



Risk in Perspective

Risk Reform: Have You Read the Levin-Thompson Bill?



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S. 981 is an important and exciting step toward a more thoughtful approach to regulation of risks to public health, safety, and the environment.

In the 104th Congress, a major effort was made to pass a comprehensive regulatory reform law that would have enhanced the roles of risk assessment and cost-benefit analysis in regulatory priority setting and rulemaking. This effort was based on the large body of evidence showing that regulatory priorities are often misordered and rules are often inefficient. A comprehensive reform bill passed the House by a large margin in March 1995, but in July 1995 supporters of a similar bill failed to overcome a filibuster threat in the Senate. The bill's failure in the Senate was a clear signal that bipartisanship, including Clinton Administration collaboration, would be critical to passage of such legislation.

It appears that the Senate will take the lead on regulatory reform in the 105th Congress, and this time a constructive bipartisan approach to the legislation has been initiated. On June 27, 1997, Senators Carl Levin (D-MI) and Fred Thompson (R-TN) of the Government Affairs Committee introduced the "Regulatory Improvement Act of 1997". The bill has an impressive list of co-sponsors: John Glenn (D-OH), Spencer Abraham (R-MI), Charles Robb (R-VA), William Roth (R-DE), Jay Rockefeller (D-WV), and Ted Stevens (R-AK). Interest groups are already playing the "spin control" game about what the bill does and does not do, even before the committee hearings begin on the bill this fall.

In this issue of **RISK IN PERSPECTIVE**, I describe the provisions of the "Levin-

Thompson" (L-T) bill (S. 981) and encourage professionals in the field to read the bill itself rather than rely on characterizations of the bill made by myself or others. In my opinion, the L-T bill deserves serious consideration. If enacted in its present form and implemented faithfully, it can achieve more protection of the public health and the environment at less cost than is occurring under the current maze of regulatory programs. However, there are important ways that the bill can be improved, as discussed below.

ASSESS RISK BEFORE REGULATING

Numerous claims about unexpected dangers in modern life are made each year, but those that become regulatory priorities of the federal government should be subjected to careful, science-based risk assessments. If a major new regulation is aimed primarily at reducing an alleged hazard to human health, safety, or the environment, the L-T bill would require the sponsoring agency to support the regulation with a risk assessment. Each risk assessment is expected to include a description of the hazard of concern, the people or natural resources at risk, the exposure scenarios and their associated likelihood of occurring, the nature and severity of harm that could reasonably be expected to occur, and the major scientific uncertainties about the risk.

Some claims about risk are not well grounded in science, such as the speculation that cellular phones cause brain cancer. The L-T bill requires agencies to consider "reliable and reasonably avail-

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able scientific information" about risk and then describe the basis for selecting such information for use in the risk assessment. The bill does not block precautionary or preventive actions, even when hard data are lacking. "Reasonable assumptions" are permitted when relevant and reliable scientific information is not available. For example, there are no hard data that prove that very low doses of benzene exposure increase human cancer risk, but it is plausible to believe that they might do so based on the leukemias observed in workers exposed to higher doses. When assumptions are used, they must be (a) identified explicitly and (b) evaluated with regard to their scientific or policy basis, including consideration of any supportive or contradictory empirical data. The basis for any single assumption or combination of assumptions must be explained.

The latter point about multiple assumptions is very important. Many official risk assessment reports depend on a layering of seemingly plausible assumptions. Suppose, for example, that a serious harm will occur if ten plausible yet independent assumptions prove to be correct (e.g., people are no less sensitive than rodents to chemical exposure, there are no safe levels of exposure to a cancer-causing substance, and children living nearby might trespass on to an abandoned waste site and ingest contaminated dirt). Even if each assumption is 60% likely to be correct, the probability that all ten assumptions are correct (assuming independence) is only 6 chances in 1,000 (or less than 1%).

