Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform

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This article reviews the empirical evidence on the results of regulation of health and safety risks. It notes dramatic variances in the costs per life saved of various health and safety regulations which implies serious misallocations of social resources. The authors argue that problems of over and under regulation are the result of political and regulatory processes insufficiently disciplined by technocratic tools, especially scientific risk assessment and cost-benefit analysis. On the other hand, both scientific risk assessment and cost-benefit analysis are themselves beset by numerous technical and normative frailties, hence requiring in turn that public participation in the regulatory process discipline the use of these technocratic tools so that scientific and technical analysts do not over-step the legitimate bounds of their disciplines and usurp value judgments more properly made ultimately by citizens in a liberal democracy. Hence, science must discipline politics and politics must discipline science. The article develops a set of institutional proposals for risk regulation designed to assign appropriate roles to technocratic and democratic tools in regulatory reform.

Cet article passe en revue les résultats de la réglementation des risques pour la santé et la sécurité. Il relève les écarts importants dans les coûts des diverses réglementations visant à sauver des vies humaines, mettant ainsi en lumière la mauvaise allocation de ressources sociales. Les auteurs sont d'avis que la sur/sous-réglementation est le fruit d'un processus politique et réglementaire insuffisamment discipliné par des outils technocratiques tels l'évaluation du risque et les analyses coûts-bénéfices. Toutefois, les évaluations du risque et les analyses coûts-bénéfices sont à leur tour soumises à des limites techniques et normatives, nécessitant conséquemment la participation publique afin que l'analyse scientifique et technocratique ne dépasse pas ses limites. Cette analyse ne doit pas usurper le pouvoir décisionnel des citoyens dans une démocratie libérale. Ainsi, la science doit discipliner la politique et vice-versa. L'article suggère un ensemble de mécanismes institutionnels de réglementation capable d'assigner un rôle approprié aux outils démocratiques et technocratiques.

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I. Introduction

We spend too much money for too little safety. This assertion lies at the heart of the recent wave of political and academic criticism levied against risk regulation.[1] In a leading study, Tammy Tengs and John Graham surveyed 185 life-saving interventions and their implementation in the United States. They found "the annual resources consumed by those interventions total approximately $21.4 billion. For such a sum, we avert approximately 56,700 premature deaths and save 592,000 years of life annually. On average we spend about $376,000 per life or $36,100 per life year saved."[2] In considering the opportunity costs of these investments, they conclude that if resources were better allocated, the same $21.4 billion could save a total of 117,000 lives annually. "That represents an additional 60,200 lives saved, or about twice as many lives saved relative to the status quo."[3] As they comment, "it is hard to defend the regulation of some toxins at a cost of billions of dollars per life saved while children go without immunizations and women cannot afford good pre-natal care."[4] To illustrate their point, consider that approximately $17 million per life year saved is expended to prevent deaths from benzene exposure, while 70 percent of women over fifty in the United States do not receive mammograms which cost a mere $17,000 per life year saved.[5] Cass Sunstein notes that in the U.S., "resources for risk reduction are badly allocated ... Some regulations cost $100,000 or less per life saved; a number cost less than $1 million; many cost between $1 million and $5 million; and many range between $5 million and over $1 billion per life saved."[6] W. Kip Viscusi and Richard Zeckhauser warn that "[u]nless we reorient our risk-management policies, we will continue to pay more than we should for health gains that are less than we could achieve."[7] Niels Lind, a Canadian risk expert from the University of Waterloo, echoes

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[1] Environmental, health and safety regulations are all aimed at reducing hazardous risks of various kinds. We will discuss examples of each type of regulation in this article, since our focus is on the efficient regulation of these risks generally.

[2] T.O. Tengs & J.D. Graham, "The Opportunity Costs of Haphazard Social Investments in Life-Saving" in R.W. Hahn, ed., *Risks, Costs and Lives Saved: Getting Better Results from Regulation?* (New York: Oxford University Press, 1996) 167 at 172 [hereinafter *Risks, Costs*].

[3] *Ibid.*

[4] *Ibid.* at 180.

[5] *Ibid.* at 167. There are differences in the nature of certain risks which might explain some discrepancies in allocations. That is, some risks are severely dreaded, and the public is willing to pay more to avoid them. For example, we are willing to pay more to avoid dying in a plane crash than in an automobile accident. Moreover, how voluntary a risk is, as well as the degree to which citizens can insure against it may also account for some of the discrepancy in resource allocation. We will address these issues in greater detail in Parts III and IV, below.

[6] C.R. Sunstein, "The Cost-Benefit State" in *Chicago Working Paper in Law and Economics* (Working Paper No. 39 (2d Series)) (1996) at 9-10.

[7] W.K. Viscusi & R. Zeckhauser, "Risk Within Reason" (1990) 248 Science 559, reprinted in W.K. Viscusi, *Fatal Tradeoffs: Public and Private Responsibilities for Risk* (New York: Oxford University Press, 1992) 149 at 149 [hereinafter cited to *Fatal Tradeoffs*]. See also A.I. Ogus, "Risk Management

this sentiment, claiming "[t]here is enormous room for improvement"[8] in Canadian regulation.

This article seeks to explain why regulatory initiatives currently achieve sub-optimal results. Although a number of factors contribute to the problem, the institutional arrangements now in place are primarily responsible. The main deficiency is that the regulatory process is undisciplined and inconsistent, often "overreacting to small and speculative risks while leaving larger and more certain risks unattended."[9]

This article is guided by a single question: what would ideal risk regulating institutions look like in a free and democratic society? We argue that such institutions would seek to maximize the following values: safety, efficiency, equity, and democratic process values, namely, transparency, legitimacy, and citizen participation. The focus of this article is conceptual issues of institutional design. It does not pursue empirical questions of the extent to which, or ways in which, Canadian risk regulating agencies, either in general or in particular cases, in fact conform to or diverge from our ideal model, which portends an important future research agenda.

A. The Drive for Regulatory Reform

Regulatory reform has become a major political issue in both Canada and the United States. The total compliance costs of regulations in the U.S. for 1995 were estimated by one expert at $668 billion U.S. The average American household carries a $7,000 yearly regulatory burden, as compared to only $6,000 for taxes.[10] Environmental, health and safety regulations comprise a significant portion of these costs.

While taxes are sometimes criticized for being too high, no one denies that some taxes are necessary. Even the most ardent libertarian acknowledges the need for taxation in order to fund essential public goods, like national defence. Rather, the argument is that greater efficiencies than presently attained can be realized through lowering taxes. Similarly, when regulatory excesses are criticized, it should be recognized that some regulations are necessary. From an economic point of view, regulation is

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and 'Rational' Social Regulation" in R. Baldwin, ed., *Law and Uncertainty: Risks and Legal Processes* (New York: Kluwer Law International, 1997) 139.

[8] N. Lind, "Policy Goals for Health and Safety" (1995) 6 Risk Analysis 639 at 643.

[9] Center for Risk Analysis, "Reform of Risk Regulation: Achieving More Protection at Less Cost", Harvard School of Public Health, (Working Paper, March 1995) at 5.

[10] See "Over-Regulating America" *The Economist* 340:7976 (27 July 1996) 19 at 19. The figures used are those of Thomas Hopkins of the Rochester Institute of Technology. Using Hopkins' 1992 estimate of $500 billion, Viscusi notes that "[t]his total can be divided up in various ways. More than half the cost is attributable to paperwork requirements arising out of regulations, but there is also more than $200 billion in direct costs of regulation, including costs to business. More than half of this amount is due to environmental regulation, and much of the remainder is attributable to various forms of risk regulation" (W.K. Viscusi, "Economic Foundations of the Current Regulatory Reform Efforts" (1996) 10:3 J. of Econ. Perspectives 119 at 119) [hereinafter "Economic Foundation"]. For a study of regulatory costs in Canada, see F. Mihlar, *Regulatory Overkill: The Cost of Regulation in Canada* (Vancouver: Fraser Institute, 1996).

justified when the marginal social benefits of each dollar spent regulating exceeds the marginal social costs.

The drive behind regulatory reform is premised on the belief that by lessening the regulatory burden on individuals and businesses, resources that would otherwise have been allocated to comply with regulations would now be allocated more efficiently. For example, when the government passes air pollution regulation requiring businesses to alter their manufacturing processes, the costs are often reflected in lower profits for business and in higher prices for consumers. Unless there are some incontrovertible countervailing benefits—in this case a cleaner environment and resultant health benefits—that exceed the costs imposed, the regulation does more harm than good. Implicit in the critique of over-regulation is that the costs of regulation exceed the benefits, or that if the benefits of certain regulations exceed their cost, even greater benefits could be realized by substituting other forms of regulation.

B. Market Failure and the Need for Regulation

Reliance on markets and a system of private exchange to allocate risks is often impracticable due to information failures of various kinds. Where product safety is concerned, this may justify the provision of mandatory information so that consumers can make more informed choices. But even assuming that perfect information were made available to all consumers, the time, energy and skill required to process such information entail additional costs. An attempt to absorb the instructions accompanying a bottle of cold medicine illustrates how complex and intimidating such information may be. Predicting consumer reactions to safety labels or instructions—especially the under- or over-reactions—will often be quite conjectural. Thus, information failures are not always easily remedied merely through the provision of additional information. In some instances more stringent regulation, such as minimum product standards or outright bans, may be required.[11] Apart from information failures, externalities (negative impacts on involuntary third parties) are another significant form of market failure — exemplified most clearly in the case of pollution — that may justify regulation and to which informational policies will rarely be responsive.[12]

C. Legal Failure and the Need for Regulation

Some would argue that a combination of the market, even given its imperfections, and the tort system is preferable to more direct forms of regulation. For those risks

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[11] For a more detailed discussion of these issues, see W.K. Viscusi & R. Zeckhauser, "Hazard Communication: Warnings and Risk" (1996) 545 Annals of the American Academy of Political and Social Science [hereinafter Annals] 106.

