The Prospects for Science-Based Reform of Public Health and Environmental Regulation in the United States

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Abstract

Public perceptions of risk in the U.S.A are not well grounded in science. As a result, misordered priorities and inefficiencies in regulation have become widespread. The trend in the United States is for regulators to make greater use of analytical tools such as risk analysis and benefit-cost analysis in decision making. If this trend continues, it will be feasible for regulators to achieve both more protection against risk and fewer economic costs when regulations are adopted. Reforms are likely to occur gradually due to opposition by organized consumer and environmental groups.

Introduction

The United States of America is governed through a representative democracy that gives considerable weight to the perceptions and opinions of the public. Although this system of government has numerous advantages, it does not necessarily promote a technically competent and efficient process for regulating hazards to public health, safety, and the environment. Efforts are now underway in the United States to improve the regulatory system by requiring better use of scientific and economic information when regulations are designed.

This article reviews recent trends in public health, safety, and environmental regulation in the United States. It argues that more and better use of risk analysis and benefit-cost analysis are gradually changing the way U.S. regulators make decisions about risk. However, these trends remain somewhat at odds with certain populist notions of how regulators should respond to risk in a democracy. If the United States does take a more scientific approach to risk regulation, it should be feasible to provide more protection for public health and the environment at less cost than is occurring under the current regulatory regime. The article concludes that the pace of reform in the United States is likely to be evolutionary rather than revolutionary because of America=s difficulty in reconciling its renewed interest in technocracy with a longstanding commitment to populism.

Public Perception of Risk

The American people appear to suffer from a syndrome of paranoia and neglect about risks to safety, health, and the environment (Breyer, 1993; Graham, 1995). An enormous amount of concern and resources are devoted to negligible or nonexistent hazards, such as the possibility that people will develop cancer from living near an electric power line or eating the minute quantities of pesticide residues on fruits and vegetables. At the same time, better proven and significant risks tend to be ignored by the American people, such as the risk of injury from not wearing a safety belt and the risk of a cancer from eating too few fruits and vegetables. Contrary to popular belief in the USA, lifestyle choices are a much more important determinant of health status than environmental pollution of various sorts (McGinnis and Foege, 1993).

An interesting literature in psychology and sociology has shed some light on public perception of risk (Plough and Krimsky, 1987; National Research Council, 1989, 1996; Noll and Krier, 1990). When asked to provide their quantitative understanding of the relative frequency of hazards, laypeople appear to work from a numerical scale that is too compressed, meaning that people tend to overestimate the probability of infrequent hazards and underestimate the probability of common hazards. Technological hazards that can be portrayed dramatically on television or in the movies (e.g., a meltdown at a nuclear power plant) may be associated with elevations in perceived risk, while technological hazards that are ordinary and familiar, such as collisions involving motor vehicles, may be associated with diminished perceptions of risk (Slovic, 1987).

More generally, it appears that public concerns about risk are influenced by numerous factors other than objective assessments of probability and consequence. Perceived risk tends to be attenuated for hazards that seem to be voluntary and controllable by individuals (Freudenburg and Rursch, 1994), such as the risk of dying from eating too many calories, and aggravated for hazards that are perceived to be involuntary and uncontrollable by individuals (Starr, 1969; Slovic, 1987), such as the risk of birth defects from unknowingly ingesting an industrial toxin in drinking water. Feelings of excessive invincibility are often expressed about risks that people think they understand and freely choose. An example is the finding that 80% of Americans think they are more competent and safer than the typical driver (Weinstein, 1989). Yet feelings of unfairness are expressed about hazards that are imposed on people without their consent (e.g., the concerns about the dioxins emitted into the air from hazardous waste incinerators) and that force some people to incur risk while other people benefit (Slovic et al, 1979).

Perception of benefit appears to play a particularly important role in determining which risks are judged to be acceptable (Margolis, 1996). Although the automobile airbag has created significant and well-publicized dangers for America=s children, the adverse public reaction toward airbag technology in the United States has been modest, presumably because adults perceive that the airbag has significant lifesaving benefits (Graham, 1997). Much smaller risks to children from chemical pollution in the manufacturing sector of the economy trigger a stronger public concern because people do not perceive the benefits of these chemicals and they see the risks as unfair. A closely related phenomenon is the tendency to downplay risks that are caused by nature (e.g., the risk of getting skin cancer from too much sunlight exposure) and overreact to smaller and more speculative risks caused by manmade technology (e.g., the electric and magnetic fields emitted from electric power lines and cellular phones).