Recognizing the role of uncertainty in risk assessment, the L-T bill compels the agency to express risk as a "reasonable range or probability distribution." This is a provision that embraces recent technical advances in the probabilistic methods of risk assessment. In addition to the ranges and distributions of risk, there is a specific requirement that "the most plausible estimates of risk" be reported, which is a sensible way of preventing optimistic or pessimistic estimates of risk

from dominating public dialogue. Agencies such as EPA often do a better job of reporting how bad a risk might be than reporting what the most plausible estimate of the risk is. When quantitative estimates of risk are not possible, the agency must disclose its qualitative reasoning about factors contributing to risk.

Special emphasis in the L-T bill is given to the need to provide ranges and distributions of risk that reflect lack of data, uncertainty, and the circumstances of highly exposed or sensitive subpopulations. It was, for example, the failure of industry and government to adequately consider the unique vulnerabilities of children in the front seat that contributed to the unexpected cases of children being injured or killed in low-speed crashes involving airbags.

Comparisons of risk are authorized in the L-T bill to help place the risk of concern in perspective relative to risks that are "familiar and routinely encountered by the general public." When comparisons are made, relevant qualitative distinctions are to be considered (e.g., voluntary versus involuntary risks). Some regulators have sought to reduce each identifiable cancer risk from modern technology to a level less than a lifetime probability of one in 1,000,000; yet few people realize that a baby born today, at current mortality rates, has roughly 4 chances in a 1,000,000 of being struck on the ground and killed by a crashing airplane! Comparisons can provide numerical perspective for people who are understandably frightened of cancer but have little intuition for numbers.

Of particular interest is the L-T bill's explicit requirement that "significant substitution risks" be described in the risk assessment. The term "substitution risk" means "an increased risk to health, safety, or the environment reasonably likely to result from a regulatory option." In a recent book (*Risk Vs. Risk*, 1995) sponsored by HCRA, we found that federal agencies often ignore or conceal the risks that are created by their regulatory programs.

STRENGTHEN THE RISK ASSESSMENT MANDATES

Overall, the risk assessment provisions in the L-T bill that relate to rulemaking are a modest step in the right direction but could be strengthened in several ways.

A notable omission in the bill is something that is perhaps obvious: an expectation that risk assessments should be as objective as possible and unbiased.

These ideals may be encouraged by the bill's peer-review provisions (described below), but it would be helpful if the bill would embrace these basic tenets of first-rate analytical practice.

The risk-assessment provisions could be strengthened considerably if they were applied to all official risk determinations issued by federal agencies. As currently written, the provisions discussed above apply only to risk assessments that are used by a federal agency to support a major rule. Yet the government's power to decide whether something is risky can be as important as the power to issue a rule. By declaring a particular technology "hazardous" or "safe" in an official risk assessment report, a federal agency can stimulate numerous marketplace impacts, liability suits, hazardous waste cleanup decisions, and state and international regulations — even though no major federal rule is adopted or even considered! For example, the federal government publicizes sensitive risk determinations on hundreds of chemicals through EPA's computerized Integrated Risk Information System (IRIS), yet none of the L-T bill's procedural protections would apply to information on IRIS (unless such data were used in a major federal rule). Much of the U.S. EPA's official information about the risks of indoor air pollution (e.g., cancer risk from inhalation of radon and second-hand tobacco smoke in homes and offices) was developed outside the rulemaking process and much of its impact on the decisions of citizens and companies occurred well before such information was ever used in support of a major federal rule.

The point here is not that the government's power to assess risk should be removed. Publicizing valid estimates of health and ecological risk is an essential function of governmental programs aimed at promoting health, safety, and environmental quality. Yet the government's power to declare what is risky and safe should be subjected to the same sorts of checks and balances that the L-T bill applies to the government's power to promulgate rules based on risk assessment.