[12] For a discussion of market failure and the need for regulation, see R. Noll, "Reforming Risk Regulation" (1996) 545 Annals 165 at 167, J. Krier, "Risk and the Legal System" (1996) 545 Annals 176, and D. Dewees, F. Mathewson & M.J. Trebilcock, "The Rationale for Government Regulation of Quality" in D. Dewees, ed., *The Regulation of Quality* (Toronto: Butterworths, 1983).

that do materialize in harms that were not voluntarily undertaken,[13] the tort system, operating *ex post*, will compensate victims and create *ex ante* incentives for firms to make cost-justified investments in safety precautions, thereby leading to a socially optimal level of safety.[14]

This argument is problematic for several reasons. First, it assumes that there is no legal failure of any kind. For the tort system to work optimally as an *ex ante* deterrent, it is necessary that all meritorious claims are brought to trial and correctly decided (or settled). Otherwise, tortfeasors can continue to create unreasonable risks without fear of paying damages, and will therefore be less likely to invest in safety precautions. However, given the enormous transaction costs, collective action and difficult causation problems many cases present, potentially successful claimants are deterred from litigating, resulting in legal failure, which can be more properly defined as the failure of the legal system to achieve welfare maximizing results.[15]

Even if we assume that there is no legal failure, there are still compelling reasons to regulate. Consider the thalidomide tragedy. Marketed as a non-toxic drug which "had no side effects and was completely safe for pregnant women,"[16] many unsuspecting women took the two pill-a-day suggested prescription in their first trimester to alleviate some of the adverse effects of their pregnancy, such as morning sickness. Tragically, the drug turned out to be teratogenic, leading to approximately 10,000 babies born worldwide[17] with deformities and internal injuries of various kinds. Tort actions can only be brought after the risks have materialized into harms. It is small comfort to the victims and their parents to receive *ex post* compensation for the injuries sustained. Full compensation for such injuries is inherently impossible. Clearly, victims and their parents would have preferred some form of direct *ex ante* regulation so that the tragedy could have been averted.

D. Public Risk Perception and the Demand for Regulation

Regulation is often necessary to redress market and legal failures. When regulation is tailored to address these shortcomings, it is typically cost-justified. Real-world politics, however, is often a far cry from ideal theory. In practice, regulations are often

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[13] For instance, due to either information failures that make the voluntary assumption of risk impossible, or externalities from other transactions.

[14] See R. Posner, "A Theory of Negligence" (1971) 1 J. Legal Studies 29.

[15] For a more detailed discussion of the obstacles to litigation, see D. Dewees, D. Duff & M.J. Trebilcock, *Exploring the Domain of Accident Law: Taking the Facts Seriously* (New York: Oxford University Press, 1996) [hereinafter *Exploring the Domain*]; D. Dewees & M.J. Trebilcock, "The Efficacy of the Tort System and Its Alternatives: A Review of Empirical Evidence" (1992) 30 Osgoode Hall L.J. 57 [hereinafter "The Efficacy of the Tort System"].

[16] The Sunday Times Insight Team, *Suffer the Children: The Story of Thalidomide* (London: Andre Deutsch, 1979) at 2.

[17] See Report on CBC's "National Magazine" (26 June 1996).

implemented without careful analysis of the resulting costs and benefits, or with a view to the market and legal failures that necessitate them.

Life threatening health and safety risks that potentially affect a significant segment of the population typically generate wide-spread public concern and, hence, political demands for government action. Witness the response to Rachel Carson's influential book, *Silent Spring*,[18] which sparked a public outcry and increased regulation of pesticides. Meryl Streep was instrumental in publicizing the successful campaign to ban the sale of Alar, a pesticide frequently used on apple crops, in the late 1980s.[19] The Love Canal incident led to major U.S. environmental legislation.[20] The Three Mile Island accident increased public demands for the regulation of nuclear power. Ontario implemented stringent regulations after conducting a Royal Commission Report examining asbestos-related health risks following the mesothelioma deaths of workers and the public furor that ensued.[21] The recent mad cow crisis in England has raised demands for increased regulation of beef.

The public's perception of risk can directly influence the intensity of the demands for regulation, but is often seriously flawed with systemic overestimation of the probability of some risks, such as dying in an airline crash, and the underestimation of others.[22] For example, Bruce Ames and Lori Gold point out that "pollution appears to account for less than 1 percent of human cancer; — yet public concern and resource allocation for chemical pollution are very high."[23] They also note that "by weight, there are more rodent carcinogens in a single cup of coffee than there are potentially

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[18] R. Carson, *Silent Spring* (Boston: Houghton Mifflin, 1962).

[19] See K. Harrison & G. Hoberg, *Risk, Science, and Politics* (Montreal: McGill-Queen's University Press, 1994) at 55.

[20] See C.R. Sunstein, *Free Markets and Social Justice* (New York: Oxford University Press, 1997) at 309 [hereinafter *Free Markets*].

[21] See *Report of the Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario*, vols. 1-3 (Toronto: Ontario Ministry of the Attorney General, 1984) (Chair: J. Stefan Dupré). See also P. Brodeur, *Outrageous Misconduct: The Asbestos Industry on Trial* (New York: Pantheon Books, 1985).

[22] Public perception of risk is not always irrational, and is at times superior to expert judgment. See P. Slovic, "Perceived Risk, Trust, and Democracy" (1993) 13 Risk Analysis 675 at 675 [hereinafter "Perceived Risk"]. He states:

> Early studies of risk perception demonstrated that the public's concerns could not simply be blamed on ignorance or irrationality. Instead, research has showed that many of the public's reactions to risk could be attributed to a sensitivity to technical, social, and psychological qualities of hazards that were not well-modeled in technical risk assessments (*e.g.*, qualities such as uncertainty in risk assessments, perceived inequity in the distribution of risks and benefits, and aversion to being exposed to risks that were involuntary, not under one's control, or dreaded). The important role of social values in risk perception and risk acceptance thus became apparent.

[23] B.N. Ames & L. Swirsky Gold, "The Causes and Prevention of Cancer: Gaining Perspectives on the Management of Risk" in *Risks, Costs, supra* note 2, 4 at 4.

carcinogenic pesticide residues in the average American diet in a year."[24] Alvin Weinberg notes that "[t]he connection between low-level insult [radiation] and bodily harm is probably as difficult to prove as is the connection between witches and failed crops. That our society nevertheless has allowed this issue to emerge as a serious social concern ... is hardly less fatuous than were the witch-hunts of the Middle Ages."[25]

A host of factors contribute to perceived risk. Paul Slovic notes:

> A major development in this area has been the discovery of a set of mental strategies, or heuristics, that people employ in order to make sense out of an uncertain world. Although these rules are valid in some circumstances, in others they lead to large and persistent biases, with serious implications for risk assessment. In particular, laboratory research on basic perceptions and cognitions has shown that difficulties in understanding probabilistic processes, biased media coverage, misleading personal experiences, and the anxieties generated by life's gambles cause uncertainty to be denied, risks to be misjudged (sometimes overestimated and sometimes underestimated), and judgments of fact to be held with unwarranted confidence.[26]

E. Government Responses

According to Roger Noll, the following problem presents itself: "How does one deal with incoherence in demands for regulation by citizens?"[27] Governments, unfortunately, have not responded well to this challenge. Instead of judiciously assessing the magnitude of the risks that are subject to citizen demands and weighing the costs and benefits of regulation, governments frequently respond with highly visible, direct forms of regulation, such as *ex ante* or *ex post* bans on hazardous products, and *ex ante* or *ex post* minimum standard setting.[28] Often this results in over-regulation of some risks and the under-regulation of others.

Economic models of government may be able to account for this phenomenon. Voters and politicians can be conceived of as demanders and suppliers of policies respectively, with the behaviour of both being primarily motivated by self-interest, just

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[24] *Ibid.* at 5.

[25] A.M. Weinberg, "Science and Its Limits: The Regulator's Dilemma" in C. Whipple, ed., *De Minimis Risk* (New York: Plenum Press, 1987) 27 at 37-38.

[26] P. Slovic, "Perception of Risk" (1987) 236 Science 280 at 281. See also R.E. Kasperson & J.X. Kasperson, "The Social Amplifieation and Attenuation of Risk" (1996) 545 Annals 95. For a discussion of the heuristics referred to, see A. Tversky & D. Kahneman, "Judgment Under Uncertainty: Heuristics and Biases" in D. Kahneman, P. Slovic, & A. Tversky, eds., *Judgment Under Uncertainty: Heuristics and Biases* (Cambridge: Cambridge University Press, 1982) c.1, reprinted from (1974) 185 Science 1124.

[27] *Supra* note 12 at 173. See also R.G. Noll & J.E. Krier "Some Implications of Cognitive Psychology for Risk Regulation" (1990) 19 J. Legal Studies 747.

