



IMPROVING THE REGULATORY PROCESS

**WRITTEN TESTIMONY OF
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**“RAISING THE AGENCIES GRADES—PROTECTING THE ECONOMY, ASSURING
REGULATORY QUALITY AND IMPROVING ASSESSMENTS OF REGULATORY NEEDS”**

**SUBCOMMITTEE ON COURTS, COMMERCIAL AND ADMINISTRATIVE LAW
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Committee on the Judiciary
Subcommittee on Courts, Commercial, and Administrative Law
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Mr. Chairman and Members of the Committee:

Thank you for the invitation to testify today on the “Raising the Agencies Grades—protecting the economy, assuring regulatory quality and improving assessments of regulatory needs.” I am an economist and the director of policy studies at the Mercatus Center, a 501(c) (3) research, educational, and outreach organization affiliated with George Mason University. For over three decades, I have been involved in rulemaking and regulatory analysis, first as a regulatory analyst then senior manager at the Center for Food Safety and Applied Nutrition (CFSAN) at the Food and Drug Administration (FDA). I also worked for a short time in the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) reviewing rules from other agencies.

The United States has a large regulatory system that is producing regulations at a fantastic rate. Each year, the Federal Register publishes nearly 80,000 pages, the equivalent of 400 novels, that announce new regulations. The result of this publication is the production of over 4,000 regulations per year.

The regulatory system is large, but regulations are largely produced in the dark. In many cases, regulators don't even know if there is a problem that needs to be solved, much less the best way to solve a potential problem. They don't know if the public thinks there is a problem. They don't know if the public has better solutions for any potential problem.

They don't know, because it's not in the agencies' interests to know. If an agency were to determine through regulatory analysis that there is no problem or that a method other than federal regulation will solve the problem, what's its reward? Agencies are not rewarded, either with budgets or political support, for not passing regulations. They are rewarded for producing them. Further, they are rarely excoriated for

producing unnecessary or ineffective rules, but they are frequently taken to task when the slightest problem manifests itself in any area under their jurisdiction for failure to regulate or enforce.

Because of the incentives they face, agencies make decisions to regulate before any evidence that might suggest regulations are not needed. They do so purposely with little—if any—input from stakeholders or internal analysis. This means that much of the regulatory process mandated by the Administrative Procedures Act is a farce in terms of the intent of that Act. According to Senator Pat McCarran, then Chairman of the Committee on the Judiciary in 1946, the APA was intended to be a “widely heralded advance in democratic government.”¹

Our institutions, including our Executive Orders and all of our existing regulatory procedural laws, have brought us to this point, and only a change in our regulatory institutions will change the outcomes. Our goal ought to be fewer, more targeted, and more effective regulations that solve real problems.

WHAT ACTUALLY HAPPENS

At FDA, the informal rulemaking process begins with new legislation, a petition, or an internal push to create a new regulation. Following that, a senior program manager typically makes a preliminary decision about the regulation and then holds a meeting to let everyone know what that decision is. Discussion of whether there is a problem and whether federal regulation is the best way to solve that problem is “off the table.” That is, there is no discussion of whether or not a regulation is required. There is also no discussion as to whether there is a failure of the market or some other reason for regulatory intervention; whether the market will solve the problem in the near future without intervention (baseline analysis); or if there is a need for federal, as opposed to some other level of government, intervention. These are issues that are typically covered in the regulatory impact analysis. But that analysis is generally begun after the decision on how to regulate has been announced. That is a key part of the problem: the regulatory analysis analyzes a decision, not a problem.

One key part of the analysis that would be extremely helpful if done before a decision is a baseline analysis. Usually by the time the government has discovered a problem, the market is also moving to solve the problem. In the baseline analysis, economists will not just describe the state of the world as it is today, but what is likely to happen given the incentives created by the market.² Baseline analysis will describe how both knowledge and practices are likely to change for both producers and consumers in the near future in the absence of a regulation. So, for example, if there is an outbreak of food borne disease tied to a particular producer of a canned vegetable, then the producer’s sales will drop, its stock price will drop, and it will face court challenges. Other producers of that canned vegetable will examine their own plants to see if they if they can avoid similar problems because it is in their best interest to do so. If, for some reason, these incentives were missing, and there were repeated problems over time (i.e., systemic problems) with known solutions, then a regulation might help. A baseline analysis can help to sort out which problems are systemic and which ones are one-time problems that markets will solve.

