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Regulatory Improvement Act of 1999 (S. 746)
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My name is John D. Graham. I am Professor of Policy and Decision Sciences at the Harvard School of Public Health where I teach graduate courses in the methods of risk assessment, cost-effectiveness analysis, and cost-benefit analysis. I am also the founding Director of the Harvard Center for Risk Analysis (HCRA), an interdisciplinary unit dedicated to promoting a more reasoned public response to health, safety, and environmental hazards. In 1996 I served as elected President of the international Society for Risk Analysis (SRA), a membership organization of 2,500 scientists and engineers dedicated to promoting the methods and applications of risk analysis. The viewpoints expressed in this testimony should be attributed to me because they may not represent the official positions of my University, HCRA or SRA.

A brief biographical sketch may serve to highlight my interest in improving the regulatory process. I earned my BA and MA degrees in public policy from Wake Forest University (1978) and Duke University (1980), respectively. My Ph.D. dissertation at Carnegie-Mellon University (1983) was a benefit-cost analysis of automobile airbag technology and was conducted while in residence at the Brookings Institution in Washington, DC. My airbag-related research was cited by the U.S. Supreme Court in the 1983 STATE FARM case against the Reagan Administration and by Secretary of Transportation Elizabeth Dole in her reinstatement of the airbag regulation in 1984. As a post-doctoral fellow in environmental health at the Harvard School of Public Health (1984-85), I investigated reform of air toxics regulation under the Clean Air Act in research published in the DUKE LAW JOURNAL. Based on this research, I later collaborated with Senator Daniel Patrick Moynihan (D-NY) on several features of the 1990 amendments to the Clean Air Act. In the 103rd Congress I worked closely with Senator Bennett Johnston (D-LA) on a risk-based amendment to the EPA Cabinet-elevation bill which passed the Senate but not the House. In the fall of 1994 I was commissioned by the American Enterprise Institute to write a blueprint for regulatory reform legislation. This paper influenced the regulatory legislation (HR 1022) passed by the House of Representatives in March of 1995. In the 104th Congress, I also worked closely with Senator Dirk Kempthorne (R-ID) on risk-based amendments to the Safe Drinking Water Act and with Senators Robert Dole (R-KS) and Bennett Johnston (D-LA) on their comprehensive regulatory reform bill (S. 343). In the 105th Congress I was proud to work closely with Senators Fred Thompson (R-TN) and Carl Levin (D-MI) on S. 981, the precursor to the bill under consideration today.

For the past fifteen years, I have studied the decision making of federal agencies responsible for protecting public health, safety, and the environment. These agencies include, for example, the Consumer Product Safety Commission, the Environmental Protection Agency, the Food and

Drug Administration, the National Highway Traffic Safety Administration, the Occupational Safety and Health Administration, and the Nuclear Regulatory Commission. Although each of these agencies serve a vital public function, I have found that the decisions of these agencies are not always based on a good understanding of science, engineering, and economics. As a result, our regulatory system is far less effective and efficient than it could and should be. One of my previous doctoral students at HCRA, Professor Tammy Tengs of the University of California at Irvine, found in her doctoral dissertation that lifesaving investments in the United States are often inefficient. Based on a sample of 200 policies, she estimated that a reallocation of lifesaving resources to cost-effective programs could save 60,000 more lives per year than we are currently saving, at no increased cost to taxpayers or the private sector! In short, a smarter regulatory system can provide the public with more protection against hazards at less cost than we are achieving today.

Please let me cite three concrete examples of this regulatory inefficiency, cases where flawed regulatory decisions resulted from inadequate regulatory analysis.

1. THE RISKS OF "CLEANER" GASOLINE (MTBE)

In the 1990 amendments to the Clean Air Act, Congress sought to reduce carbon monoxide pollution in city air by ordering EPA to force an increase in the oxygenated content of gasoline. EPA later issued a rule that permitted a particular chemical, MTBE, to be used in compliance with the oxygenated fuel mandate. However, EPA never conducted a careful, quantitative analysis of the risks and benefits of MTBE compared to the alternative oxygenated fuels. Instead EPA allowed politics and market forces to shape implementation of the Clean Air Act, without any real understanding of the resulting risks and benefits to public health and the environment. Now that MTBE is widely used in gasoline in cities throughout the United States, serious questions are being raised about the safety and toxicity of MTBE. There are also reports that MTBE, a highly persistent chemical, is contaminating groundwater supplies in several regions of the country. Not surprisingly, political opposition to MTBE is rapidly increasing throughout the country and thus EPA is scrambling around to find evidence in support of the oxygenated fuel requirement. EPA Administrator Carol Browner recently kicked this "hot potato" to an independent commission chaired by Dan Greenbaum of the Health Effects Institute. Such independent review is helpful. Yet what is missing today is the same thing that was missing in 1990: a careful risk-benefit analysis of MTBE and its alternatives. To make matters worse, it may be that the necessary scientific data to assess the risks and benefits of widespread use of MTBE in the fuel supply was never assembled by EPA or the private sector, making an authoritative risk-benefit study impossible.