The importance of governmental power to assess risk is not appreciated by many administrative lawyers who have devoted their careers to perfecting the rulemaking process. Yet realizations are changing as agencies begin to pursue objectives through public information that previously might have been pursued through rulemaking. If the discrepancy in procedural protection in the L-T bill is not rectified, it may encourage agencies to pursue informational approaches instead of rulemaking when the government's scientific case is weak or when the government's administrative resources are constrained.

The provision regarding comparison of risks for public understanding, while intuitively appealing, will need to be evaluated for its ultimate value as a risk communication tool. Experts in the field of risk communication are currently divided on precisely how to make risk comparisons in a way that helps people understand risk. Fortunately the bill permits agencies to experiment with different approaches. The bill's requirement that comparisons consider qualitative distinctions about risk (e.g., voluntary versus involuntary risk) is a sound application of findings from two decades of risk-perception research. Evaluation of public reaction to the comparisons mandated in the bill should be authorized.

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EVALUATE COSTS, BENEFITS, AND ALTERNATIVES BEFORE REGULATING

The L-T bill also requires each major rule to be accompanied by a cost-benefit analysis that contains a description of the information and evaluations used by the agency. Unquantifiable as well as quantifiable benefits and costs are to be reported. The analysis is expected to explain how the benefits would be achieved, what costs would result, and which people would be affected. The relationship between benefits and costs is to be examined for a reasonable number of alternative policy options, including "flexible options" (e.g., marketable permits for pollution prevention) that would achieve the same regulatory objective and options that account for geographic differences and variations in the resources available to different people.

In addition to the analysis, the agency head is required to make a cost-benefit "determination" about the major regulation. The agency must state "whether the rule is likely to have benefits that justify the costs of the rule" and whether the rule is likely to be more cost-effective than other alternatives considered in the analysis. The cost-benefit test is not a strict one. The agency is authorized to consider nonquantifiable as well as quantifiable factors when making these determinations. If the agency head cannot make favorable benefit-cost and cost-effectiveness determinations, the agency may still proceed with the rule by explaining why a favorable determination cannot be made and explaining what might have been done had feasibility considerations allowed a wider range of alternatives to be analyzed.

The "findings" at the outset of the bill make it apparent that the authors of the L-T bill do not regard economic analysis as a replacement for "judgment" or for "values" such as "equity" and "distributional consequences." For example, concerns raised by low-income groups and small businesses may deserve special consideration. A less cost-effective option might be preferable if its outcomes were judged to be more equitable. Moreover, the analytical requirements in the L-T bill can be waived

if there is an emergency or imminent threat to public health or the environment.

The alternatives that must be considered by the agency are only "reasonable" alternatives, defined as those "that would achieve the objective of the statute as addressed by the rulemaking and that the agency has authority to adopt under the statute granting rulemaking authority, including flexible regulatory options." This definition has important ramifications, because it means that the agency is not required to consider alternatives, even highly cost-effective ones, that were not permitted (or even envisioned) when Congress crafted the law governing the agency's rulemaking authority.

STRENGTHENING THE ECONOMIC ANALYSIS PROVISIONS

The proposed requirement for cost-benefit analysis is straightforward and reasonable, tracking closely the approach in President Clinton's 1993 executive order on regulatory planning. The precise formulation of the cost-benefit determination in the L-T bill has two laudable features. First, it does compel an explicit agency judgment about whether the benefits of the rule justify the costs compared to various alternatives. The public has a right to know about the anticipated costs and benefits of major regulatory actions, even if such information does not control regulatory decisions. Second, the bill does offer the agency flexibility to promulgate a regulation that is judged to be desirable yet cannot be defended through a strict economic analysis. Among practitioners of cost-benefit analysis, this "soft" requirement is generally preferred to a "hard" requirement that any rule must pass a strict net-benefit test. The "hard" test is simply too prescriptive given the emerging state of the science and the need to consider important factors (e.g., equity to the poor) that are not meaningful within a narrow interpretation of the benefit-cost framework.

The cost-benefit determination could be strengthened by adding a specific determination about whether the risks to be

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