

Testimony on Regulatory Improvement Act of 1999

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S. 746, "Regulatory Improvement Act of 1999"
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I am Lester M. Crawford. My current position is that of Director of the Center for Food and Nutrition Policy at Georgetown University. Our Center operates a graduate program and conducts the Ceres Forum, a series of conferences and other mechanisms designed to analyze and report on complex issues in food and nutrition policy. From 1978 to 1991, I served in the Federal government in a number of positions relating to food safety. These were Director of the Center for Veterinary Medicine at the Food and Drug Administration and Administrator of the Food Safety and Inspection Service of the United States Department of Agriculture. I currently serve on the Expert Advisory Panel on Food Safety to the World Health Organization and on the Committee on Scientific Freedom and Responsibility of the American Association for the Advancement of Science.

I have read and am conversant with S. 746, the "Regulatory Improvement Act of 1999." I appreciate having been asked to give testimony on the bill. In my remarks, I will concentrate primarily on the relationship of S. 746 to food safety.

I previously testified on the predecessor to S. 746 which was numbered S. 981 and named the "Regulatory Improvement Act of 1998. In that testimony I mentioned some possible improvements in the bill primarily related to ensuring that the mechanisms prescribed by the bill did not in any way impede public health measures. I am pleased to note that those concerns have been adequately addressed by more explicit language in S. 981. The bill as currently written therefore meets my objectives and I would enthusiastically encourage its passage. I also am most pleased to learn that the Administration has concurred that S. 746 meets its objectives.

In my view and based on my experience, the bill would remedy a pernicious problem that has increasingly bedeviled the US rule-making process. That problem is a lack of rigor that gives rise to an absence of transparency in decision-making at many of the steps in the regulation development process especially including the role of the Office of Information and Regulatory Affairs (OIRA). Absence of transparency can occasion delay, denial and politicization or at least the suspicion thereof. At this point, I should point out that I am not condemning any particular administration; I have worked more with the four administrations that preceded the present one.

The hallmark of the World Trade Organization (WTO) treaty is transparency. Briefly described, the concept of transparency embraces openness, fairness and a detailed description of the decision making process. For matters involving public health, it furthermore implies that the decision will be science-based. Transparency is a standard we now demand of all other nations. The current trade disputes between Europe and the US are essentially over science-based decision-making that can only be evaluated in the presence of transparency. If transparency is required of our trading partners, it is axiomatic that we must operate in a like manner. To do less is unethical and terribly risky in today's trading environment. S. 746 would convert the current black box approach to one that is transparent.

S. 746 institutionalizes three widely accepted tools for risk managers including governments. These are cost-benefit analysis, risk assessment, and peer review. My area of experience is in public health regulation. Cost-benefit analysis would not normally be applied to public health measures because no cost can ethically be affixed to human health, suffering and death. Risk assessment on the other hand has become the universal language of scientific and public health deliberation. And peer review is the surety bond of science.

Risk assessment may be briefly described as the process of threat identification coupled with likelihood estimation with the end result being risk determination. For example, pasteurization of cheese is thought by some to be commercially objectionable but when the threat of cheese borne disease is identified and the likelihood of that disease is calculated the risk associated with not pasteurizing is generally found to be unacceptably high.

I was privileged to have been invited to be a member of the Expert Consultation on Risk Assessment in Food Safety by the World Health Organization in Geneva from March 15-19, 1999. Among the conclusions of our Consultation was that all nations must implement risk assessment in their public health procedures at the earliest instance. This was because risk assessment is state-of-the-art in regulatory decision-making. The opposite of risk assessment is intuitive decision-making which may be based on either whimsy or politics or both.

I would now like to turn to peer review. This is the scientific equivalent of the old adage, "two heads are better than one." Its practical application comes when a panel of qualified individuals evaluate scientific papers, research projects, or the like. When used in the government, peer review has been successful. FDA's system of Generally Recognized as Safe (GRAS) is a form of peer review. This grew out of the 1958 Food Additives Act. GRAS affirmation generally means that if you can empanel a group of qualified individuals and they as a group attest that a substance is safe for the intended use at the recommended level, then FDA can consider it safe. The product specific advisory committees in FDA's Center for Drug Evaluation and Research constitute another useful example of peer review.

Peer review can and does broaden the expertise available to the government and it makes the process more open and democratic. In my personal and professional experience, OIRA could very much benefit from peer review.

Finally, let me address some of the criticisms that S. 746 has precipitated. The first is that the bill involves a "one size fits all" approach. This is wrong. S. 746 allows for exemptions for significant public health and other regulatory measures in the national interest. S. 746 also categorizes certain measures on the basis of the perceived impact on the economy. Therefore, it does not represent a one size fits all approach.

Much also has been made of the exemption from the Federal Advisory Committee Act (FACA) (section 625, page 24). While I have been and continue to be subject to that Act in my advisory committee and Special Government Employee roles and was charged to enforce the Act while at FDA and USDA, I think much can be learned from the National Academy of Sciences (NAS) anguished decision to seek exemption from FACA last year. That effort resulted in Congress deciding to grant the exemption because it was persuaded that FACA requirements impeded peer review by intruding in a deleterious way on the deliberations of NAS committees. It is one thing to provide a transparent record of the conclusions of a committee and quite another to subject committee members to interruptions from non-committee members including the press during the deliberative process. FDA, when it approves a product provides to the public what is called a Freedom of Information Summary. These are transparent descriptions of the scientific basis upon which the approval is being made and are not in any sense a transcript of the deliberations. Even without FACA committee members have a legal and moral duty to recuse themselves from issues that stand to directly and/or financially benefit them.

The last point being made by opponents of S. 746 is that the bill "lowers the bar" on OMB-OIRA accountability. I cannot agree. The OMB that I was used to dealing with was buffeted from all sides by lobby groups of all kinds pressing subjective solutions to regulations of all types. And OIRA, being bereft of scientific expertise, overworked to the point of exhaustion, and increasingly unsure about what was best for America discovered new devices on a regular basis to delay or pigeonhole desperately needed regulations. I cannot tell you how many times I had to explain to OIRA that even deregulation requires a regulatory process that required their approval.

S. 746 will lead to better, more efficient government. I am convinced the bill provides a framework wherein regulatory initiatives can be fairly and openly judged in a transparent manner. My conclusion is that the bill will institutionalize risk assessment as the calculus for regulatory decision-making. To the extent that this is the case, S. 746 will bring the US in congruence with its international trading partners and the long-sought goal of science-based decision-making will at last have been realized.

Once again, thank you for inviting me to testify. I would be pleased to respond to questions.