2. MANDATORY FUEL ECONOMY STANDARDS FOR MOTOR VEHICLES

During the oil crisis of the mid-1970s, Congress responded by creating the Corporate Average Fuel Economy (CAFE) program. A federal agency, NHTSA, was charged with regulating the average fuel economy of the new vehicle fleets produced by each domestic and foreign vehicle manufacturer. Tougher standards were established for passenger cars than for light trucks. In the early years of the CAFE program, domestic vehicle manufacturers responded with some new technologies but they also made passenger cars smaller and lighter. As a result, cars have become somewhat more fuel efficient, but they have also became less safe than they would have been

otherwise -- causing an additional 2,000 to 3,000 traffic fatalities each year due to the inferior occupant-crash protection provided by smaller vehicles. More recently, the objectives of the CAFE program have been circumvented by the growing popularity of sport-utility vehicles, a class of vehicles that has yet to be seriously analyzed for its safety and environmental consequences. To the best of my knowledge, the relevant federal agency, NHTSA, has never conducted a careful cost-benefit analysis of the CAFE program, even though they issue new rules under the program for each model year of vehicle production. The careful analyses of the CAFE program in the peer-reviewed scientific literature suggest that the entire CAFE program needs to be reconsidered, with greater attention to safety considerations and to the need for consumer incentives to purchase fuel-efficient vehicles.

3. PASSENGER AIRBAGS AND CHILDREN

When airbags and other automatic restraints were mandated in 1977 and again in 1984, concerns were raised that the passenger airbag might be dangerous to children seated in the front seat. Technical papers by engineers from General Motors Corporation and Honda Motor Company had already quantified the potential dangers of airbags to children. The relevant federal agency, NHTSA, did perform in 1980, and again in 1984, a (non-quantitative) risk assessment of airbags, with special attention to the safety of children. In these assessments, which was never subjected to independent peer review, NHTSA analysts concluded that the passenger airbag could endanger children under rare circumstances but the problem was unlikely to be widespread and serious. Moreover, NHTSA concluded (optimistically) that the number of children saved by airbags would far outweigh the number of children who might be killed or injured by the device. To the agency's credit, NHTSA published a real-world analysis in 1996 that showed how wrong the 1980 predictions were. Passenger airbags are causing a net increase in fatality risk to children under the age of ten, variously estimated as a net 20% to 100% increase in risk to children. Consequently, NHTSA has belatedly joined the private sector in a massive campaign to encourage children to sit in the rear seats of vehicles with proper safety restraints. Given the technical concerns that were being raised about passenger airbag safety in 1980, I seriously doubt that NHTSA's 1980 assessment would have survived independent peer review. NHTSA would have been forced to either revise its passenger airbag rule to better protect children or to accompany the rule with warnings to parents that kids must be seated in the rear seat with proper restraint. In this case, NHTSA designed a regulation that has harmed children unnecessarily because the underlying regulatory analysis was flawed and never subjected to independent peer review.

Looking back on these three examples, it must be noted that we have much more knowledge today than Congress and regulators had when these decisions were made. The benefits of hindsight are considerable. Nevertheless, it is my opinion that each of these regulatory decisions and subsequent actions by Congress might have been quite different if the agency had performed the kinds of analyses envisioned in S. 746.

I am indeed honored to offer my enthusiastic support for S. 746, "The Regulatory Improvement Act of 1999." This bill would take four important steps toward a smarter regulatory system.

First, S. 746 requires agencies to support major rules with regulatory analysis that includes risk assessment, substitution risk analysis, cost-effectiveness analysis and cost-benefit analysis.

Although agencies do employ these tools today, their use by agencies is sporadic and inconsistent. S. 746 would set in motion a process, led by OMB, aimed at bringing more rigor, transparency, and quality to regulatory analysis in the federal government. The analytic guidelines mandated by S. 746, both the general guidelines prepared by OMB and the agency-specific guidelines, will be a major step toward a more analytical regulatory system.

Second, S. 746 requires agencies to make a cost-benefit determination about each major rule. The regulator must determine whether the anticipated benefits of the rule justify its costs, or why the rule is being issued without such justification. The bill does not alter the decision criteria in existing regulatory statutes enacted by Congress. This is an important weakness of S.746 since it is the flawed mandates of Congress that are often the cause of inefficiency! Yet the uniform informational requirement in S. 746 is useful. It will provide future Congresses with valuable information that can be used to refine specific regulatory statutes in the years ahead.

Third, S. 746 requires peer review of agency analyses by scientists, engineers, and economists who are independent of the agency or program responsible for the rule. Today, any scientist has an opportunity to participate in either formal or informal rulemakings but the best scientists are unlikely to participate unless they are invited by the federal government to serve on a peer review panel or similar body. Some scientists currently serve as hired consultants to specific stakeholder groups but the testimony of stakeholder groups is not a substitute for independent, objective peer review. Agencies that are currently performing competent regulatory analysis have nothing to fear from independent peer review. Experience shows that peer review, although not error-free, is a constructive device to enhance the technical competence and credibility of regulatory agencies.

Finally, S. 746 authorizes an important national study of risk-based priorities in the federal government. The results of this study are to be used by agencies to focus resources on the most serious risks, in conjunction with related requirements in the Government Performance and Results Act. By setting more rational agency priorities and stimulating better use of science in agency risk assessments, S. 746 will cause agencies to achieve more protection of public health and the environment than is occurring under our fragmented and inefficient regulatory system.

In conclusion, I see S. 746 as a modest yet important step toward a regulatory system that is more rational and transparent than the system we have today. Our regulatory debates will become better informed while our regulatory decisions will become more effective and less costly. Please do not hesitate to contact me if you should desire advice about how to make S. 746 an even stronger and more significant piece of legislation. Thank you very much for the opportunity to testify today.