms of analysis and ensuring that presidential priorities are reflected in regulatory policy, OIRA holds a doubly unique role in the regulatory process. Numerous scholars have noted that the role of the supporting the President takes precedence when OIRA's two roles are in conflict (Arbuckle 2011). Still, OIRA's influence highlights the role of giving analytical responsibility to an organization (or part of an organization) independent of the program making a policy choice.

There are two important caveats to this recommendation for increased independence of analysts. The first comes from the world of risk assessment. Risk assessors work on priority setting for agencies rather than the evaluation of policy choices. As such, independence is not only not as desirable for risk assessors as for other analysts, but perhaps it is even undesirable. A generation of risk assessors were given independence because of what some contend was a serious misreading of the Red Book, the 1983 NAS report (NRC 2009). Risk assessors I spoke with agreed with the more recent report that their work was much better accomplished if they could communicate with those who would be using their work. If analysis is playing a role in agenda setting rather than policy formulation, then independence may not be the proper organizational structure.

The second caveat about analytical independence regards timing. Taylor (1984) noted a fundamental paradox regarding the independence of analysts. The more independent the analysts were, the easier it was for programs to leave them out of decisions or not include them until the decision was practically irreversible.[1] Indeed, some of the more independent economists (and one of the environmental analysts) confirmed that they fought constant battles to be involved at the early stages of agency decisions.[2] If agency analysts are to be given separate reporting structures from the program they are analyzing, they must also be guaranteed inclusion at the early stages of decisions. Bureaucratically this is admittedly a challenge.

Analysis is a process as well as a product (see NRC 2009 on risk assessment). I have focused primarily on the analytical product rather than the analytical process. In order to achieve the benefits of the analytical process, changes in the bureaucracy are necessary. In particular, the culture of an organization has to be at a minimum open to analysis, and preferably, it has to see analysis as part of its routine functions. Of the types of analysis discussed here, the only one that has

demonstrated that level of permeation into agency culture has been environmental impact analysis. And agencies are required by law to conduct environmental impact analysis. This is an example of the law affecting a bureaucratic culture (or at least some bureaucratic cultures) to the benefit of analysis.

LAW AND ANALYSIS: SETTING THE RULES OF THE GAME

When Congress passes a law it rarely uses anything approaching comprehensive-rational analysis to make decisions. Certainly it relies on estimates from the Congressional Budget Office regarding the impact of its decisions on the federal budget. And it may rely upon particular studies from scientists or economists or other experts. But there is no systematic way to ensure that when Congress has decided to solve a problem with legislation its solution is supported by analysis.

Nor should there be. Congress responds to public pressures as it was designed to do. Yet Congress, when it delegates policy-making to the executive branch, as it has done regularly over the past century, sets the terms by which agencies use analysis to make their policy decisions. Congress can prohibit agencies from considering the costs of their regulatory decisions as it did with portions of the Clean Air Act. Congress can instruct agencies how to make their decisions and in doing so leave more or less room for analysis. As examples, Congress specifies that agencies must regulate "to the extent feasible," or "protect human health with an adequate margin of safety." Or Congress can require agencies to conduct analysis as it did with the National Environmental Protection Act (NEPA) and the Regulatory Flexibility Act.

Congress can also mandate certain parameters for regulatory decisions that will affect the use of analysis. When the EPA receives a pesticide application, it must render a decision on that application within a fixed period of time. Deadlines for its decision-making have helped the EPA pesticide program rely upon risk assessments in a way that the IRIS program has been unable to do. Admittedly the political circumstances of the two programs are very different. But torpor and delay are well-known bureaucratic pathologies in the best of political circumstances (Downs 1967). A statutory deadline has helped ensure that the EPA makes optimal use of the risk assessment as it reaches its decision.

The literature on the use of deadlines in the regulatory process is sparse. One study found that deadlines on finalizing proposed rules lead to fewer regulations in the U.S. states (Shapiro and Borie-Holtz 2013).