¹ Robert Boyd, “A Hearing Examiner Comments on the APA and the Rule Making or Adjudication Controversy,” *William and Mary Law Review* 11, 2 (1960), <http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=2796&context=wmlr&sei-redir=1#search=legislative+history+testimony+administrative+procedures+act+1946>.

² Market failures are often market opportunities for entrepreneurs who will seek to profit by finding and marketing remedies for those problems.

As the decision moves up the chain, more senior managers will typically ask questions about any potential political opposition they are likely to encounter. Discussion of regulatory options, which are often only about minor adjustments, occurs much later in the process, but it is rare for any major change from the early decision.

OPACITY NOT TRANSPARENCY

Federal agencies are contained in their own little microcosm. They need the vast supply of knowledge that comes from stakeholders. As the Administrator of OIRA Cass Sunstein says, “Government should actively solicit expertise from outside Washington so that it makes policies with the benefit of the best information.”³ But agencies do not seek stakeholder input, particularly stakeholder input that might suggest that no regulation is needed when “making policies.” This is not surprising. There is no incentive for them to do so.

The incentives that exist in the current system to take contrary stakeholder opinions into account are, at best, weak, and they don’t even apply until late in the rulemaking process. Most regulations today are passed by what is known as informal rulemaking, also known as notice and comment. Federal laws that gave us notice and comment have also made federal documents and meetings available to all stakeholders. But that access and transparency do not equate to having equal ability to influence rules. In informal rulemaking, agencies are required to respond to comments made to proposals. But too often responding to contrary arguments means dismissing them swiftly and easily. This doesn’t mean that no stakeholders have influence over the early decisions. Generally, those that have petitioned for and favor regulations are heard from early in the process to help shape the initial decisions.

In a rule on seafood processing that I worked on at FDA, the vast majority of commenters to the proposal disagreed with FDA’s approach. But the summary in the final rule said that “some people agree and some people disagree.” A common dismissal that rule writers use is the commenter did not provide “sufficient evidence to alter the agencies conclusion.” A simpler one is just that “the agency disagrees with the commenter.” Having leapt the low hurdle, the agency proceeds to steamroll the decision made early on in the process.

A REAL SYSTEMIC PROBLEM

For virtually my entire career at FDA, I worked to improve the Center for Food Safety and Applied Nutrition’s (CFSAN) regulatory analysis to produce better, more informed rules. At one point, I designed a Standard Operating Procedure (SOP) for use in the development of new regulations. In its simplest form, the SOP sought to ensure that the agency would define the problem, identify the options for solving it, and conduct all the relevant analyses (e.g., scientific, economic, and legal) before initiating new rulemaking.

The SOP was included in a lengthy code of practices that was supposed to determine how regulations would be developed in CFSAN. However, once it was developed, agency program managers essentially ignored it by continuing to make decisions first and then starting the regulatory process. By making

³ Cass Sunstein, “The Power of Open Government” (speech, The Brookings Institution, Washington, DC, March 10, 2010) http://www.whitehouse.gov/omb/oira_speech_03102010/.

decisions first, the more basic questions about defining the problem, whether or not we actually needed a regulation, and a discussion of the options were completely precluded.

Curious as to whether other economists working in the health, safety and environmental areas had agencies similar to mine, I interviewed senior economists in all of the health, safety, environmental, and security agencies for information on how they conducted their respective regulatory processes and how policy makers used their analysis.⁴ The findings indicated that policy makers use regulatory analysis as a means to justify a pre-determined course of action, not a tool for problem-solving.

