

Beyond Process Excellence: Toward Enhancing Societal Wellbeing

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Draft Paper Prepared for Discussion at the
University of Pennsylvania conference on “Regulatory Excellence”

Penn Program on Regulation

March 19-20, 2015

University of Pennsylvania Law School

Executive Summary

Regulatory excellence is often defined primarily or exclusively by reference to procedural metrics that have been championed by the field of administrative law: opportunities for public comment, including an obligation for the regulator to respond to comments; avenues for formal stakeholder input and negotiation; transparency about the rationales for decision making; adherence to the letter and intent of the statutes that authorize and constrain the regulator’s authority; and opportunities for judicial review when stakeholders are injured by regulatory action. We argue that procedural metrics of excellence should be understood as minimums, and that the primary criterion for regulatory excellence should be societal wellbeing. We perform case studies at multiple federal agencies that illustrate success and failure in the design of regulations to achieve wellbeing. Two principal obstacles are identified to a stronger regulatory focus on societal wellbeing: interest-group politics and presidential electoral politics. Reforms are suggested to strengthen the voice of societal wellbeing, including a statutory requirement for benefit-cost reasoning subject to judicial review to ensure regulations do more good than harm.

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...High-Quality Scientific and Technical Information

In order for a regulatory system to achieve excellence, regulators need access to the best available scientific and technical information, including objective and unbiased interpretation of that information. Close coordination between scientists and regulators is necessary to achieve well-designed regulations.⁹ In a regulatory system where interest group and presidential-politics are dominant concerns, the quest for high-quality scientific and technical information may become a secondary concern.

The federal government has substantial technical resources to assist in estimating the physical consequences of regulatory alternatives. Unfortunately, the best available expertise is not necessarily located in the federal agency with the statutory authority to regulate. For example, when there was public concern about “sudden acceleration” in Toyota cars, the National Highway Traffic Safety Administration (NHTSA) of the Department of Transportation (DOT) realized that there were technical issues that were best addressed by another federal agency, the National

Aeronautics and Space Administration. When the Environmental Protection Agency (EPA) regulates the energy industry, agency professionals sometimes seek (or resist) the technical contributions from analysts at the Department of Energy (DOE), as DOE may be best positioned to deploy appropriate expertise on some questions. In the field of chemical risk assessment, DOE, the Department of Defense, and the Food and Drug Administration (FDA) have argued in various cases that EPA has not made proper use of the best available science, and in some cases the National Research Council of the National Academy of Sciences has concurred with the criticism of EPA.¹⁰

On the science issues in regulation, judicial deference to agency expertise does not recognize the complexity of the federal government. Federal courts extend deference on technical issues to the federal agency with the relevant statutory authority rather than to the federal agency with the best expertise on the issue. Moreover, current regulatory procedures do not always require or encourage the agency with regulatory authority to give emphasis to – or even consult with – the agency with the best access to relevant data and expertise. The White House – practicing a unitary theory of the Executive Branch -- typically discourages one agency from making public criticisms of the technical work of another agency. **A more promising approach is to seek advice on – or peer review of regulatory science by qualified experts organized by objective institutions that are separate from the regulatory body.**¹¹ Thus, one cannot have great confidence that the first step in the wellbeing criterion – projecting the physical consequences of regulation – are handled with excellence under current procedures. (pp. 4-5)

Regulators face even more difficulty using scientific and technical information submitted by regulated entities in the private sector, even when it is the most relevant and authoritative, since regulatory procedures sometimes treat scientists and engineers in regulated entities as if they were more biased than experts in academia, think tanks, consulting firms, or the government. There is no compelling evidence to support such a general claim of bias, especially when information-quality requirements are applied to influential data (e.g., replicability of experiments and transparency of models). **The U.S. Office of Management and Budget (OMB) has issued guidelines on information quality and peer review, but those guidelines are not typically seen as enforceable in federal court.**¹²

Looking forward, regulatory excellence requires an appreciation of how to make sound decisions when the scientific and technical information is uncertain, but when there is a cost (or risk) of waiting for improved scientific information.¹³ **The value-of information (VOI) framework, a close cousin of benefit-cost analysis, is well suited to addressing this pervasive dilemma, but it is rarely utilized by regulatory agencies. The VOI stance provides a more promising framework for harmonizing U.S. and European regulations than does uneven application of a subjective precautionary principle.**¹⁴

12 But see Lawrence A Kogan. Revitalizing the Information Quality Act as a Procedural Cure for Unsound Regulatory Science: A Greenhouse Gas Rulemaking Case Study. Washington Legal Foundation. Critical Legal Issues Working Paper Series Number 191. Washington Legal Foundation. February 2015.

¹³ Howard Raiffa. Decision Analysis: Introductory Lectures on Choices Under Uncertainty. Addison Wesley, 1970; Robert T Clemen. Making Hard Decisions: An Introduction to Decision Analysis. Second Edition. Brooks/Cole Publishing Company. 1996.

¹⁴ For a real-world view on how Europe and the USA differ on science-based regulation, see Jonathan B Wiener, Michael D Rogers, James K Hammitt, Peter H Sand (eds). The Reality of Precaution: Comparing Risk Regulation in the United States and Europe. Resources for the Future Press. Washington, DC. 2011. (pp. 5-6)