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My name is John D. Graham. I am Dean of the School of Public and Environmental Affairs, Indiana University (Bloomington and Indianapolis). From 2001 to 2006 I served as the Senateconfirmed Administrator, Office of Information and Regulatory Affairs (OIRA), US Office of Management and Budget (OMB). Prior to serving at OMB, I was the founding Director of the Center for Risk Analysis at the Harvard School of Public Health (1990-2001). I have published ten books and hundreds of articles on topics related to regulatory reform, especially on topics related to health, safety, and environmental regulation. I earned my BA in economics and politics from Wake Forest University, my Master's degree in public affairs from Duke University, and my Ph.D. in public affairs from Carnegie-Mellon University. My doctoral dissertation was one of the early analyses of the benefits and costs of the automobile airbag.

My testimony today addresses a classic issue in health, safety and environmental regulation: whether a regulation should prescribe certain technologies, designs, practices and/or behaviors ("prescriptive standards") or whether a regulation should compel achievement of a particular type and level of performance ("performance standards"), leaving the choice of compliance strategies to the discretion of the regulated entity (the "regulatee") (Coglianese et al, 2002). Since the 1970s, when the law and economics literatures made a strong case for a focus on performance (Breyer, 1982), regulatory practice has shifted away from prescriptive rules toward performance-oriented standards, but the trend is faster in some fields of practice than in others. The trend toward performance-based approaches to regulation began in the United States but is now a global trend (Shapiro, 2013). In the diverse world of transportation regulation, regulatory practices vary considerably, not just between agencies but from regulation to regulation.

The Case for Performance Standards

Performance standards have several advantages over prescriptive standards (Mannan, 2012). I offer a concrete illustration of each advantage below.

First, a performance standard tends to be less costly to the regulatee because the regulatee has the flexibility and the incentive to find the least-cost method(s) of compliance. Under the Clean Air Act, EPA shifted from a mandate of pollution-control equipment (e.g., scrubbers) to numeric emission limitations on powerplants. When given the flexibility of a sulphur-dioxide emission limitation (instead of a prescriptive standard), some owners of powerplants found that it was less

costly to shift from high-sulfur to low-sulfur coal than to install expensive and energyconsuming scrubbers.

Second, a performance standard is more receptive to industrial innovation because the standard is not written to mandate certain technologies, designs, practices and/or behaviors. When a prescriptive standard requires that safety be accomplished by human labor, it discourages industry investment in labor-saving technologies that achieve the same safety outcome without human labor. Given the possible future of safer, driverless cars, it may be unwise for NHTSA to craft prescriptive regulations that presume that a licensed human being is driving the vehicle. A similar issue arises in freight safety regarding the optimal number of crew in the cab and the prospect of future implementation of automatic speed control technologies.

Finally, opportunities for "rent-seeking" (the inappropriate use of regulatory power to benefit some technologies/firms over others) may be curtailed when standards are defined objectively in terms of performance. If a regulator is permitted or inclined to prescribe specific technologies, there will be a temptation on the part of suppliers of safety equipment to lobby the regulator in ways that ensure that their type or brand of equipment is prescribed in the standard. A performance standard does not eliminate the incentives for rent seeking but it may diminish them since the standard is not defined in terms that specify a particular design or technology. Elsewhere, I have written about how lobbies favoring the electric car have succeeded in biasing recent regulatory systems in favor of electrification as opposed to other effective ways of improving fuel economy and reducing greenhouse gas emissions (e.g., conventional hybrid engines, such as used in the Toyota Prius, and the clean diesel engines now marketed be German vehicle manufacturers) (Graham et al, 2014). The same lesson applies to requirements, such as inspection technologies, in the pipeline, trucking, railroad and maritime industries.

When Performance Standards are Impractical

There are situations when it is not feasible or practical to devise a performance standard, usually because a viable system of measuring performance and inspecting firms/products for their performance is not available (Metzenbaum, 1998). In order to be feasible, a performance-based system must be capable of distinguishing the performance of one firm versus another and must be capable of documenting changes in a firm's performance over time. Without firm-specific measurement capability, a regulator cannot hold firms legally accountable for performance.

A performance-based system must also be practical in the sense that it can be coupled with an inspection/enforcement system that can determine which firms are in compliance and which are out of compliance. Since some companies are not averse to breaking the law when enforcement systems are weak, a performance standard must be framed in ways that inspection and enforcement systems can detect and deter violators.

One of the purported strengths of the prescriptive standard is that it can be framed in ways that facilitate inspection/enforcement (i.e., an inspector may have a checklist of hardware or operational practices that he or she uses to determine whether a facility or product is in

compliance with the standard). However, in order to have knowledge that specific hardware and operational practices are safer, a regulatory agency presumably has access to performancerelated data. The question becomes whether such data can be utilized to inform a practical performance standard.

When the outcome of interest can be measured continuously on a day-to-day basis (e.g., emissions from a smokestack), a performance standard is clearly feasible. When the outcome of interest is extremely rare and potentially catastrophic (e.g., a meltdown of a nuclear reactor), it is not practical to define performance by measuring directly the frequency of meltdowns. A similar situation exists with low-probability mishaps involving transport of hazardous materials.

In the nuclear sector, it is practical to use as a performance measure a precursor of meltdowns such as the frequency of reactor shutdowns. In airline safety, performance-oriented analyses focus on near misses as well as actual crashes. My understanding is that FRA and the railroads have launched a pilot program called confidential close-call reporting that is similar to the concept of near misses (FRA, 2015). In my opinion, this is a constructive development.