Another looked at deadlines across the rule-making process (including deadlines on completing a regulation) and expressed concern about the possibility of a reduction in accountability when deadlines were used. The authors also found that agencies diverted resources from endeavors without a deadline to endeavors with a deadline (Gersen and O'Connell 2008). Lavertu and Yackee (2012) found that while deadlines may speed up regulations (see also Yackee and Yackee 2010), they also prompt agencies to set unrealistic expectations for when they will finish work on a rule. For example, the Aircraft Transfer Security regulation discussed in Chapter 3 was issued several years after the Congressional deadline for its promulgation.

None of the academic works looks at the effect of imposing a deadline on the use of analysis in decision-making. The pesticide example in Chapter 4 shows that deadlines can lead an agency to use analysis to make decisions without allowing those decisions to stretch out over years. Deadlines may also come with negative impacts in terms of public accountability and diversion of resources from other endeavors. They may also affect the quality of the analysis. But because one of the chief criticisms of both the regulatory process and the role of analysis in that process is long delays, Congress should consider imposing deadlines when it imposes analytical requirements.

One of the most important ways in which law influences the use of analysis is by making the contents of the analysis reviewable by courts. The case of EISs told us a great deal about making analysis judicially reviewable. But the lessons were not exactly clear. On the one hand, as described in Chapter 5, courts have overturned very few agency decisions because of an insufficient analysis (ever since the early days of NEPA when agencies refused to do an EIS and the courts told them they had to). In addition, courts are one of the culprits for the production of EISs that are thousands of pages long and are by no measure transparent.

Judicial review, however, has also helped foster a culture of environmental analysis in agencies. Examples in the literature (Taylor 1984) and in my interviews highlight cases of agencies like the U.S. Forest Service and the National Oceanic and Atmospheric Administration (NOAA) which have incorporated environmental reviews into their planning process. This is not true of all agencies (the Department of Energy (DOE) was cited as a contrary example by one interview subject) but the overall trend is encouraging. Judicial review, along with participation requirements, has also empowered environmental groups who use environmental analysis to delay projects and sometimes stop them. The

combination of requirements has also alerted environmental groups to potential violations of other environmental laws beside NEPA (Lazarus 2011).

Should analytical requirements be made judicially reviewable? The experience with EISs argues caveat emptor. It is impossible to know whether the experience with one form of comprehensive-rational analysis would translate to another. If it does, then one would expect judicial review of cost-benefit analysis to lead to analyses that are even longer and more convoluted than they are today, and to lead to courts upholding these analyses as justifying all manners of agency regulations. However, judicial review may do much to inculcate the economics mentality in agencies that have largely been hostile to this type of thinking over the past few decades. As a particularly cautionary tale, judicial review under the Regulatory Flexibility Act mirrors the negative impacts of judicial review under NEPA without copying the positive ones (Raso 2015, forthcoming).

Laws written in a particular era with a particular set of conditions in mind can affect the role of analysis in policy-making. But how these effects will manifest themselves is very unpredictable. Clearly this is the case with judicial review. As a result, I would suggest caution regarding the placement of analytical requirements in law. The one exception that I would make, based on the research for this book, is to encourage the use of deadlines on decisions (and the analysis to support those decisions). I would not go farther than that, however.

THE LIMITS OF ANALYSIS, STRIVING FOR SIMPLICITY AND TRIAL AND ERROR

The most basic criticism that Lindblom and other critics apply to comprehensive-rational analysis is that it is impossible. And as applied to analysis in its most comprehensive form, this criticism is undoubtedly true. Measuring all of the impacts of a policy change and reducing all of those impacts to a common denominator so that alternatives can be compared is a hopeless enterprise. Even if it were possible, the concern voiced by Lindblom (1959) and his heirs (McGarity 1992); that analysis would take years, thereby putting off all decisions, is clearly valid when these decisions occur in the most political of circumstances.

