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 bipartisanism, 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 cosponsors: 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-
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.
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 quantified 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...
reduced by the rule justify any substitution risks created by the rule. While it is useful to require consideration of substitution risks in the benefit-cost balancing (as the L-T bill authorizes), it also would be useful to compel an explicit risk-tradeoff determination that precedes any of the monetary considerations in cost-benefit analysis. In other words, the agency should be required to make a determination about whether, taking into account substitution risks as well as reduced risks, public health and environment quality will be enhanced by the regulation. The public certainly has a right to know the net health or environmental calculus as well as the net monetary calculus. This net-risk determination should be required of all risk-related rules, even those adopted under statutes that prohibit or discourage consideration of monetary costs and benefits.

A more serious objection to the L-T bill is the restrictive definition of "reasonable alternatives." The narrow definition in the bill will not encourage or reward innovative thinking by agency personnel. A better approach would be simply to require consideration of a reasonable number of regulatory alternatives, regardless of whether they are authorized under current law. EPA and firms have found that perceptions of what current laws require can hinder adoption of measures that are "cleaner, smarter, and cheaper." One of the primary purposes of regulatory reform should be to broaden the range of alternatives considered and used by firms and agencies, particularly alternatives that perform well on cost, risk, and benefit criteria.

PEER REVIEW

The L-T bill would require that a process of peer review be applied to risk assessments and cost-benefit analyses used in support of major rules. Peer review panels are to have membership with appropriate expertise as well as balance, including participants who are independent of the agency program. Public disclosure is required of any panel member who has a financial interest in the outcome of the rule.

The peer-review requirements do not represent a major departure from current practice in the field of risk assessment. They would be a notable change in the practice of regulatory cost-benefit analysis, which has not typically been subjected to the same kinds of external review that are typical, for example, of some EPA risk assessments. The peer-review requirements can be expected to enhance the quality and credibility of the agency’s work. Agencies are required to document their responses to comments made by peer reviewers. The requirements are workable because the agency retains the discretion to tailor the nature and intensity of the review to the importance of the rule and available resources.

JUDICIAL REVIEW

The consensus among scientists and economists is that it does not make sense for federal judges to be referees in detailed technical disputes about how a risk assessment or cost-benefit analysis is conducted. The L-T bill reflects this point of view by carefully limiting the timing and scope of judicial review.

If the agency fails to perform the required analyses, the L-T bill directs a court to remand or invalidate the rule. The court is authorized to examine the analyses that are performed but only as indicated in the following key provision in the L-T bill: "The cost-benefit analysis, cost-benefit determination . . . and any risk assessment shall be part of the whole rule making record for purposes of judicial review of the rule and shall be considered by a court in determining whether the final rule is arbitrary or capricious unless the agency can demonstrate that the analysis or assessment would not be material to the outcome of the rule."

In the field of administrative law, "the arbitrary and capricious" test is a deferential standard that compels the judge to grant substantial leeway to agency expertise and judgments. The "materiality"
exception is also important. If the outcome of the rulemaking was determined by some overriding legal factor (e.g., a statutory mandate to ban a certain chemical or install a particular type of airbag) and thus could not have been influenced by risk assessment or cost-benefit analysis, then shortcomings of the analyses may not be used by a court to block the rule.

It is not always easy to predict how judges will interpret a new law, but the language in the L-T bill gives the benefit of the doubt to the agency when questions are raised — as they inevitably will be — about the validity of an agency’s determinations about risk, cost, benefit, and substitution risk. If an agency performs the required analyses, has them peer reviewed properly, and responds carefully to the comments of peer reviewers, it does not seem likely that a judge would be inclined to invalidate the rule due to analytical deficiencies. The bill does put a regulator in legal jeopardy if the analytical processes mandated in the bill are ignored.

**REVIEW OF EXISTING RULES**

The L-T bill includes an extensive provision aimed at selecting a limited number of existing rules at each agency for re-analysis and review based on consideration of risk, cost, and benefit. An advisory committee process is authorized to inform the process of selecting existing rules for review. This provision should be reconsidered in light of the budgetary resources that are likely to be available to agencies in the future. Care needs to be exercised to make sure that this “look-back” provision does not become an onerous vehicle for the reopening of arguments about old rules that are unlikely to be revised based on benefit-cost considerations.

**COORDINATION, GUIDELINES, RESEARCH, STUDY, AND DISCLOSURE**

The L-T bill also contains important provisions calling for the Director of the Office of Management and Budget, in consultation with the Director of the Office of Science and Technology Policy, to oversee the development of guidance about how risk assessments and economic analyses should be conducted by agencies. It authorizes these same offices to exercise leadership on research and training needs related to these analytical tools.

The provisions in this section of the bill need to be strengthened to make sure that OMB fairly considers agency requests for resources and staffing to implement the analytical requirements in the L-T bill. If adequate resources are not provided to agencies, then the quantity and quality of both analyses and rules can be expected to decline without any rational relationship to residual risk or benefit-cost considerations.

The L-T bill also authorizes a major study in comparative risk analysis that can be used in the future to facilitate comparison of dissimilar risks addressed by various programs and agencies. The study is aimed at stimulating a more analytical approach to the allocation of resources across agencies with authority to reduce risks to human health, safety, and the environment.