[28] See G. Hadfield, R. Howse & M.J. Trebilcock, "Rethinking Consumer Protection Policy" (Center for the Study of State and Market Working Paper) (University of Toronto Roundtable on New Approaches to Consumer Law, 20 June 1996) at 6.

as it is in private markets. Self-interest in the case of voters encompasses an infinitely wide range of sources of utility. Self-interest in the case of politicians might also entail a wide range of objectives, but an immediate objective that must be met in order to meet more ultimate objectives would seem to be the attainment of electoral office. In this sense, vote maximization might be viewed as the dominant factor governing politicians' behaviour. Toward this end, direct forms of regulation are often in politicians' best interests and will accordingly be pursued in many cases. Highly dogmatic forms of regulation — "hazardous products are banned" or "pollution must stop" —drastically reduce the information costs faced by voters in determining a government's policies on these matters and have high symbolic value in signaling strong ostensible commitment by government to these goals. Direct regulation demonstrates to the population that proactive steps are being taken whereas relying on market forces even supplemented by mandated provision of information and tort liability may create the impression that too little or nothing is being done. Even though in some instances the more efficient response would be to rely on the market and tort system where the costs of regulation would be higher than maintaining the status quo (although for the reasons considered above this will not always be the case, given market and legal failures), the fact that these benefits may be unperceived by voters creates a strong incentive to take more decisive action.[29]

Although regulators are not subject to the same direct political pressures as politicians, and many regulations are implemented without any public scrutiny whatsoever, agency problems exist which one would predict, if left unchecked, would lead to overregulation. Regulators regulate. The more of it they do, the more likely they are to receive prestige, power and recognition, at least within their own bureaucratic circles. Thus, there is an incentive for regulators to regulate more aggressively than is perhaps optimal, just as there is for politicians.

U.S. Supreme Court Justice Stephen Breyer, in his book, *Breaking the Vicious Circle*, argues that inefficiencies in U.S. regulation are a product of institutional design. Three problems are particularly pressing, including what he calls "tunnel vision of agencies" that single-mindedly pursue goals to the point of bringing about more harm than good; "random agenda selection" where agencies respond to public opinion in an undisciplined fashion; and "inconsistency" among different regulatory agencies in the assessment of risks and implementation of regulations.[30]

The vicious circle Breyer describes, in which these three problems manifest themselves, comes about through the dynamic interplay of another three factors: (1) public risk perception, (2) Congressional action and reaction, and (3) uncertainties in the technical regulatory process. The public pressures Congress on the basis of perceived risk. Congress in turn pressures agencies to act. The regulatory process is initiated, and there is invariably controversy and uncertainty in the risk assessments.

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[29] See Dewees, Mathewson & Trebilcock, *supra* note 12.

[30] See S. Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Cambridge: Harvard University Press, 1993).

When the public learns of these uncertainties through a sensationalist media, it becomes more anxious and increases its pressure on Congress, leading to the vicious circle. The results, according to Breyer, are random agenda selection, tunnel vision and inconsistency.[31]

F. Results of Regulation

Not surprisingly, the regulatory efforts of governments have met with mixed reviews. A recent study by Robert Hahn of the Brookings Institute concludes that "we have reason to believe that most regulations implemented in the [U.S.] since 1990 would not pass a cost-benefit test."[32] The following table illustrates some of the dramatic discrepancies in resource allocation to various risk regulations:[33]

[31] See *ibid.* at 11-29.

[32] R.W. Hahn, "Regulatory Reform: What Do the Government's Numbers Tell Us?" in *Risks, Costs, supra* note 2, 208 at 225.

[33] Table modified from Sunstein, *supra* note 20 at 304, which in turn was taken from R. Lutter & J.F. Morrall, "Health-Health Analysis" (1994) 8 J. Risk and Uncertainty 59.

Resource Allocation to Risk Regulations			
Budgeted Regulations	Year	Agency	Cost Per Life Saved (Millions of 1992 (U.S.) $)
Steering Column Protection	1967	NHTSA	0.1
Unvented Space Heaters	1980	CPSC	0.1
Cabin Fire Protection	1985	FAA	0.3
Passive Restraints/Belts	1984	NHTSA	0.4
Fuel System Integrity	1975	NHTSA	0.4
Trihalomethanes	1979	EPA	0.4
Underground Construction	1989	OSHA-S	0.4
Alcohol & Drug Control	1985	FRA	0.7
Servicing Wheel Rims	1984	OSHA-S	0.7
Seat Cushion Flammability	1984	FAA	0.8
Floor Emergency Lighting	1984	FAA	0.9
Children's Sleepware Flammability	1974	CPSC	1.8
Side Doors	1979	NHTSA	1.8
Hazard Communication	1983	OSHA-S	2.4
Asbestos	1986	OSHA-H	2.8
Grain Dust	1987	OSHA-S	8.8
Benzene	1987	OSHA-H	23.1
Ethylene Oxide	1984	OSHA-H	34.6
Acrylonitrile	1978	OSHA-H	50.8
Asbestos	1989	EPA	72.9
Coke Ovens	1976	OSHA-H	83.4
Arsenic	1978	OSHA-H	125.0
DES (Cattlefeed)	1979	FDA	178.0
Arsenic/Glass Manufacturing	1986	EPA	192.0
Benzene/Storage	1984	EPA	273.0
Radionuclides/DOE Facilities	1984	EPA	284.0
Acrylonitrile	1978	OSHA-H	416.0
Benzene/Maleic Anhydride	1984	EPA	1,107.0
Formaldehyde	1987	OSHA-H	119,000.0

Empirical studies of safety standards adopted by the U.S. Consumer Product Safety Commission (CPSC) find trivial to non-existent safety benefits from regulations pertaining to such matters as child-resistant caps, mattress flammability standards, bicycle safety regulations, carpet and rug flammability regulations and children's crib regulations. Similar studies find that even where product safety standards do generate safety gains, often the safety benefits are outweighed by the costs, both direct and indirect, generated by the standards. This appears to be so, for example, with respect to urea formaldehyde foam standards, power lawnmower standards, matchbook standards and architectural glazing standards.[34] Other regulatory expenditures have proved much more cost effective and beneficial — for instance, steering column protection, airplane cabin fire protection and passive restraints and seat belts required in automobiles.

In light of these findings, what can be done to make risk regulation more efficient? We argue that a more judicious use of science and cost-benefit analysis in the regulatory process would lead to significant improvements. Currently, inconsistent and irrational demands by citizens are met with undisciplined government responses, contributing in part to the inefficient results observable today.

Science and cost-benefit analysis can help address these difficulties and discipline politics. To achieve the primary goal of risk regulation — maximizing safety at least cost — two steps must be taken. The first is an assessment of the magnitude of the risks confronted, while the second is a determination of the costs and benefits of proposed regulatory responses. Consider the regulation of a supposedly carcinogenic substance such as saccharin. Is saccharin carcinogenic? If so, how potent a carcinogen is it? How many annual cases of cancer are expected per year given a certain level of consumption? These questions, which are amenable to scientific inquiry, must be answered if we are to regulate effectively. Once risks are assessed scientifically, cost-benefit analyses should be conducted on proposed regulatory responses to determine whether they are cost-justified.

The use of science and cost-benefit analysis, then, is warranted because these technocratic tools will constrain the political process by targeting the most pressing risks and tailoring measured responses to them. Decisions based on these techniques are also of value because they can be more easily justified to the public, since they are made by following a well-defined process that citizens can scrutinize.

However, both science and cost-benefit analysis are subject to serious limitations, most notably significant uncertainties. It is extremely difficult to arrive at accurate assessments of the magnitude of risks, such as the probability of a nuclear reactor core meltdown. Perhaps even more complex is a determination of the costs and benefits of proposed regulatory responses. For instance, in considering the costs and benefits of

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[34] See "Efficacy of the Tort System", Dewees & Trebilcock, *supra* note 15 at 101. See also *Exploring the Domain*, *supra* note 15 at 223-30.

building a nuclear reactor and the appropriate safety features it should have, what is the appropriate value to assign to a life that may be lost in the event of a nuclear accident?

In light of these pervasive uncertainties, experts are often required to make value judgments. Sheila Jasanoff claims that "most risk analysts, regardless of their disciplines, would probably agree ... that facts and values frequently merge when we deal with issues of high uncertainty."[35] These value judgments are in essence a political matter, and experts are no better than other members of the public in making them. Thus, the role of experts, necessary to discipline the excesses of unconstrained politics, must be limited. Experts should not overstep their bounds—politics must also discipline science. Without politics tempering science, there is a risk of excluding the public from the decision-making process and relying on relatively unaccountable experts to make decisions that are not wholly technocratic in nature. As Jasanoff states, "the cost of risk management by technical experts is that the public relinquishes control over important political and value choices."[36]

Part II analyzes the strengths and limitations of science, while Part III does the same for cost-benefit analysis. Part IV contains proposals for regulatory reform—how best to use science and cost-benefit analysis to maximize efficiency, while at the same time providing mechanisms for the public to participate meaningfully in the regulatory process.

II. Strengths and Limitations of Science

A. Risk Assessment and Risk Management

Consider first the use of science in the process of risk regulation. Following William Lowrance, a fundamental distinction must be made between "*measuring risk*, an objective but probabilistic pursuit; and *judging the acceptability of that risk (judging safety)*, a matter of personal and social value judgment."[37] Former EPA Administrator William D. Ruckelshaus defines the terms as follows:

> Risk assessment is the use of a base of scientific research to define the probability of some harm coming to an individual or a population as a result of exposure to a substance or situation. Risk management, in contrast, is the public process of deciding what to do where risk has been determined to exist. It includes integrating risk assessment with considerations of engineering feasibility

[35] S. Jasanoff, "Bridging the Two Cultures of Risk Analysis" (1993) 13 Risk Analysis 123 at 123.