Advocates of analysis have fallen into the trap of touting analysis as a way of solving policy problems. "The commitment to cost-benefit analysis … should be deepened through efforts to strengthen its actual role" (Hahn and Sunstein 2002, p. 1494), and "NEPA could also use

revitalization and sharper teeth compelling environmental justifications" (Lindstrom 2000, p. 264). Even when advocates of analysis acknowledge that they support a "Ben Franklin" version of analysis (Sinden 2014), whereby analysis merely lists the major impacts of a regulation, they generally evaluate the analysis according to relatively comprehensive criteria (see Hahn and Dudley (2007), using a 79-question scale evaluating cost-benefit analysis.)

The one fault with analysis common to each type examined in this volume is the ever-growing complexity and density of analysis. While this trend is doubtlessly fed by the presence of judicial review for EISs and regulatory flexibility analyses, it is also present in the non-reviewable forms of analysis, cost-benefit analysis and risk assessment. Agencies appear to be attempting to meet an ideal of analysis that mirrors the types of analysis criticized by Lindblom and others. As a result, the process can stretch on for years and in some cases may never conclude. "Economic analysis is often subject to a rapid decline in marginal returns" (Leman and Nelson 1981, p. 101). Leman and Nelson also urge economists to be "quick and dirty" citing the experience with EISs. "Because of legal requirements and political pressure to cover everything comprehensively, rough approximations and other shortcuts are usually avoided. Such statements are crammed with exact data, but data that often prove irrelevant to the important issues and come too late to be useful" (Leman and Nelson 1981, p. 101).

If the purpose of analysis is to improve policy decisions, analyses that number in the thousands of pages are an unacceptable outcome. Complexity in analysis leads to the avoidance or the hiding of decisions and it besmirches the reputation of analysis. Those of us who care about maintaining analysis as a tool in policy-making should be advocating for a simpler form of analysis. The Ben Franklin approach described by Sinden (2014), which she argues supporters of cost-benefit analysis claim to support, should form more of a model for analytical requirements.

In a paper with Christopher Carrigan (Carrigan and Shapiro 2014), I have proposed just such a modification to the requirement for cost-benefit analysis in the regulatory process. We argue that requiring "back-of-the-envelope analysis" earlier in the regulatory process, where agencies focus on comparing realistic policy alternatives in either qualitative or roughly quantitative terms, will rescue analysis from the trend toward impenetrability and will actually help agencies make policy decisions. It will also, we believe, strengthen the relationship between analysis and participation as affected interests will see an analysis that is far more comprehensible than those they currently are confronted with.

Such analyses should of course be explicit and transparent in their assumptions (Robert and Zeckhauser 2011).

Agencies will need protection from the courts if they are to provide more rudimentary analyses. Judges generally determine whether to uphold agency actions based on whether they are "arbitrary and capricious." The risk exists that courts will view back-of-the-envelope analyses as inherently arbitrary and capricious; in order to conduct them, agencies will have to make more assumptions and necessarily gloss over considerable nuance. To avoid this, statutes that direct agencies to pursue a simpler form of analysis will have to explicitly instruct the courts not to dismiss such efforts.

While the back-of-the-envelope suggestion applies to cost-benefit analysis, a similar approach could benefit risk assessment and environmental impact assessment. Both of these forms of comprehensive-rational analysis have also been plagued by excessive complexity. EISs have something of an analogue to back-of-the-envelope analyses in environmental assessments. Environmental assessments are done first, and an EIS is then conducted – if the environmental assessment shows a significant environmental impact. However, environmental assessments can also be dense, and if there is a significant impact then the more complex EIS is required. A simpler EIS that illustrates the environmental trade-offs between different projects or policy options is not currently a legal possibility.

This lack of flexibility has created significant incentives for the mitigated Finding of No Significant Impact (FONSI). In a sense, the mitigated FONSI is another form of simplicity. It effectively allows an agency to avoid a complicated analysis by taking an action that eliminates the conditions that require that analysis. Just as the back-of-the-envelope idea could be expanded to risk assessment and environmental impact assessment, mitigated FONSIs could be expanded to cost-benefit analysis and other forms of impact analysis. Agencies could be given permission to avoid a full-blown cost-benefit analysis if they take certain measures to reduce the cost of a regulation below a certain threshold.