Although such a study is certainly worthwhile, the L-T bill should also require agencies, during regular budgetary processes, to justify their requests for funds based on consideration of relative risk, cost, and benefit.

In order to promote public understanding of and confidence in OMB review of rulemaking activities, the L-T bill contains a useful provision giving more public access to the communications between executive branch officials and outside parties. Changes in rules that are made in response to OMB suggestions are to be explicitly documented in the public record.
**SPIN CONTROL: MYTHS & TRUTHS ABOUT THE L-T BILL (S. 981)**

**CHARGE:** The L-T bill will push agencies toward adopting rules that are less protective of public health because only benefits that can be quantified in dollars and cents are accorded legal significance.

**FACT:** The definition of “benefit” in the L-T bill includes both quantifiable and unquantifiable effects that the agency judges to be favorable. These benefits do not have to be expressed in dollar units in order to be given weight by the regulator.

**CHARGE:** The L-T bill is meaningless because it does not require that future regulatory decisions be based on the scientific and economic analyses mandated in the bill.

**FACT:** Although the L-T bill does permit regulators to make decisions outside a benefit-cost framework under various circumstances, that deference to agency discretion does not render the bill meaningless. The information generated by the required analyses will stimulate public debate after the rule is proposed and can be used by elected officials during the period of congressional review after the rule is finalized. If agencies completely ignore the findings of the required analyses, such behavior will set the stage for more prescriptive legislation in the future unless the agency decisions to ignore scientific findings are very carefully and cogently defended.

**CHARGE:** The L-T bill is unethical because it seeks to reduce all discussion of public health and environmental protection to a cold economic calculus.

**FACT:** The findings at the outset of the L-T bill acknowledge that a variety of non-economic factors, such as equity, values, and distributional considerations, must be considered in regulatory decision making. Regulators are granted authority in the L-T bill to give weight to these non-economic values in conjunction with economic considerations so as they are not precluded from doing so by existing laws passed by Congress.

**CHARGE:** The L-T bill won’t change anything because bureaucrats will simply fudge the risk, cost, and benefit numbers to suit their own preferences.

**FACT:** The fields of risk analysis and cost-benefit analysis have matured considerably in the last thirty years. There are acknowledged experts in the fields at universities throughout the country as well as textbooks on these subjects and databases known to have various strengths and limitations. Even granting the limited nature of the scientific peer review and judicial review authorized in the L-T bill, it will not be easy for even a highly creative analyst to fudge a case for a major new regulation.

**CHARGE:** The L-T bill undermines the protections found in existing health, safety, and environmental laws.

**FACT:** If an existing health, safety, or environmental law passed by Congress provides for a particular protection regardless of cost-benefit considerations (e.g., mandatory airbags in cars and light trucks or mandatory health-based air quality standards for ubiquitous air pollutants), then questions about the analyses required in the L-T bill cannot be used by a court to invalidate an agency’s rule that implements the existing law. Such analytical questions are not material to the outcome of the rulemaking. If current laws permit consideration of risk, cost, and benefit, then the information generated by the L-T bill must be considered by the regulator in the context of existing legal requirements and the provisions of the L-T bill.

**CHARGE:** The scientific peer review panels mandated in the L-T bill will be stacked with members who have a financial interest in the outcome and have insidious connections with the regulated community (or who share the agency’s ideological predispositions and have research grants from the agency interested in the rulemaking.)

**FACT:** The scientific peer review panels commissioned by EPA and FDA under various programs have, with some notable exceptions, generally done a competent and credible job of performing the kinds of peer review functions envisioned in the L-T bill.

**CHARGE:** The L-T bill will cause endless judicial second-guessing of technical judgments made by agency scientists.

**FACT:** The L-T bill employs the “arbitrary and capricious” standard of judicial review, which grants a wide range of technical discretion to expert agency judgments.
CONCLUSION

The 105th Congress is taking a fresh, bipartisan approach to regulatory reform based on risk assessment and cost-benefit analysis. The comprehensive bill (S. 981) recently introduced by Senators Fred Thompson (R-TN) and Carl Levin (D-MI) is an important and exciting step toward a more thoughtful approach to regulation of risks to public health, safety, and the environment. It is already apparent that a variety of interest groups are seeking to exercise "spin control" over what this bill would and would not do. Under these circumstances, it is recommended that anyone seriously interested in this issue obtain a copy of the bill, study it, and form his or her own opinion on the matter. The fate of legislation in Congress is notoriously difficult to predict, but there is a persistence to the regulatory reform movement that is encouraging to those of us committed to better use of science and economic analysis at regulatory agencies.

Further Reading


Note: Copies of S. 981 are available on the World Wide Web at http://frwebgate.access.gpo.gov/cgi-bin/multidoc.cgi

PEER REVIEWERS

George M. Gray, Ph.D.
James K. Hammitt, Ph.D.
Kimberly Thompson, Ph.D.

RIP correction: The July 1997 RRP, "Airbags: Benefits and Risks" contained a typo. In the seventh line of the sixth full paragraph on page 3 it reads "...fewer than 1%..." where it should read "...fewer than 10%...". We apologize for any inconveniences that this error may have caused.