Although some authors have suggested that public opinion about risks and regulatory

responses should be determinative in a democracy (Commoner, 1994), it is not clear that the American people are aware of the degree of inefficiency that characterizes the current regulatory system (Pildes and Sunstein, 1995; Sunstein, 1997). Blind faith in public opinion can be dangerous (Cross, 1992). In the field of environmental health, for example, there appears to be little relationship between those hazards of most concern to scientists, such as global warming from burning fossil fuels, and those hazards of most concern to the lay public, such as exposures to chemicals from hazardous waste sites (U.S. EPA, 1987; U.S. EPA, 1990). When laypeople and scientists work together in Acomparative-risk@ projects, significant learning occurs and new opportunities for efficient regulation are identified (Davies, 1996; Minard, 1996; Jones, 1997). According to one estimate, a nationwide reallocation of resources from cost-ineffective to cost-effective programs could save an additional 60,000 lives annually in the United States, at no increased cost to the public or private sectors (Tengs and Graham, 1996; Hahn, 1996)!

In recent years there has been increased public recognition of these inefficiencies in the United States. A small yet growing coalition of scientists, business leaders, Mayors, Governors and journalists have been making the case for a more scientific and analytical approach to regulation of health, safety, and environmental hazards. A variety of consensus reports have recommended more and better use of analytical tools such as risk analysis and benefit-cost analysis in future regulatory decisions (Carnegie Commission, 1993; NAPA, 1995; HGRMR, 1995; Presidential/Congressional Commission on Risk Assessment and Management, 1997). Some environmental activists and consumer advocacy groups are opposing analytical reforms because they fear that the reformed system will become too cumbersome and less protective (Hawkins, 1997). It is too early too assess how much reform will occur in the United States but it is apparent what the general directions of reform are likely to be.

Making Better Use of Science When Assessing Risk

In the United States it is customary for a regulatory agency to perform a risk assessment before a decision is made about whether a hazard should be regulated. The risk assessment report is important because it represents the federal government=s official determination about whether the hazard is significant and worthy of concern. Even if regulatory plans are delayed or abandoned, the federal government=s risk determination can have a powerful influence on the decisions of businesses, international bodies, state and local regulators, and judges and juries in liability cases. The regulatory reform movement is advocating several major changes in how risk assessments are conducted in the United States.

First, official risk assessment reports should be subjected to independent peer review by a panel of qualified scientists. Some agencies tend to resist peer review because it consumes time and resources and may diminish the power of those agency scientists who prepare a risk assessment report. However, it has been well demonstrated that the scientific quality and credibility of an agency=s risk determination tends to be enhanced by the application of well-functioning peer review procedures (Graham, 1991; Jasanoff, 1990).

Second, the weight of the scientific evidence should be considered when determinations are made about potential hazards. Historically, some governmental risk assessments have considered only evidence of harm and neglected evidence of safety or protective effects. For example, the U.S. Environmental Protection Agency=s draft report on the carcinogenicity of dioxin has been criticized by the Agency=s Science Advisory Board on the grounds that the draft report does not consider

seriously the evidence from animal and human studies that exposure to dioxin is associated with a reduction in the risk of breast cancer (Gierthy et al, 1993; Holcomb and Safe, 1994; Kociba et al, 1978; Bertazzi et al, 1997). Since decision makers and the public may not be aware of the possibility that dioxin exposure can have anti-carcinogenic effects, the weight-of-the-evidence principle would require that a risk assessment report disclose this possibility, with appropriate qualifications.

Third, when quantitative estimates of risk are estimated in the face of limited data and scientific uncertainty, a central estimate of risk should be reported as well as upper and lower bounds on the risk (Graham, 1997). Some federal agencies have exhibited a tendency to report only pessimistic estimates of risk, perhaps because these estimates appear prudent and are likely to draw attention to the target risk. However, failure to report central estimates of risk as well as the full distribution of risk estimates will induce bias in both the ranking of risks and benefit-cost analysis of interventions to reduce risk (Zeckhauser and Viscusi, 1991) . Significant technical progress has been made recently in the ability of analysts to generate probability distributions that reflect both model and parameter uncertainty about risk (Morgan and Henrion, 1990; Pate=-Cornell, 1996).