Another solution that some have proposed to the quagmires of regulatory policy is regulatory experimentation (Greenstone 2009). These proposals suggest that new policies be applied to a smaller population first and then expanded after they have demonstrated effectiveness. Lindblom (1968) himself suggested something similar. Such an approach would dovetail well with simpler analysis. With a smaller initial scope, analysis could be simpler as well. Then the results from the "pilot" program would form the basis of any analysis of an expansion. Obviously this works more effectively in some areas than others (it is hard to

use where the benefit of a policy is curbing a disease with a long latency period, for example), but where applicable it could work well with simpler analysis.

The movement toward more simplistic analysis and an expansion of mitigated FONSIs requires a change in mindset followed by a change in the legal regime governing analysis. Advocates of analysis have to be able to accept a half-a-loaf of analysis and opponents have to be willing to tolerate some degree of analysis and the resultant delays. Since a full loaf of analysis is conceptually impossible, and since the past 50 years have shown an inexorable trend toward more analysis, this half-a-loaf of a simpler analysis should have an attraction to both sides of the analytical divide.

CONCLUSIONS

Throughout this book, I have attempted to cast the debate over comprehensive-rational analysis in more moderate terms. Many of the analysts within the federal government tend to view their work in these terms as well. There were a few who were bitter about being ignored too often during their careers, or who held out hope that policy could be divorced from political input. Most, however, saw their jobs as economists, scientists, or environmental analysts as making small changes that improved policies. Ironically, those who have implemented comprehensive-rational analysis in the bureaucracy recognize that the changes they have most effectively wrought are incremental. I return to this theme in the concluding chapter.

The reforms that I have described in this chapter are intended to allow analysis to make these changes in policy-making more effectively. Empowering constituencies with analysis (particularly those typically omitted from the political process), structuring analysis with the proper degree of independence and ensuring its early involvement in decision-making, putting deadlines on decisions involving analysis, and making analysis simpler and therefore more transparent (and broadening the lessons of the mitigated FONSI), are all intended to help achieve this aim.

If there is one theme that runs through these reforms, it is that government should be using analysis to facilitate political decisions rather than to trump them. A 7000-page analysis (described by one of the NEPA specialists I talked with) is impressive for its size but is unlikely to affect any decision on policy. The goal of analysis should be to inform both decision-makers and the public of the consequences of agency

actions. It should allow them to look at alternative policy choices and compare them in a meaningful way. Analysis manages to do that now as numerous cases in this book attest. Hopefully these reforms can expand that reach.

NOTES

1. Leman and Nelson (1981) also note the trade-off between the objectivity that comes from keeping analysts outside the program office and the difficulty of integrating them into the process if they are outside.
2. This is not a new observation, "analysis is most useful in the early stages of policy" (Meltsner 1976, p. 280) and "the agenda-setting and adoption stages are essentially political processes … Therefore analysis has a more difficult time finding a way to insinuate itself into the dynamics of these two stages" (Radin 2013, p. 127).

9. Building better branches

I began this project when I was struck by the similarities between debates over cost-benefit analysis and environmental impact statements (EISs). In both cases, the advocates of the analysis were frustrated with the failure of the analytical requirement to achieve its goals; lower cost of regulation in the case of cost-benefit analysis, and deterrence of projects with harmful effects on the environment in the case of EISs. And in both cases, the opponents of analysis were just as frustrated that decisions they favored (regulations protecting the environment in one case, and projects with economic gain in the other) were delayed because of the need to carry out the analysis. Making the similarities more striking was the fact that the same interests that favored EISs, opposed cost-benefit analysis, and vice versa.