[36] S. Jasanoff, *Risk Management and Political Culture: A Comparative Study of Science in the Policy Context* (New York: Russell Sage Foundation, 1986) at 81.

[37] W.W. Lowrance, *Of Acceptable Risk: Science and the Determination of Safety* (Los Altos, Calif.: William Kaufmann, 1976) at 8 [emphasis in original].

> and figuring out how to ... reduce risk in the light of social, economic, and political factors.[38]

Lowrance elaborates that

> [f]ailure to appreciate how safety determinations resolve into the two discrete activities is at the root of many misunderstandings. In one of the most common instances, it gives rise to the false expectation that scientists can *measure* whether something is safe. They cannot, of course, because the methods of the physical and biological sciences can assess only the probabilities and consequences of events, not their value to people.[39]

The distinction between risk assessment and risk management is a common feature of both the Canadian and U.S. regulatory regimes[40] and is also now recognized in the WTO *Agreement on Technical Barriers to Trade* and the *Agreement on the Application of Sanitary and Phytosanitary Measures* negotiated during the Uruguay Round of multilateral trade negotiations (and similar provisions in the North American Free Trade Agreement (NAFTA)).[41]

A hypothetical example serves to illustrate Lowrance's point. Suppose that a new food additive is developed, and that the manufacturer seeks regulatory approval of the additive before distributing it on the market. Scientists will conduct a variety of tests and studies to determine the risks associated with the use of the product. Suppose further that the scientists can conclude with near certainty that the additive, if consumed in a certain amount over a certain period of time (for instance a typical daily intake), will lead to a 1/1000 chance of developing cancer within five years. Have the scientists concluded the product is safe or unsafe?

Clearly the scientists have not answered this question. They have merely provided the decision-maker with a highly useful set of facts about the risks associated with the product that the decision-maker can then use to make a judgment about the product's acceptability. Whether a 1/1000 risk of developing cancer in five years by consuming the product is acceptable or not depends on a host of non-scientific factors. What are the benefits of the product? Can we do without it? Are there alternatives available? If so, how much more expensive are they? What risks do they entail? Should the product be allowed on the market if information is provided to the consumers so that they can voluntarily choose whether to assume the risks associated with it? Lowrance writes that "[d]eciding whether people, with all their peculiarities of need, taste, tolerance,

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[38] W.D. Ruckelshaus, "Risk in a Free Society" (1984) 4 Risk Analysis 157 at 157.

[39] *Supra* note 37 at 9 [emphasis in original].

[40] See "Health Risk Determination: The Challenge of Health Protection" (Canada: Health Protection Branch (1993)) [hereinafter "Health Risk Determination"]. See also R.A. Pollak, "Government Risk Regulation" (1996) 545 Annals 25 at 26.

[41] *Agreement Establishing the World Trade Organization*, Annex 1A (1994), online: WTO <http://www.wto.org/wto/legal/Finalact.htm>. See also the recent WTO Panel Decision in the Beef Hormone case for an extensive discussion of this distinction, *EC — Measures Concerning Meat and Meat Products* (1997), WTO Doc. WT/0548/R/CAN (Panel Report), online: <http://www.wto.org/wto/dispute/distab.htm>.

and adventurousness, might or should be willing to bear the estimated risks is a value judgment that scientists are little better qualified to make than anyone else."[42]

B. Is Risk Assessment a Science?

Accepting in principle the distinction between risk assessment and risk management, we may ask, just how scientific is risk assessment? First, we should clarify what is meant by "science". Cumming writes that "[s]cience uses the 'scientific method' as an investigative tool, whereby experimental observations are interpreted as supporting or failing to support well defined hypothetical alternatives."[43] In the context of risk assessment, science seeks to answer questions such as "how hazardous is X?" If X is a suspected carcinogen, presumably scientific studies can be conducted that can predict the effects of exposure at different doses. If X is a complex engineering system, such as a dam, presumably science can make predictions about the probabilities of an accident.

Science, however, is able to explain only relatively simple causal mechanisms with a great deal of accuracy. The more complex the system and the more variables at play, the more difficult it becomes to design effective experiments and reach definitive conclusions. Much risk assessment is concerned with complex problems where experiments are difficult to design and control. Consequently, the results of scientific risk assessments are often uncertain. As John Graham and Lorenz Rhomberg observe, "all studies provide some information, albeit imperfect, about the nature and magnitude of the true risk. Each study is a view through a blurry window at the truth."[44]

Alvin Weinberg has coined the term "trans-science" to describe questions which can be asked within the framework of science but which are beyond the capacity of science to answer:

> Many of the issues which arise in the course of the interaction between science or technology and society — *e.g.*, the deleterious side effects of technology, or the attempts to deal with social problems through the procedures of science — hang on the answers to questions which can be asked of science and yet *which cannot be answered by science*. I propose the term *trans-scientific* for these questions since, though they are, epistemologically speaking, questions of fact and can be stated in the language of science, they are unanswerable by science; they transcend science.[45]

In a later article, he writes "[o]ne can think of a somewhat fuzzy demarcation between what I've called science and trans-science: the domain of science covers phenomena that are deterministic, or the probability of whose occurrence can itself be stated pre-

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[42] *Supra* note 37 at 9.

[43] R.R. Cumming, "Is Risk Assessment a Science?" (1981) 1 Risk Analysis 1 at 1.

[44] J. Graham & L. Rhomberg, "How Risks Are Identified and Assessed" (1996) 545 Annals 15 at 19.

[45] A. Weinberg, "Science and Trans-Science" (1979) 10 Minerva 209 at 209 [emphasis in original].

cisely; trans-science, the domain of events whose probability of occurrence is itself highly uncertain."[46]

C. Sources of Uncertainty

Uncertainty in risk assessment is inescapable. Ruckelshaus claims "[w]e should remember that risk assessment data can be like the tortured spy. If you torture it long enough, it will tell you anything you want to know."[47] The amount of uncertainty will vary depending on the nature of the risk to be assessed. Some risks are relatively well understood, such as the probability of being killed in a car accident or airline crash, since much actuarial data has accumulated over the years. Even this data, however, is unable to predict whether any particular driver or airline passenger will be killed, but it is sufficiently accurate upon which to base well-informed policy choices. M. Granger Morgan points out that it is considerably more difficult to assess risks where good actuarial data are unavailable. "The development of risk assessment during the past two decades has been in large part the story of finding ways to determine the extent of risks that have little precedent."[48]

Consider the risks associated with complex engineering systems, such as nuclear reactors or hydro-electric dams. Brooks writes that

> In an increasing number of cases, it is impossible to design an integral test of a whole engineering system; one can only infer its performance theoretically by compounding the results of experiments on separate components or by extrapolating the findings of experiments in a different regime of parameters than applicable in real life.[49]

Such is the case with nuclear reactors, where probabilistic risk assessments ("PRA") are used to measure risk. A PRA "seeks to identify all sequences of subsystem failures that may lead to a failure of the overall system" and "estimate the consequences of each system failure so identified."[50] A PRA is required for nuclear reactors because of the practical impossibility of building full-scale prototypes and testing them for their useful lives when immediate decisions need to be made about whether to proceed with the technology.

Probability risk assessments are fraught with uncertainties. In the case of nuclear reactors, Weinberg notes that a PRA "requires two separate estimates: first, an estimate of the probability of each accident sequence, and second an estimate of the consequences — particularly the damage to human health — caused by the uncontrolled

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[46] *Supra* note 25 at 29.

[47] *Supra* note 38 at 157-58.

[48] M. Granger Morgan, "Risk Analysis and Management" (1993) 269:1 Scientific American 32 at 33.

[49] H. Brooks, "The Resolution of Technically Intensive Public Policy Disputes" (1984) 9:1 Science, Technology & Human Values 39 at 43.

[50] Weinberg, *supra* note 25 at 29.

effluents released in the accident."[51] With respect to the first estimate, Rasmussen, in the famous WASH-1400 nuclear reactor study, noted that "his estimate of core-melt probability might be in error by a factor of 10 — that is, the probability may be as high as 1 in 2000 reactor years or as low as 1 in 200,000 per [reactor year.]"[52]

The estimates of the possible health effects from the uncontrolled effluents released in the event of an accident are equally difficult to ascertain. Particularly problematic is modelling the effects of low level exposure to possible toxins. Various techniques are used by scientists to assess these types of risk, and regulation of possible carcinogens and other toxic substances are based upon them.

To illustrate some of the pervasive uncertainties in the assessment of exposure to hazardous substances, following Lave, we consider four common methods used by scientists towards this end: (1) case clusters, (2) structural toxicology, (3) long-term animal bioassays, and (4) epidemiology. Each of these techniques differs in cost, quality of information, and length of study time.[53]

Case clusters, or inferences from real world observation, are "the most rudimentary form of risk assessment."[54] Health professionals notice "one or more cases of a rare disease or an unusual concentration of a common one"[55] and attempt to find the cause. Lester Lave gives the example of Percival Pott, who inferred the cause of scrotal cancer among chimney sweeps,[56] and John Graham and Lorenz Rhomberg use the example of the Turkish hematologist Muzaffer Aksoy, who having noticed that a large number of shoe workers began to develop aplastic anemia and certain forms of leukemia, traced the cause to the growing use in shoemaking of commercially prepared, benzene-based adhesives. His findings were later confirmed by more detailed epidemiological studies.[57] Case clusters, however, are of limited value.[58] They are a good beginning point for further, more detailed research into potential health hazards, but on their own they are neither accurate nor definitive, in large part because they do not rigorously analyze causal relationships but instead rely on intuitive inferences from correlations.