Fourth, a frequency distribution of risk estimates should be reported that reflects variation in exposure and suscepibility to harm (National Research Council, 1996). The number of people exposed to different levels of risk is essential information for computing the expected population risk (a critical summary statistic for use by benefit-cost analysts) and for making judgments about whether the hazard is distributed fairly in society. Failure to consider highly exposed or susceptible subpopulations can lead to poor regulatory decisions. For example, the failure of the U.S. government and industry to consider seriously an unrestrained child=s vulnerability to injury from airbag deployment has caused airbags to be designed in a manner that creates unnecessary harm to children (Graham, 1997).

Finally, a risk assessment report should address the full range of human health and ecological concerns. Early risk assessment reports in the United States tended to focus exclusively on cancer, perhaps due to strong public concern about this disease. More recently, it has become more customary in chemical risk assessment to consider a wide range of endpoints such as neurological effects, developmental and reproductive effects, and immunological disorders. The scientific foundations for risk assessment in these areas are still at an early stage of development.

Considering Unintended Risks that May Result from Regulation

U.S. regulators often focus on a Atarget risk@ that is of immediate concern to the mass media, politicians, and the public. In the process of reducing or preventing the target risk, a Acountervailing risk@ is often created (Graham and Wiener, 1995). In medicine, the countervailing risks of treatment are the side effects of drugs and the risk of complications that arise due to surgery. Although it is well accepted that the risks of medicine must be compared to therapeutic benefits, regulators in the United States are only beginning to apply this principle in a rigorous manner.

For example, the new amendments to the U.S. Safe Drinking Water Act require that EPA consider, when setting new maximum contaminant levels, the risks that might be created by the new standard as well as the target risks that should be reduced. Concern about risk tradeoffs in drinking water regulation has been magnified by a realization that efforts to regulate the carcinogenic byproducts of chlorination could inadvertently increase microbial contamination of drinking water.

More recently, concerns have been raised that ill-considered regulations of toxic chemical emissions at cement kilns could induce kiln operators to switch from hazardous waste to coal as the primary fuel source, thereby causing a net increase in total pollution and risk (Thompson and Graham, 1997).

At a minimum, it is critical for regulators to identify, quantify (where feasible), and consider countervailing risks as well as target risks. Some authors also believe that before issuing a regulation or standard, regulators should be required to make a finding that any countervailing risks justify the reduction in the target risk (Warren and Marchant, 1993). These kinds of risk-tradeoff judgments require consideration of values as well as science. In the United States, for example, the best estimate is that the ratio of lives saved to lives lost due to the mandatory driver airbag rule is about 75 to 1. In contrast, the benefit-risk ratio for mandatory passenger airbags is less than 10 to 1 and most of the motorists who are losing their lives are children under the age of 10 (Graham et al, 1997). It is questionable whether a regulator could make a persuasive ethical defense of the current passenger airbag, even though net lifesaving effects are positive.

It is important to recognize that concern about countervailing risks is not necessarily an argument aimed at blocking regulations aimed at reducing a target risk. Analysis of countervailing risks can lead to identification of superior regulatory alternatives. For example, if regulators had informed the public of the risk that passenger airbags pose for children, then more parents may have insisted that their children sit in the rear seat. If children are occupying the rear seat, the passenger airbag=s benefit-risk ratio is more impressive. Reducing the number of regulations that have serious adverse effects will increase the competence and credibility of the regulatory process.

Considering the Costs and Cost-Effectiveness of Regulations

In the United States, some public health and environmental programs call for the reduction or elimination of risks, regardless of how much it will cost industry, consumers, and taxpayers. Even when regulators are permitted to consider costs, there may be a reluctance to do so on the grounds that allowing cost to influence protective regulation would be like allowing a physician to consider cost when recommending how a patient is treated for a disease. Yet the costs of medical care and environmental protection are too large and are growing too rapidly for even a wealthy industrialized nation to ignore altogether.

Despite the reluctance to consider costs, there are compelling reasons to require that all health, safety, and environmental regulations be subjected to a benefit-cost or cost-effectiveness analysis (Arrow et al, 1996). If costs are not considered, regulators may fail to discover the least-cost means of achieving a given health or environmental objective. Moreover, when health or environmental objectives are set without regard to cost, they may produce extravagant expenditures that produce little reduction in risk. Studies have shown, for example, that the marginal cost of each year of life saved from carcinogen regulation is often a factor of 100 or more larger than the amount that well-informed considers are willing to pay for their own protection (Tengs et al, 1995; Viscusi, 1996). Regulations that make citizens poorer will ultimately increase the risk of premature death and illness, since there is a strong relationship between a household=s income level and health status (Keeney, 1990). Although it is not appropriate to hold regulators to a strict economic test for each regulation, since equity issues and qualitative considerations may also be important, it is certainly appropriate to require regulators to consider how they have treated economic matters in their decision. If cost considerations are not addressed explicitly, they may nonetheless be considered implicitly without serious rigor or peer review.