I find it easy to be sympathetic to both ends of the debate on the role of comprehensive forms of analysis in regulation (and in policy-making more broadly). I have often encountered individuals unfamiliar with the regulatory process who wonder why government can't just analyze the impacts of its decisions before making them. This desire for a process that involves careful examination of consequences is quite intuitive. This is particularly true in cases where the impact of the decisions is likely to be large, and the decisions are (seemingly) made by unelected officials. Greater analysis would give people confidence that bureaucratic agencies have considered the welfare of all those who will be affected by their actions.

On the other hand, as a social scientist myself, I know very well that most complicated questions do not have clear answers. It is easy to jump down the proverbial rabbit hole in pursuit of a clear answer to a question that does not have one. The fact that many of those pursuing analytical requirements are the same parties that disagree with the potential actions of the federal agencies cannot help but breed cynicism. Perhaps that rabbit hole is exactly where these advocates want agencies to end up. Endless analysis is a preferable outcome to regulations that impose high costs on opponents of regulation or projects that damage the environment.

But with 35 years of analysis in the regulatory process (and 45 years of National Environmental Policy Act (NEPA) analysis on all government actions), surely we can move beyond an all-or-nothing approach when we debate analysis. In fact, perhaps we can largely concede the basic frameworks of both sides of the analytical divide. Analysis makes decisions harder, and the more comprehensive we want the analysis to be, the harder it will be for regulatory agencies to make decisions. Analysis also makes decisions better, and the more comprehensive the analysis, the better the decisions will be. But there is a declining marginal utility of analysis where the improvement in the policy decision is not worth the additional time and effort (Leman and Nelson 1981).

So the question in structuring requirements for analysis should be: how do we reach the point where the declining marginal utility of analysis sets in? The first goal of this book was to figure out when analysis helped make decisions and when it didn't. That inevitably involved examination of the roles of politics, bureaucracy, law, and the limits of analysis itself. The second goal was to suggest reforms so that regulatory (and perhaps all policy) decisions would be informed by something approaching the "right" amount of analysis. In thinking about the answers to these two questions, I kept coming back to where we started, the root and branch methods of making decisions.

BRANCHES AND ROOTS: ONE MORE TIME

In Chapter 1, I discussed Lindblom's two modes of bureaucratic decision-making. Comprehensive-rational analysis was described as the root method. In the root method, agencies pore through every possible policy alternative and measure the consequences of each. They then choose the policy alternative that maximizes social welfare (or satisfies some alternative criterion). In the branch method, agencies immediately discard impractical alternatives and compare practical choices along a limited number of dimensions. They stop the process when they find a policy choice that satisfies some minimum set of criteria.

Lindblom argues that the branch method is superior. After conducting the research presented here, I agree with him. There is an important caveat, however, that is forgotten all too often in debates over comprehensive-rational analysis. We do not need to move bureaucratic policy-making all the way to the root method in order to improve upon the branch method. In fact, there are many ways in which analysis has already improved policy-making without being anywhere near the root method described by Lindblom.

In a sense, those of us engaged in the policy analysis profession have been ill-served by our own over-promising of the benefits of analysis. When we argue that analysis, in any of the forms described in this book, will help decision-makers optimize, maximize, render efficient, minimize the impacts of, or rationalize public policy, we set it up for failure. If it is given these goals, analysis can never and will never fulfill them.

In part this is because of the limitations that Lindblom described. Herbert Simon argued that humans do not make decisions rationally, they satisfice. In the years since Simon, many more scholars, particularly those in the field of behavioral economics, have expanded upon this limitation on human cognition (see e.g. Kahneman 2011). If humans are unable to comprehensively analyze different options, bureaucratic organizations may be even less able to do so (Bendor 1995). Analysis will not be able to answer policy questions concretely in a finite amount of time. "Talmudic debate is splendid for training the mind and deep exegesis is appropriate for Supreme Court opinions … But neither of these methods is feasible or appropriate for addressing a vast number of and broad array of policy decisions on a timely basis" (Robert and Zeckhauser 2011, p. 630).