A recent example of the use of case clusters in risk assessment is the mad cow crisis in Britain.[59] A higher than expected number of cases of Creutzfeldt-Jakob dis-

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[51] *Ibid.*

[52] *Ibid.* at 30.

[53] See L.B. Lave, "Methods of Risk Assessment" in L.B. Lave, ed., *Quantitative Risk Assessment in Regulation* (Washington, D.C.: Brookings Institution, 1982) 23.

[54] Graham & Rhomberg, *supra* note 44 at 19.

[55] Lave, *supra* note 53 at 28.

[56] See *ibid.* at 29.

[57] See *supra* note 44 at 16-17.

[58] Graham and Rhomberg note that "[c]linical intuition is fallible, however, and even if true, clinically based insights are hard to prove." (*ibid.* at 17).

[59] The following discussion is drawn from "Made in Britain" *The Economist* 338:7959 (30 March 1996) 17; "The BSE Scare: Mad Cows and Englishmen" *The Economist* 338:7959 (30 March 1996)

ease (CJD) was observed in humans. CJD causes victims' brains to rot, finally killing them. Some scientists believe there may be a link between this recent outbreak and bovine spongiform encephalopathy (BSE), a similar condition afflicting cattle. England has a high number of cows infected with BSE that have been slaughtered and sold in beef markets, and there is speculation that the recent rash of CJD has been triggered by people eating tainted beef. Although there is more information than merely the case clusters and the similar molecular structure of CJD and BSE upon which scientists have based their tentative findings, there is nevertheless significant uncertainty concerning the etiology of the disease, which has created considerable political and economic perturbation in the United Kingdom and the European Union.

Structural toxicology attempts to draw comparisons in chemical structure between suspected toxins and known toxins. For instance, if substance A is known to be carcinogenic, and substance B has an extremely similar molecular structure, an inference may be drawn that substance B is likewise carcinogenic. Such reasoning is highly speculative, although it is a fairly cheap and quick way to obtain at least some information about potential hazards.

Animal bioassays and epidemiological studies are the two best methods of the four we are considering, yet both are subject to serious limitations. Bioassays are controlled studies done on animals, typically mice and rats, where the potential risks to humans are predicted based on the responses of test animals to the hazardous substance. These studies are done on animals for a number of reasons. First and most importantly, conducting experiments of this nature on humans would be unethical. When we say we do not want to treat people like guinea pigs, we say it with good reason — test animals are given massive doses of potentially harmful substances and are subject to rigid controls before dying or being killed and dissected. Doing the same to a human being, needless to say, would be unconscionable. Second, rodents have short lifetimes and are relatively inexpensive to feed and house.[60] As a result, studies can be performed cheaply and quickly.

Underlying bioassays is the basic assumption that it is possible to extrapolate from animals to humans. This premise is not without some empirical corroboration. Virtually all human carcinogens are known to be animal carcinogens as well, although the converse is not true — we cannot assume that all animal carcinogens are human carcinogens.[61]

Selecting "the animal species that best predicts the response of man"[62] is a source of uncertainty. As Lowrance points out, "[m]an is unique. Therefore any extrapolative step can only be a hesitant one. No animal is a best model for man; for any given ex-

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25, "Coping with BSE" *The Economist* 346:8059 (14 March 1998) 15; "The Science of BSE: Bungled" *The Economist* 346:8059 (14 March 1998) 21.

[60] See Graham & Rhomberg, *supra* note 44 at 18.

[61] See Harrison & Hoberg, *supra* note 19 at 18.

[62] G. Majone, "Science and Trans-Science in Standard Setting" (1984) 9:1 Science, Technology & Human Values 15 at 17.

periment, one can only use the species that appears to be most like man in the aspects at question."[63] Lowrance then proceeds to describe some of the anomalous results obtained when conducting bioassays even on closely related species:

> For example, the median lethal dose for the physiologically active compound histamine is 400 milligrams of histamine per kilogram body weight for rats and 200 milligrams per kilogram for mice, but less than 1 milligram per kilogram for rabbits and guinea pigs. The infamous thalidomide, so horribly teratogenic to the human fetus, also causes birth defects in monkeys and rabbits — but not at all in rats.[64]

Majone notes that "[u]sing multiple species in toxicological experiments could improve predictions somewhat, but heterogeneity in human populations is often social in origin, and social conditions cannot be reproduced in the toxicologist's laboratory."[65]

Additional difficulties beyond selecting the correct species are determining how many tests will be run, what the mode of exposure to the impugned substance should be in the test, how large the dose should be, and how dosages should be extrapolated from animals to man.[66] These decisions are often subject to economic and time constraints. Majone provides the following example:

> [I]f we assume that a chemical ageut will cause cancer in 1 out of 10,000 people who are exposed to it, and that humans and test animals do not differ significantly in sensitivity with respect to the given agent, we must test at least 10,000 animals (but preferably something like 30,000 animals) to detect one case of cancer. In practice, no more than 50 or so animals are usually available per dose level; hence high doses are used on small samples of animals.[67]

Extrapolating from high doses to low doses is the subject of intense scientific controversy. "The theory is that a chemical that causes cancer at high doses will probably do so at low doses as well, though with less frequency at lower doses."[68] The choice of an extrapolating function is based on fitting an appropriate model to the data. There are three basic approaches that can be used: (1) a linear-dose response, (2) a threshold (nonlinear) dose-response leading to a virtually safe standard set at the threshold value, and (3) a non-linear curve at low doses that may indicate more or less serious health effects than the linear model would predict.[69]

Ames and Gold note that "[l]inear extrapolation from the maximum tolerated dose in rodents to low-level exposure in humans has led to grossly exaggerated forecasts of mortality."[70] Hendee adds that "we do not know, and probably cannot know

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[63] *Supra* note 37 at 64.
[64] *Ibid.*
[65] *Supra* note 62 at 17.
[66] See Lowrance, *supra* note 37.
[67] *Supra* note 62 at 17.
[68] Graham & Rhomberg, *supra* note 44 at 18.
[69] See Majone, *supra* note 62 at 16.
[70] *Supra* note 23 at 6.

with certainty, whether low doses cause any damage at all. Numerous studies of humans exposed to low doses of radiation have failed to show any statistically significant adverse health effects."[71] Important regulatory decisions are nevertheless made on this basis. In the famous saccharin studies of the 1970s, rats were given the saccharin equivalent of 800 diet beverages a day, as a result of which they developed bladder tumors.[72] An extrapolation then had to be made to humans from rats, problematic enough in itself, and complicated further by the need to extrapolate from high to low doses.

Establishing a virtually safe dose, or no observable effects level ("NOEL") is likewise subject to great uncertainty. A safety factor of 100 is often used, "meaning that test animals should show no adverse health effects from a given pollutant when exposed to doses at least 100 times greater than the likely human dose."[73] This number is somewhat arbitrary, although it is justified on the grounds that "humans may be ten times more sensitive than the experimental animals used, and that, in addition, there may be a tenfold variation in sensitivity among individuals."[74] The Health Protection Branch of Health Canada utilizes such safety factors,[75] as do provincial health and safety regulatory agencies, as well as state and federal agencies in the U.S. and other countries. Notwithstanding the somewhat arbitrary use of a safety factor of 100, there is deviation even from that norm. Harrison and Hoberg discuss the varying safety factors used by Health and Welfare Canada, Ontario, the Netherlands, New York State, and Germany — 100, 10, 4, 2, and 1 respectively — in assessing the risks of dioxin.[76]

Compounding the difficulties of bioassays is determining the best way to extrapolate from animals to humans once the best species has been selected as well as the best dose-response model. Lave points out that there are different ways of extrapolating from rodents to humans: "dose per unit body weight, body area, or concentration in inhaled or ingested substances."[77] As Lave says,

> The methods used for extrapolating from mouse to man can have significantly different results, as seen in the following example. Since a human weighs about 2,500 times as much as a mouse, a dose of 1 milligram per day to a mouse would be equivalent to a dose of 2,500 milligrams per day to a human, if extrapolation were done by weight. If extrapolation were done by surface area (which is proportional to weight to the two-thirds power), the mouse dose would be equivalent to a dose of 184 milligrams per day to a human. Thus if 1

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[71] W.R. Hendee, "Modeling Risk at Low Levels of Exposure" in *Risks, Costs, supra* note 2, 46 at 46.

[72] See Harrison & Hoberg, *supra* note 19 at 84-85. See chapter 5 for a discussion of the regulation of saccharin in Canada and the U.S.

[73] Majone, *supra* note 62 at 17.

[74] *Ibid.*

[75] See *supra* note 40 at 23-24.

[76] See *supra* uote 19 at 49.

[77] *Supra* note 53 at 42.