It is not currently feasible to quantify and monetize all of the benefits or costs of regulation in this area. In the field of ecological and natural resources protection, for instance, better tools and data need to be developed to facilitative comprehensive economic analyses. Our inability to quantify all benefits and costs is a valid reason to treat the findings of these studies with caution but not a valid reason to reject economic analyses completely (Arrow et al, 1996).

The Pace of Reform

When the control of Congress in the United States shifted in November 1994 from the Democratic Party to the Republican Party, there was a dramatic effort, as part of the so-called Contract with America, to achieve far-reaching reform of the U.S. regulatory system with one unified statute. Although a far-reaching reform measure passed the House of Representatives with significant bipartisan support in March 1995, a similar measure failed to pass the Senate in July 1995 when liberal Democratic Senators successfully threatened a filibuster (Sunstein, 1995). Organized environmental and consumer advocates demonstrated their determination to block any sweeping reform effort. In light of the intensity of opposition to sweeping regulatory reform, it is likely that reform in the United States will occur in an evolutionary fashion.

What can be expected is that requirements for better use of scientific and economic analysis will gradually be built into the standard operating procedures of agencies. In the last Congress, for example, strong bipartisan majorities in the U.S. Congress passed new legislation covering the safety of drinking water, foods, and oil pipelines. Each of these laws provides an essential role for risk analysis and, to a lesser extent, benefit-cost analysis in the future decisions of federal agencies.

The Presidency can also be expected to be a continued source of interest in risk analysis and benefit-cost analysis. The Clinton Administration=s 1993 executive order on regulatory planning reinforced the commitments of the Reagan/Bush Administrations to proper use of risk analysis and benefit-cost analysis in regulatory decision making. In 1996 the Clinton Administration issued a Abest practices@ document for agencies that embraces much of the agenda that is described in this paper. Although the Clinton Administration often does not implement its own policy toward regulatory review, Democratic leaders do not openly oppose risk analysis and benefit-cost analysis as appropriate contributions to the regulatory process. Interestingly, the Clinton Administration is currently working with key members of Congress to determine whether modest regulatory reform legislation can be passed that will make the process of regulatory review more open, scientific, and analytical.

A key to making significant analytical reforms is persuading environmental and consumer adocates that reform is not antithetical to their interests. Efforts in this direction are being made and there are some indications that these analytical tools are perceived to have value (Graham and Hartwell, 1997; Tal, 1997). But it is not likely that organized environmental groups and consumer advocates will embrace tools that have, as a premise for their use, that limitations should exist on the amount of resources devoted to public health and environmental protection.

Technocracy Versus Populism

There will always be a tension between populist and technocratic notions of regulation. By

their nature, analytic tools such as risk analysis and benefit-cost analysis tend to entrust power in scientists and technical experts. Advocates of public participation in regulatory decision making will tend to mistrust these tools because it is difficult for people who lack access to expertise and specialized data to gain insight from these tools and to compete effectively in the technical arena (McGarity, 1990; Martin, 1991). Moreover, there are numerous situations where experts disagree about what the facts are, what should be done about risks, and even about what research should be conducted (Graham et al, 1988). There is plenty of evidence that social values do play a role in how scientists and engineers in a society interpret uncertain knowledge for use in regulatory contexts (Jasanoff, 1990).

Although the public in the United States may indeed move in the direction of granting more power to scientists in administrative agencies on matters of public health and environmental protection, the public is unlikely to relinquish ultimate popular control of regulatory decision making. In the final analysis, decisions about which risks to regulate and how much to regulate them are a matter of values as much as a matter of science. Just as patients are insisting final control over what physicians recommend be done to enhance health, the public will insist on final control over what regulators recommend be done in the name of protection against risk.

A successful marriage of technocracy and populism in risk regulation is not impossible but will require important changes in American culture. Public faith in the adversarial approach to dispute resolution, including the public=s faith in the legal profession, will need to be scrutinized. Respect for scientists, engineers, and economists among citizens and the mass media needs to be reinforced. Meanwhile, a greater degree of scientific literacy on the part of the public will need to be cultivated at the same time that scientists learn to acknowledge the uncertainties in their knowledge and the appropriate place for value judgements in regulatory decision making. Obviously, changes of these sorts in American culture will take generations to occur.

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