Even if perfect analysis were possible, placing analysis within a democratic law-bound system of decision-making ensures its ultimate failure. While many feared that analysis would subvert politics, the relevant question is whether politics has subverted analysis (Jenkins-Smith 1990). "When the stakes are high enough, no committee of experts, however credentialed, can muster enough authority to end the dispute on scientific grounds" (Jasanoff 1990, p. 234). In a democratic system of government, politics must subvert analysis, at least to some degree. The fact that analysis is also constrained by legal limitations imposed by democratically elected officials, and by bureaucratic pathologies inevitable to large organizations, also limits its potential.

Therefore both sides of the analytical divide are doomed to be correct. Analysis will never achieve the goals of optimally efficient policy, rational priority setting, nor of minimizing the impact of a policy on the environment or small businesses. Without the recognition that these goals are unachievable, debates over analytical questions on a policy issue will stretch out over long periods of time as competing interests duel over any of the millions of components of a comprehensive analysis. The IRIS program reflects this phenomenon very well.

But what if we recognized that we shouldn't pursue comprehensive-rational analysis much as we shouldn't pursue the Loch Ness Monster? Both are mythical apparitions that we will never catch. Instead, we should set our sights on improving decisions incrementally through the

use of analysis. Lindblom argued that policy changes incrementally (initiating a generation of academic debate over the premise that I will not review here). If it does change incrementally (or even if it doesn't) can these changes be improved by smart transparent analysis of the policy choices at hand?

In order to structure analysis so that it can contribute more to the policy-making process, we must keep in mind the two things that make truly comprehensive-rational analysis impossible. The design of analytical requirements must take into account the limitations on human and bureaucratic cognition (and hence the limits on analysis itself). Analytical requirements also need to be set up so that they work with politics, bureaucracy, and law, rather than working against them.

The reforms suggested in Chapter 8 are all intended to fulfill these criteria. Analytical requirements should be partnered with the participation of outside parties. Ideally, this partnership should be structured in such a way that there is a constituency which has an interest in seeing the analysis done well. Impact analyses can meet this criterion as shown by some of the experiences with panels of small businesses and the use of EISs by environmental groups. Most impact statements fail to make a difference, however. Those that work, consciously empower small businesses and environmental groups by giving them (or making it easy for them to force their way to) a seat at the table. Merely directing agencies to analyze particular impacts is insufficient.

Analysis should also be placed within (or outside of) bureaucratic organizations as befits the goal of the analysis. If, as is often the case, analysis is intended to evaluate policy solutions to a potential problem, then analysts need to be independent of the agency officials deciding on the solution. That independence could be within the policy-making organization but through a different reporting structure. Or it could be outside the organization altogether, as is the case with the Office of Information and Regulatory Affairs. In either case, however, independence should not mean that the analysts are brought into the decision-making process after a policy option is selected. Being present when options are discussed is critical.

Throughout the cases it became clear that the two most serious pathologies associated with analysis are impenetrable analyses and years of delay. The legal structuring of analytical requirements has the potential to deal with both of these concerns. Deadlines and requirements for earlier and simpler analysis both would push agencies away from using analysis to obscure and delay decisions rather than facilitate them. The enforcement of deadlines and simplicity (especially in light of the arbitrary and capricious standard) is not a trivial enterprise. But holding

agencies responsible for carrying out their analyses quickly and in a transparent manner holds tremendous promise for public policy-making.

All of these reforms, in addition to working with institutions that are permanent parts of the U.S. policy-making framework, also have the virtue of modesty. Too much of the debate over comprehensive-rational analysis has focused on the idea that, if done correctly, analysis can solve our policy problems. It can't. What it can do is improve policy decisions. If advocates of analysis lower their expectations (and their rhetoric) about the potential accomplishments of different forms of analysis, they may find that analysis has accomplished a great deal and has the potential to accomplish even more. Structured wisely, analytical requirements may even gain the support of traditional opponents.