> milligram per day were the highest safe dose in a mouse, the highest safe dose in a human might vary from 184 to 2,500 milligrams per day.[78]

Epidemiological studies, unlike bioassays, focus on human populations, but despite this improvement, they too are subject to serious limitations. "The inherent difficulties with epidemiology include the inability to control for all relevant factors and the need for inordinately large samples in order to deal with conditions of low incidence."[79] Epidemiological studies are also frequently of little value to regulators who have to make immediate decisions about whether to regulate a potentially hazardous substance. To conduct a thorough epidemiological study with suitable controls (assuming it is possible) may take years, or even a generation, while a regulator may be forced to make a decision immediately, such as in the mad cow crisis. If regulators wait until solid epidemiological evidence is available before making decisions, the potential harms that were initially feared may have already materialized. The information gleaned from such studies may prove helpful in preventing future harms, but is of little help to those who have already been injured. Use of control groups who are exposed to different levels of risk from other populations may also be ethically controversial.

Thus, the risk assessment of hazardous substances is fraught with scientific uncertainty and value judgments. Kristin Shrader-Frechette points out that

> Assessors must make value judgments about which data to collect; how to simplify myriad facts into a workable model; how to extrapolate because of unknowns; how to choose statistical tests to be used; how to select sample size; determine criteria for NOEL (no observed effects level); decide where the burden of proof goes, which power function to use, what size of test to run, and which exposure-response model to employ.[80]

Brooks notes that "[t]he more an issue is in the public eye, the more expert judgments are likely to be influenced unconsciously by pre-existing policy preferences or by supposedly unrelated factors such as media presentations, the opinion of colleagues or friends, or even the emotional overtones of certain words used in the debate."[81] Weinberg echoes this sentiment. Commenting on the intermingling of facts and values in trans-science, he writes,

> A scientist who believes that nuclear energy is evil because it inevitably leads to proliferation of nuclear weapons (which is a common basis for opposition to nuclear energy) is likely to judge the data on induction of leukemia from low-level exposures at Nagasaki differently than a scientist whose whole career has been devoted to making nuclear power work. Cognitive dissonance is all but

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[78] *Ibid.*

[79] *Ibid.* at 36.

[80] K.S. Shrader-Frechette, *Risk and Rationality: Philosophical Foundations for Populist Reforms* (Berkeley: University of California Press, 1991) at 57.

[81] *Supra* note 49 at 40.

> unavoidable when the data are ambiguous and the social and political stakes are high.[82]

In response to ubiquitous uncertainty, many risk estimates are "not guided by the formal statistical properties of risk but rather by administrative procedures incorporating various types of 'conservatism.'"[83] Ruckelshaus writes: [H]istorically at EPA it has been thought prudent to make what have been called conservative assumptions; that is, our values lead us, in a situation of unavoidable uncertainty, to couch our conclusions in terms of a plausible upper bound."[84]

The decision to be conservative in risk assessment under conditions of uncertainty is decidedly a risk management decision. As such, scientists are no better qualified than other members of the public to make this decision. As Zeckhauser and Viscusi caution, there are several problems with this approach. They give as examples the use of results from the most sensitive animal species in bioassays from which regulators draw conclusions about the magnitude of a risk, as well as the tendency to focus on the upper end of the plausible risk assessments that are commissioned.[85] The "most fundamental problem" with this approach is that "tilting risk assessments in a conservative direction confuses the informational and decisional aspects of research about risks. A conceptually sound form of conservatism would have the decision maker (not the risk estimator) adjust the weights on the consequences. Adjusting the probabilities amounts to lying to ourselves about what to expect."[86] They further note that excessive conservatism, even at the risk management stage, can lead to inefficiencies.[87] The issue of whether conservatism in risk estimates is in fact a wise policy decision is discussed in more detail in Part IV.

Thus far we have argued that science in the context of risk assessment is subject to serious limitations. Nevertheless, it is indispensable for at least two reasons. The first is that, despite the pervasive uncertainties, science is capable of identifying and ranking many risks in a somewhat reliable way. For instance, scientists can say that dioxin is more hazardous than saccharin. There is absolutely no doubt about this. We agree with Harrison and Hoberg, who state, "[w]e begin from the premise that some substances do present greater risks than others and that the norms and methods of science, while imperfect, constitute our best bet for distinguishing among them."[88]

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[82] *Supra* note 25 at 33.

[83] *Fatal Tradeoffs*, *supra* note 7 at 156.

[84] *Supra* note 38 at 158.

[85] Viscusi is critical of the use of upper bound estimates in assessing the risks of second hand tobacco smoke. See W.K. Viscusi, "Secondhand Smoke: Facts and Fantasy" (1995) 18 Regulation 42.

[86] *Fatal Tradeoffs*, *supra* note 7 at 157.

[87] Hendee notes that "if the no-threshold model is overly conservative, and if risks are less—or nonexistent—at low levels of exposure, then the costs of radiation protection may be higher than necessary, and the intrusiveness of regulations into the beneficial applications of radiation may be excessive." He cites as an example the US Department of Energy's $200 billion program of radiation cleanup at DOE facilities, *supra* note 71 at 55.

[88] *Supra* note 19 at 8.

Second, scientific analysis is valuable in a democracy because scientific procedures are systematic and can be well documented. When decisions are made on a scientific basis, they are available for public inspection and review. The public and stakeholder groups can monitor the regulators by conducting experiments of their own, or hiring scientists to do the analyses for them. In this way they can be reassured that regulatory decisions are being made with the best possible information, and if not, that something can be done to remedy the situation.

The limitations of science have already been pointed out. First, science is valuable only at the stage of risk assessment. Science does not tell us whether something is safe or not; it merely provides us with facts about the probability of harm under certain conditions. Judgments as to the acceptability of risk are beyond the scope of science and belong more properly in the domain of risk management. Second, there are questions as to how accurately science can perform its more limited role of risk assessment. Uncertainty is inherent in risk assessments. This is a fact of life, and one we may lament. But what are the alternatives to scientific risk assessment? There seem to be no viable alternatives, so the challenge now becomes dealing effectively with uncertainty. This issue is discussed further in Part IV.

III. Strengths and Limitations of Cost-Benefit Analysis

Once scientists have assessed the risks associated with a hazard, a decision must be made about whether to regulate and if so by what means. Weiss and Strickland write,

> Not every environmental or health and safety problem is worth the social cost of "solving" it. If we continue to ignore the costs imposed on industry, we are likely to pay with low productivity and a stagnant economy. If we ignore the environmental, safety, and health effects of some aspects of modern industry, we will face a deteriorating and maybe dangerous environment and continuing human costs of industrial disease and danger to consumers.[89]

Cost-benefit analysis is a formal, prescriptive technique that seeks to inform decisions of this kind.[90] Arrow *et. al* point out:

> Because society has limited resources to spend on regulation, benefit-cost analysis can help illuminate the trade-offs involved in making different kinds of social investments. In this regard, it seems almost irresponsible to not conduct such analyses, because they can inform decisions about how scarce resources can be put to the greatest social good.[91]

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[89] L.W. Weiss & A.D. Strickland, *Regulation: A Case Approach* (New York: McGraw-Hill, 1982) at 384.

[90] See generally A.I. Ogus, "Regulatory Appraisal: A Neglected Opportunity For Law and Economics?" (Law and Economics Programme, University of Toronto Workshop — 1996-1997 (8)).

[91] K.J. Arrow *et al.*, "Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?" (1996) 272 Science 221 at 221 [hereinafter Science]. For a more detailed discus-

As an indication of just how scarce resources are, Viscusi notes that "if the entire U.S. gross domestic product were devoted to avoiding fatal accidents, we would have only $55 million to spend per life at risk."[92] The results of more judicious use of cost-benefit analysis, it is argued, would be greater safety for the same cost, or the same amount of safety for less cost.

We agree with Sunstein, who argues that in addition to the justification of cost-benefit analysis "on economic grounds, as a way of promoting economic efficiency and thus eliminating unnecessary and wasteful public and private expenditures," there "also are strong democratic justifications"[93] for cost-benefit analysis. According to Sunstein, it "can be understood as a way of diminishing interest-group pressures on regulation and also as a method for ensuring that the consequences of regulation are not shrouded in mystery, but are instead made available for public inspection and review."[94] With respect to safeguarding the regulatory process from inappropriate interest group pressure, Herman Leonard and Richard Zeckhauser note that although "any technique employed in the political process may be distorted to suit parochial ends and particular interest groups ... [o]ur claim is that [cost-benefit analysis'] ultimate grounding in analytic disciplines affords some protection."[95]

Cost-benefit analysis in the context of risk management, however, as with its technocratic analogue, science, in risk assessment, is subject to serious uncertainties. The entire method is contingent on the ability to value accurately both costs and benefits. As we shall see, there are enormous difficulties associated with monetizing the costs and benefits of regulation.

A. Valuation Problems — The Value of Life

Suppose a company is emitting a pollutant as a byproduct of its manufacturing process. Assume that this pollutant is known to increase the annual risk of a certain kind of fatal cancer by 1/100,000. There are 200,000 people living in the vicinity of the facility who are all equally exposed to this risk. We can predict that two statistical lives will be lost each year if nothing is done to regulate the company's manufacturing process. Government is under pressure to regulate. A plan is proposed that will eliminate this risk at an estimated annual cost of $30 million. This figure includes the costs of complying with the regulations by changing the manufacturing process, the higher prices consumers will have to pay for products that are now more expensive to pro-

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sion, see K.J. Arrow *et al.*, *Benefit-Cost Analysis in Environmental, Health, and Safety Regulation: A Statement of Principles* (Washington: American Enterprise Institute for Public Policy Research, 1996) [hereinafter *Benefit-Cost Analysis*].