Using Risk Analysis to Inform Performance Standards

When events are rare in frequency, the tools of risk analysis can be employed to define performance standards. With risk analysis, a predictive mathematical model is used to estimate the probability of an adverse event as a function of the technologies, designs, practices and behaviors observed in the industry (NRC, 2013). The inputs to the model are based on historical data, known physical/biological/behavioral relationships, and expert judgement. The performance standard might be defined as a threshold probability of the adverse event (e.g., a small probability of an airplane crash, since zero probability is infeasible).

Compliance with the performance standard is demonstrated when the firm shows the regulator that, given the inputs at their firm, the predicted probability of an adverse event is below the threshold probability ("safety") specified by the regulator. Some companies might comply with the safety threshold through investments in technology; others may invest in superior training programs for their employees. In either case, the firm must be able to show, through risk analysis, that their compliance approach meets the risk-based standard specified by the agency.

When predictive models of risk analysis are used in performance regulation, it is common for regulatory agencies to offer technical guidance to companies on how the models should be constructed, tested, and validated. Default values for certain inputs may be specified by the regulatory agency, unless a firm can supply valid data to support an alternative value. When a company submits their risk analysis, using the template suggested by the regulatory agency, it may be appropriate for the company to subject their analysis (choice of inputs and calculations) to independent peer review by qualified experts in the field. Alternatively, the regulatory agency may organize its own peer review processes, on the guidelines for models or on the risk analyses submitted by specific companies. In order to rely less on prescriptive standards, greater use of risk analysis may be required in the pipeline, trucking, railroad and maritime industries.

Suggestions to Accelerate the Trend Toward Performance Standards

My experience in regulatory reform around the world suggests that there is growing recognition of the value of performance-oriented approaches to regulation. In order to accelerate the trend toward performance standards, I suggest three directions for Congress and federal regulatory agencies.

1. All prescriptive standards should be amended to permit alternative compliance mechanisms that are supported by performance information and achieve at least an equivalent level of protection.

When a regulatee can make an analytically rigorous case that an alternative compliance strategy provides at least equivalent safety performance to a prescriptive standard, the regulatee should be permitted by the agency to pursue the alternative strategy, subject to an inspection/enforcement regime that is established with the alternative strategy. Even if a regulatory agency cannot imagine a viable alternative compliance strategy, rules should be written to permit regulatees to propose alternative compliance mechanisms, since specialists in industry may be able to innovate in ways that regulators cannot anticipate.

Given the large number of prescriptive standards that have already been codified at numerous regulatory agencies, it would take decades to amend each of the standards on a rule-by-rule basis. A better approach would be for Congress, in a generic regulatory reform statute, to authorize -- at any health, safety or environmental agency -- alternative compliance mechanisms that achieve at least the same amount of safety performance as the prescriptive standard. The language I am referring to is sometimes referred to as "an equivalency clause" because the regulatee is obliged, with their alternative compliance methods, to accomplish an equivalent level of health, safety or environmental protection. The evidentiary burden of proving equivalent safety protection should be placed on the regulatee but, in the event that an agency declines to permit alternative compliance, the agency should be required to state its reasons publicly, and the agency's decision should be reviewable in federal court under the "arbitrary and capricious" test. That test provides a measure of deference to the agency's judgment, which I think is necessary to assure public confidence in the system.

With regard to new rulemakings, performance standards should be preferred whenever possible. If new prescriptive standards are enacted, they should be coupled with permission for regulatees to propose alternative compliance mechanisms that achieve equivalent protection.

2. When new safety regulations are proposed, agencies should be required to include, in their regulatory impact analyses, a plan for how they intend to evaluate the regulation after it is implemented.

The term “retrospective evaluation” is often used to describe the process whereby agency analysts evaluate how effective a safety rule has been after the rule is enacted. Regardless of

whether the rule is prescriptive or performance based, the agency should describe what data they plan to collect and how they intend to analyze the data. My experience is that, if an agency does not know how they would evaluate a new rule, after it is implemented, then OMB and the regulated community should begin to ask hard questions about whether the resources invested in the rulemaking might be better invested elsewhere.

3. Congress should provide additional resources to federal regulatory agencies for training in modern methods of performance assessment and risk analysis, so that agency personnel can transition more rapidly to the world of performance-based regulation.

Many of the professional staff at federal regulatory agencies have extensive experience with prescriptive regulation but little to no experience or training related to performance measurement or the development of performance standards. The need for training in risk analysis is particularly acute because many of the existing regulations that are prescriptive address lowfrequency adverse events, the types of situations where direct measurement of performance will not be feasible. In order for those rules to be redrafted as performance standards, the analytic tools of risk analysis will be required.

The cost of this suggestion is not large, as intensive courses in risk analysis for mid-career professionals have already been developed and are offered by the Society for Risk Analysis (SRA), a mission-oriented association of 2,000+ engineers and scientists. SRA is a nonprofit group dedicated to enhancing the application of risk analysis methods in government and industry.

In summary, the trend toward performance-based approaches to regulation is evident throughout the world (Coglianese, 2012). The advantages of performance standards are intuitive and compelling. If Congress does not act, federal agencies will move in this direction but progress will continue to be slow and uneven. I have made three suggestions for legislative action that may accelerate the replacement of prescriptive standards with performance standards.

Thank you for your time and attention, and I look forward to questions and comments about my testimony.

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