- 1) Agency policy makers commonly make decisions well prior to the completion of the regulatory analysis.
- 2) Agency managers often discourage comprehensive, quality economic analysis. As one economist put it, “I think it would have an immense difference if we were allowed to do good regulatory analysis.”⁵
- 3) Some economists noted that their agencies often did not define the problem.
- 4) Another economist noted that agency policy makers “foreclose any discussion of meaningful options [for solving a problem] at a pretty early stage.”⁶ Another said, “We do what we always do: just trotting out the same old thing. That’s why we don’t come up with better regulations; we just come up with the same regulations in different areas.” Another described the atmosphere for those who try and talk about regulatory options as “oppressive.”
- 5) Because they decide the course early in the process, agency policy makers put a lot of pressure on economists to come up with the “right” answer, one that justifies their premature decisions. The pressure works because the economists are organizationally under the people making the decisions. This is an enormous problem for federal regulatory economists. Within agency bureaucracies, pointing out potential flaws in one’s superior’s decision rarely helps the course of one’s career.

INCENTIVES

These findings are not unexpected. Scholarly research evaluates and analyzes the incentives that drive agencies to produce regulations. And, to the best of my knowledge, there are no theories that hypothesize that there are incentives for agencies not to regulate.

Some examples of the theories of regulation include public interest theories that generally point to market failures and assume that governments can correct market problems (without any problems with the

⁴ Richard A. Williams, “The Influence of Regulatory Economists in Federal Health and Safety Agencies” (working paper, Mercatus Center at George Mason University, Arlington, 2008)
http://mercatus.org/sites/default/files/publication/WP0815_Regulatory%20Economists.pdf.

⁵ Ibid.

⁶ Ibid.

operation of government).⁷ The “capture theory” suggests that industries will “capture” the agencies that regulate them, causing the agencies to produce regulations that benefit those industries. Industries are able to do this because the benefits of the regulation go to concentrated industries that can launch an effective lobbying campaign whereas the cost are spread out to a broad, a diffuse group, typically consumers. Dr. Bruce Yandle of Clemson University takes this idea a step further with his theory of “Bootleggers and Baptists.”⁸ This theory suggests that industries will tacitly join with activists seeking to advance a cause and align their interests to create regulation. For example, environmental activists may find an unexpected regulatory ally in the fight for clean air in a firm that sells smokestack scrubbers.

Private-interest theories hypothesize that politicians and bureaucrats are self interested and pass laws and regulations to reward themselves. It is certainly true that both agencies and bureaucrats within agencies have their own goals. Bureaucrats desire “salary, perquisites of the office, public reputation, power, patronage, ease of managing the bureau, and ease of making changes” and all areas are “positive monotonic function of the total budget of the bureau.”⁹ As one writer puts it, “Despite the absence of any obvious increase in social product on its part, the bureaucracy shows an insatiable appetite for consuming an increasing share of resources over time.”¹⁰ In fact, as another writer points out, “Budgets... are a recurring and pervasive need; indeed, they are often the ‘bottom line’ in the matter of survival.”¹¹

In all cases, there is an absence of incentives to use rational analysis based on exterior incentives such as is found in the private sector. In private firms, there is a reason to control costs and target specific markets. Businesses have an instantaneous feedback from the market, the effect on profits of poor decisions. For example, if costs are excessive, then revenue will not cover costs or generate a profit. Similarly, if marketing targets consumers or firms who are unlikely to buy the product, then costs will again exceed the revenue generated from those efforts. If a firm does not make a profit or cover its costs, it goes out of business.

Regulatory agencies do not have a similar feedback mechanism to help distinguish well-informed decision making from pre-determined decision making. Without feedback, there isn’t sufficient incentive to ensure that decisions are made after stakeholder input and rigorous analysis of the need for and consequences of regulation.

ALTERING INCENTIVES

Changing the incentives so that agencies regulate only when there is a systemic, significant problem that will not solve itself and needs to be addressed at the federal level will require major structural changes in the institutions that govern and reward agencies. One thing that will make a difference immediately is to decouple the agency’s decision from both early analysis of and democratic input into a problem. That is,

⁷ See, for example, Johan den Hertog, “General Theories of Regulation,” 224, <http://www.scribd.com/doc/239491/General-Theories-of-Regulation>.