[92] W.K. Viscusi, "The Dangers of Unbounded Commitments to Regulate Risk" in *Risks, Costs*, *supra* note 2, 135 at 135.

[93] "The Cost-Benefit State", *supra* note 6 at 4.

[94] *Ibid.*

[95] H.B. Leonard & R.J. Zeckhauser, "Cost-Benefit Analysis Applied to Risks: Its Philosophy and Legitimacy" in D. MacLean, ed., *Values at Risk* (Totowa, N.J.: Rowman & Allanheld, 1986) 31 at 31.

duce, the lower profits the company will receive, which we will assume are reflected in lower wages for employees, as well as the costs of the regulatory agency's monitoring of the company. Assume further that these cost calculations are accurate, and all possible costs have been properly accounted for.[96]

Should the proposed regulations be implemented? Do the benefits of saving two statistical lives outweigh the $30 million in costs? In other words, are the two statistical lives worth at least $30 million in costs, giving a value of $15 million per statistical life?

Based on currently accepted figures, the answer would, in all probability, be no. In *Fatal Tradeoffs*, Viscusi states: "Although the estimates of the risk-dollar trade-off vary considerably depending on the population exposed to the risk, the nature of the risk, and similar factors, most of the reasonable estimates of the value of life are clustered in the $3 to $7 million range."[97] Costs in this instance exceed the benefits.

There are two serious objections that can be raised at this point. The first is that it is "morally and intellectually deficient"[98] to attempt to place a dollar value on human life; life is a priceless commodity. In response to this objection, note that people routinely and voluntarily trade off safety for cost. Consider automobile purchase decisions. Individuals frequently choose to buy smaller, more fuel efficient cars without added safety features such as airbags, as opposed to larger cars equipped with such risk reducing amenities, despite their knowledge that the car they choose to purchase places them at greater risk of death in the event of an accident.[99] This indicates that citizens do not place an infinite value on their lives, as they are "willing to trade off small risks of death for other valued objectives."[100]

Furthermore, recall the discussion above about the scarcity of resources and how cost-benefit analysis can inform decisions about how they can be put to the greatest social good.[101] Given the fact that individuals trade off safety for cost, coupled with the fact that difficult decisions with respect to the allocation of scarce resources across a range of potential regulatory initiatives must be made, it is not unreasonable to use value of life figures when fashioning regulatory policy. Viscusi notes

> [T]he man in the street — and the ordinary member of Congress — has an instinctive aversion to placing a dollar value on a life. But economists do not calculate such values because they are unfeeling technicians. They do so because

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[96] Lave notes that "[f]or many projects, we cannot enumerate all the consequences of a decision, which implies that all important consequences may not have been considered." See L.B. Lave, "Benefit-Cost Analysis: Do the Benefits Exceed the Costs?" in *Risks, Costs, supra* note 2, 104 at 115.

[97] *Fatal Tradeoffs, supra* note 7 at 73.

[98] J.D. Graham & J.W. Vaupel, "Value of a Life: What Difference Does It Make?" (1981) 1 Risk Analysis 89 at 89.

[99] See *Fatal Tradeoffs, supra* note 7 at 3-4.

[100] *Ibid.* at 19.

[101] See *supra* notes 89-92 and accompanying text.

> sensible regulation — the making of sound choices — in many cases requires it. There is no escape from this aspect of regulatory policy.[102]

The second objection accepts the principled argument underlying the use of a value of life figure, but questions the specific values employed in the analysis. Notwithstanding the need to make tough policy choices, who is to say that a life is worth less that $15 million? If one were offered that amount in exchange for their life, it is virtually certain everyone would refuse such a deal. How, then, can a figure such as $5 million dollars be used in making regulatory decisions?

The answer is that life is not actually being valued. Rather, what is being valued are individuals "attitudes toward lotteries involving small risks of death."[103] It also bears pointing out that it is statistical lives, and not certain identified lives, that are being valued.[104]

In the example considered above, we know that the costs of the proposed regulations are $30 million. Each individual faces an increased annual risk of death of 1/100,000. Presumably, the affected individuals would rather not face the additional annual risk of death.[105] The question, though, is how much, in dollar terms, do they value the elimination of this risk? Faced with a lottery in which each faces a 1/100,000 risk of death, what trade-offs between safety and cost are those affected willing to make?

The willingness to pay measure, which is the standard measure of benefits in cost-benefit analysis[106] would have us ask each citizen how much they would be willing to pay to eliminate the risk. Suppose the average amount the 200,000 affected individuals would be willing to pay to eliminate the risk is $50. Altogether, $10 million could be raised to eliminate the risk, thereby averting two statistical deaths. Pursuant to this methodology, the implicit value of a statistical life is $5 million. "Another way of conceptualizing this calculation is to view it as simply ascertaining the value we are willing to pay per unit risk."[107] The estimate of the value of a statistical life would then equal the willingness to pay for additional safety, $50, divided by the risk increment that is involved, 1/100,000, giving a value of $5 million.[108]

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[102] *Supra* note 92 at 137.

[103] *Fatal Tradeoffs*, *supra* note 7 at 17.

[104] The fact that life is not actually being valued as such, but rather our attitudes toward lotteries involving small risks of death, and that it is statistical lives, not certain identified lives, that are at issue provides another ground for responding to the first objection, *viz.* that it is "morally and intellectually deficient" to place a dollar value on human life.

[105] This is likely true, notwithstanding any countervailing benefits accruing from bearing the risk.

[106] See E.J. Mishan, *Cost-Benefit Analysis* (New York: Praeger, 1976) for a more detailed discussion.

[107] *Fatal Tradeoffs*, *supra* note 7 at 20.

[108] See *ibid.* This approach, which is premised upon an "implied assumption of linearity", only holds for risks of very low probabilities. See Mishan, *Cost-Benefit Analysis*, *supra* note 106 at 303, n. 11. See also *infra* note 114 and accompanying text.

But where do we get the values people place on risk-dollar tradeoffs in their lives? Maclean states: "The idea is that individual preferences for risk and safety trade-offs are revealed in certain areas ... to justify decisions in other areas ... safety standards can be set through centralized decisions that mimic the trade-offs that market data reveal."[109] These areas include, most prominently, labour markets, where workers receive wage premiums for assuming jobs with higher risks,[110] automobile speed choices, seat belt use, smoke detector purchase, property value decisions, and cigarette smoking decisions.[111] Other sources of data are contingent valuations[112] or expressed preferences which are obtained through surveys and psychometrics.[113]

It is important to stress that the value of life figures are only meaningful when dealing with small risks of fatality. As the probability of death increases, compensation demanded by those exposed to the risk rises exponentially. No rational person will accept compensation for certain death, absent some bequeathment motive, as they will not survive to enjoy the proceeds.[114] Economists therefore tend to focus on the amount of compensation people demand in exchange for exposure to relatively small risks of fatality, (as well as the amount people are willing to pay to reduce risks of this nature). These are the types of risks that are most frequently involved in risk regula-

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[109] D. MacLean, "Risk and Consent: Philosophical Issues for Centralized Decisions" in *Values at Risk*, *supra* note 95, 17 at 22-23.

[110] Economists use the willingness to accept measure, the economic measure for losses, in calculating the value of life from labour market data. If data from labour markets consistently show that workers are willing to accept an increased risk of death of 1/10,000 for a wage premium of $500, then the implicit value of a statistical life will be represented as $500 divided by 1/10,000 or $5 million. Both the willingness to pay and willingness to accept measures are used in relation to lotteries involving small risks of death, and as illustrated, both can be used to value life. Viscusi notes that "[f]or sufficiently small changes in risk, the willingness-to-pay and willingness-to-accept amounts should be approximately equal, but in practice, they are not" (*Fatal Tradeoffs*, *supra* note 7 at 19). In actuality, willingness to accept measures tend to be significantly greater than willingness to pay measures. This creates a difficulty for practitioners of cost-benefit analysis, who must determine which measure ought to be used in a particular analysis. See *infra* notes 130-34 and accompanying text for a more detailed discussion.

[111] See *Fatal Tradeoffs*, *supra* note 7 at 8.

[112] Paul Portney defines "contingent valuation" as follows: "[t]he contingent valuation method involves the use of sample surveys (questionnaires) to elicit the willingness of respondents to pay for (generally) hypothetical projects or programs." The debate "raises broad questions about what economists have to say about the values that individuals place on public or private goods" (P.R. Portney, "The Contingent Valuation Debate: Why Economists Should Care" (1994) 8 J. Econ. Perspectives 3 at 3).

[113] See B. Fischhoff *et al.*, *Acceptable Risk* (Cambridge: Cambridge University Press, 1981). Viscusi notes that "[t]he advantage of using market-based estimates of money-risk trade-offs is that those exposed to risk have a greater incentive to think carefully about the implications of the risks for their lives than do respondents who are quickly briefed on potential risk trade-offs" (*supra* note 92 at 140). He does, however, acknowledge the utility of surveys where good market data are unavailable.

[114] See W.D. Schulze & A.V. Kneese, "Risk in Cost-Benefit Analysis" (1981) 1 Risk Analysis 81.

tion and they are also risks where there is at least some market data available from which to derive valuations.