CONCLUSIONS

Ironically, the desire to have government solve problems through regulatory interventions and the desire to optimize policy choices by comprehensive-rational analysis may have common origins. Some trace the roots of both back to the Progressive Era, when the idea that there were "right" answers to social problems was at its peak (Nelson 1987). Both the use of regulation as a policy tool and the use of more comprehensive-rational analysis to evaluate policy choices gained prominence in the 1960s. Over the course of the 1970s, however, these two forces began to come into opposition with one another.

Lindblom presaged this conflict when he detailed the faults with comprehensive-rational analysis. The "root" method as described by Lindblom was inevitably going to engender the opposition of those who favored government action to deal with what were seen as pressing societal problems. Meanwhile, opponents of government action adopted analysis as a way to deter regulatory actions by government agencies (Eisner 2000). Thus, analysis became cast as an absolute both by its supporters and its opponents. Only recently have a few scholars stepped back from this divide (Revesz and Livermore 2008).

When one looks at how analysis actually functions in the bureaucracy, however, one sees a much more nuanced picture. Analysts, whether they are scientists, economists, or environmental experts, generally understand the limitations both of their practice and their ability to influence policy. While some chafe at these limitations, many accept them as the price of being part of a democratic decision-making process. Most have ideas about how to better utilize the work they do day in and day out as civil servants or contractors.

None of these ideas involves making analysis truly comprehensive or anything approaching the root method that Lindblom describes. What they (and the ideas proposed in this book) do involve is making the alternative espoused by Lindblom – the branch method – work better. The increasing complexity of society and social problems has necessitated the delegation of answering important policy questions to the unelected bureaucracy. While the branch method of bureaucratic decision-making has its advantages, it also has considerable room for improvement. Using analysis to build better branches can help us to reach better policy decisions.

Appendix: questions for interview subjects

INTERVIEWS WITH ECONOMISTS FOR CHAPTER 3

1. How long have you worked at [Fill in Agency name]?
2. What are your current job responsibilities?
3. How long have you had these responsibilities?
4. How many [Cost-benefit, environmental impact, risk assessment, regulatory flexibility] analyses have you conducted for [Agency name] regulations?
5. When in the agency policy-making process are you brought in? Does this vary?
6. What is the most recent one you have worked on (could be current)?
7. Do you feel as if that analysis made a difference in the agency policy decision?
8. Why or why not?
9. Now I would like to ask you to describe a [Agency] regulation where the policy decision was affected by your analysis.
10. Probe for details.
11. Was there anything special about that regulation or that analysis that allowed it to play a more significant role than is typical?
12. Who else do you suggest I talk to, to learn more about this regulation?
13. Finally, I would like to ask you to describe a [Agency] regulation where the policy decision was not affected by your analysis.
14. Probe for details.
15. Was there anything special about that regulation or that analysis that led to it playing less of a role than is typical?
16. Who else do you suggest I talk to, to learn more about this regulation?
17. How would you reform your agency's decision-making process to get [Type of analysis] to play more of a role?
18. Is there anyone else at your agency that you haven't already

mentioned that I should talk to about the role of [Type of analysis] at [Agency]?

Thank you for your time.

INTERVIEWS WITH RISK ASSESSORS FOR CHAPTER 4

Replace questions 5–8 (above) with these three questions:

5. The literature on risk assessment (Red Book) talks about the separation between risk assessment and policy making. In your experience, is this separation real?
6. How is risk assessment structured at your agency (who does it and what is their connection to regulatory decisions)?
7. To what degree have you felt that policy considerations affected decisions about how to do a risk assessment?

INTERVIEWS WITH ENVIRONMENTAL IMPACT ANALYSTS FOR CHAPTER 5

Replace questions 5–8 (from Chapter 3 above) with the following three questions:

5. How is environmental impact assessment structured at your agency (who does it and what is their connection to regulatory or project decisions)?
6. The literature on EISs emphasizes the interaction between the analysis and participation of the public. Have the EISs spurred useful participation from outside the government?
7. To what degree have you felt that judicial review affected decisions about how to perform an environmental impact assessment?

Also modified questions 9–16 to refer to projects as well as regulations.

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