⁸ Bruce Yandle, “Bootleggers and Baptists—The Education of a Regulatory Economist,” *Regulation* (May/June 1983): 12–16.

⁹ William A. Niskanen, “Nonmarket Decision Making, the Peculiar Economics of Bureaucracy,” *The American Economic Review* 58 (1968): 293–4. The hypothesis is challenged in Ronald N. Johnson and G. Libecap, “Agency Growth, Salaries and the Protected Bureaucrat,” *Economic Inquiry*, 27 (1989).

¹⁰ Daniel K. Benjamin, “A Users Guide to the Regulatory Bureaucracy,” in *Regulation and the Reagan Era*, eds. Roger E. Meines and Bruce Yandle (New York: Holmes and Meirs, 1989), 253.

¹¹ Paul J. Quirk, *Industry Influence in Federal Regulatory Agencies* (Princeton: Princeton University Press, 1981), 96.

initially, agencies should perform regulatory analysis and make that analysis available for public comment. There should be no discussion of the agency's preferred solutions in this document.

Specifically, this document should contain:

- 1) A clear definition of the problem that the agency seeks to solve and the evidence it relied on to define the problem. An agency could not satisfy this requirement by simply stating that it is issuing a rule in order to satisfy an enabling statute. Instead it must specify the contours of a significant, systemic problem and the evidence it used to identify those contours. If the problem involves risk, a risk assessment should be provided.
- 2) An explanation of and evidence for why a federal solution is required for this problem including:
 - i) Is the problem a failure of the market or other significant problem?
 - ii) Is it a large enough problem to warrant a federal solution, particularly given other priorities?
 - iii) Is it a problem better solved at the state or local level?
 - iv) Will normal market forces solve the problem within the relevant timeframe? The answer to this question comes from the above-described baseline analysis.
- 3) The possible ways to solve the problem. One answer may be to gather more information particularly if there are no solutions that are effective or cost-beneficial. Options generated should be broad including, for example, providing or requiring information, providing guidance, establishing performance objectives, and technology-based standards (command and control). Alternatives can also include levels of stringency, covering different sectors of the economy, different time frames for compliance, exemptions for certain sizes of firms, encouraging industry-established standards, or enhancing liability laws.
- 4) A preliminary estimate of the benefits and costs of each of the options listed.

All of this analysis should be of a regulatory problem, not a regulatory decision. This pre-proposal document should make all data and assumptions available to the public, and the agency should request public comments on all parts of the document. This publication would serve several purposes. First, it would make the agency's analysis and data transparent to interested parties and the public. Second, it would provide interested parties and the public with an opportunity to evaluate the agency's data and research and contribute data and information that the agency may not have identified. Third, it would reinforce the agency's focus on problem-solving rather than the narrower activity of promulgating regulation.

CONCLUSION

As an earlier Congressional testimony noted, "Often what occurs before a notice of proposed rulemaking has been published produces commitments that, in the words of President George H.W. Bush's General Counsel at the EPA, convert notice and comment rulemaking into a form of Kabuki theater—a highly stylized process for displaying in a formal way the essence of something which in real life takes place in other venues."¹²

¹² Subcommittee on Courts, Commercial and Administrative Law Committee, *The APA at 65—Is Reform Needed to Create Jobs, Promote Economic Growth, and Reduce Costs? Hearing before the Committee on the Judiciary, United States House of Representatives*, 112th Cong., 1st sess. (February 28, 2011).

Regulation though isn't a theatrical performance. Regulatory agencies, by virtue of their extensive reach into every aspect of American life, have become big business, and they are not well run. Decisions are made with minimal democratic input and analysis of whether or not regulations are necessary. Decisions are made this way because the institutions that govern agencies rulemaking create incentives to do so. If we change the institutions, we will get fewer, more effective, and more targeted regulations that will help to solve our serious social problems.