Notwithstanding the availability of market data, however, the valuation of life is highly uncertain. Lave notes that "clever people have found ingenious ways to value" life and other goods, but he "would not want to bet the family jewels on the numbers estimated."[115] Sunstein comments that "smoke alarm purchases, safety cap expenditures, and the use of suntan lotion cannot plausibly be said to reflect general judgments about the value of life."[116] He adds that "actual choices are highly geared to the context in which they are made; it is not clear that one can infer from actual choices in one context people's valuations about other choices in a different context."[117]

One of the fundamental objections to the use of market data in determining the value of life is that "the willingness of individuals to pay for reductions in risk depends on their income levels, their expectations, and the hypothesized method of financing."[118] Using the methodology employed by labour economists to determine the value of life, we might find that workers in high risk jobs tend to be poorer on average that those in lower risk jobs, and thus might be more likely, due to economic pressures, to assume higher risks for the prospect of increased pay than would wealthier people who do not need the extra money. This would lead to the result that the wealthy value their lives more than the poor. Besides the morally problematic claim that might arise from these findings — that wealthier persons' lives are more valuable than poorer persons' lives — there is another more practical quandary confronting decision-makers: given a potentially disparate set of value of life figures, which ones should be used in conducting the cost-benefit analysis? Coal miners will likely value their lives less than university professors, meaning that they will accept risks for less compensation. Using a lower end figure, such as the value coalminers attach to their lives, might make a proposed regnlation appear to be unjustified, while using a higher end fignre may have the opposite effect.

To remedy this situation, it has been suggested that an average figure, such as $5 million, be used in cost-benefit analysis. Even if economists were able to discount differences in wealth and individually idiosyncratic tastes for risk (discounting the pathologically risk averse as well as daredevils) and arrive at an agreed upon figure for the value of life (which would be no small accomplishment), it is unlikely that this figure will be suitable for use in every risk situation. As Nicholas Rescher points out, "there is substantial variation in people's valuation of the 'social cost' of different

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[115] *Supra* note 96 at 114.

[116] *Free Markets, supra* note 20 at 141.

[117] *Ibid.* at 310.

[118] L.A. Cox & P.F. Ricci, "Legal and Philosophical Aspects of Risk Analysis" in D.J. Paustenbach, ed., *The Risk Assessment of Environmental and Human Health Hazards: A Textbook of Case Studies* (New York: John Wiley & Sons, 1989) 1017 at 1039.

modes of death."[119] Our attitudes towards death by murder, industrial accident and sporting misadventure are all different.[120] Consequently, we will be willing to pay more or less to avoid certain kinds of fatal risks.

Research by Slovic, Fischhoff and Lichtenstein[121] has shown that public risk perception differs from expert risk perception in important respects. As we noted in Part I, lay people sometimes lack certain information about hazards, and have "a well-documented tendency to overestimate risks with low probabilities and risks that have received substantial media attention."[122] However, "their basic conceptualization of risk is much richer than that of the experts and reflects legitimate concerns that are typically omitted from expert risk assessments."[123]

Experts often judge risk solely in terms of the expected number of fatalities or injuries likely to arise in the event the risk materializes in harm. The public, though, is sensitive to two additional factors. Factor one, or the "dread factor", is defined by "perceived lack of control, dread, catastrophic potential, fatal consequences, and the inequitable distribution of risks and benefits."[124] Nuclear weapons and nuclear power are examples. Factor two, "unknown risk", comprises risks that are "judged to be unobservable, unknown, new, and delayed in their manifestation of harm."[125] HIV infection is an example of an unknown risk that is also dreaded.

The perceived acceptability of risk, not surprisingly, is also strongly correlated to its voluntariness. Chauncey Starr, in his pioneering study on risk, notes that "[t]he indications are that the public is willing to accept 'voluntary' risks roughly 1000 times greater than 'involuntary' risks."[126] Sound social policy requires experts to take the voluntariness factor into account.[127]

Given these differences in expert and public judgments, it is likely that the use of a standardized value of life figure will tend to systematically underestimate the benefits stemming from the regulation of dreaded and unknown risks. Making adjustments

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[119] N. Rescher, *Risk: A Philosophical Introduction to the Theory of Risk Evaluation and Management* (Washington: University Press of America, 1983) at 176.

[120] See *ibid.* at 171.

[121] P. Slovic, B. Fischhoff & S. Lichtenstein, "Why Study Risk Perception?" (1982) 2 Risk Analysis 83.

[122] Viscusi, *supra* note 92 at 152.

[123] Slovic, "Perception of Risk", *supra* note 26 at 285.

[124] *Ibid.* at 283.

[125] *Ibid.*

[126] C. Starr, "Social Benefit Versus Technological Risk" (1969) 165 Science 1232 at 1237.

[127] For an instructive discussion, see P. Slovic, N. Kraus & V.T. Covello, "What *Should* We Know About Making Risk Comparisons?" (1990) 10 Risk Analysis 389 at 389. They are critical of comparisons of unrelated risks which "are frequently advanced as a means for setting priorities and determining which risks are acceptable." They state that "risk acceptability depends on a wider range of factors than the probabilities of expected fatality or morbidity estimates that are typically compared. Comparisons that stress acceptability of risk are, therefore, vulnerable to criticism."

in the value of life figure used depending on the nature of the risk confronted is a possibility, but is subject to considerable uncertainty.

The rationality of this move, despite its uncertainties, is easy to defend. The public, assuming it is well-informed about the probabilities of death stemming from two different kinds of risk, may rationally prefer to allocate more resources to risk A than to risk B, even though the same allocation of resources to risk B would yield a greater expected number of lives saved. This is because the public does not merely desire an absolute reduction of fatalities. It also has an interest in reducing fatalities of a particular kind. As Amartya Sen has argued:

> There are deep and fundamental and intuitively understood grounds for rejecting the view that confines itself merely to checking the parity of outcomes, the view that matches death for death, happiness for happiness, fulfilment for fulfilment, irrespective of how all this death, happiness, and fulfilment comes about.[128]

B. Valuing Harms to the Environment

How much is peace and quiet worth? A view? The preservation of an endangered species? If cost-benefit analysis is to be used, there needs to be some meaningful way to determine these values. Economists have attempted to derive shadow prices for these goods from market data and contingent valuation research, just as they have done for the value of life. Steven Kelman claims that the methodological obstacles confronting analysts in these endeavors are so great that it is virtually impossible to arrive at meaningful figures. For instance, in discussing studies aimed at identifying the value of clean air or peace and quiet by comparing property values, he notes the difficulties in controlling for all dimensions of quality other that the presence or absence of the good in question. One might pay a higher price for a house not only because it is in a quieter area of town, but also because one's friends and family live nearby, or it is close to one's work or children's school. Moreover, Kelman claims that the dollar values imputed to non-market goods which most people would wish to avoid, such as a polluted environment, will be lower than they should be because people with weak aversions or limited resources will take the bad bundle at lower prices than average, thereby skewing the results.[129]

In their article, Robin Gregory, Thomas Brown and Jack Knetsch make similar arguments.[130] They too are critical of current valuation techniques and strategies. One of their more trenchant observations is that the willingness to pay measure, used to assess the economic valuation of environmental benefits, may seriously understate them and therefore adversely affect the implementation of environmental regulations. This is due to the fact "that people commonly value losses much more than commensurate

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[128] Quoted in *Free Markets, supra* note 20 at 298.

[129] See S. Kelman, "Cost-Benefit Analysis: An Ethical Critique" (1981) 5 Regulation 33 at 37.

[130] R. Gregory, T.C. Brown & J.L. Knetsch, "Valuing Risks to the Environment" (1996) 545 Annals 54.

gains."[131] However, the prevailing assumption among practitioners of cost-benefit analysis is that the willingness to pay measure (the economic measure for gains) and the willingness to accept measure (used for losses) ought to be equivalent. Therefore, to the extent that cost-benefit analysis uses willingness to pay measures, there may be "serious understatements"[132] of benefits. To illustrate their point, they note that "[r]esults of tests demonstrating large disparities in valuations of environmental losses were first reported two decades ago, based on responses to hypothetical questions indicating that duck hunters would demand four times as much money to give up habitat than they were willing to pay to maintain the same resource."[133] In light of these findings, practitioners of cost-benefit analysis must make a value judgment about which measure to use. Cost-benefit analysis cannot resolve this question within its own terms.[134]

The use of cost-benefit analysis when decisions are made to preserve wildlife and endangered species is also the subject of serious criticism. Many of these decisions are made for aesthetic reasons such as preserving our natural history. Trying to derive shadow prices by looking at how much individuals are willing to pay to go to state parks or trips such as safaris in which to see wildlife are at best poor approximations of the benefits of such regulation and ignore "existence" values that many people attach to these resources, even if they themselves are unlikely ever to avail themselves of them (*e.g.*, the preservation of endangered species or rare natural treasures in distant locations). In the United States, there was recently a debate over a federal proposal that will cost more than $1 billion per year to preserve the spotted owls in their forest homes. Lave notes that "[w]hether the United States should incur a cost of more than $1 billion per year requires examining a large bundle of benefits, including romantic notions about preserving the primeval forest."[135] He also points out that in cases such as these, "wisdom calls for stating the benefits and costs in multidimensional terms, not in dollars."[136] Kelman argues that it is as absurd to make such valuations on a strictly cost-benefit basis as it is to value sex by reference to the current price for prostitution services.[137]

C. Risk Equity and Distributive Justice

Another significant problem with cost-benefit analysis is its relative insensitivity to the distributional consequences of regulatory options. Cost-benefit analysis seeks to

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[131] J.L. Knetsch, "Assumptions, Behavioral Findings, and Policy Analysis" (1995) 14 J. Policy Analysis and Management 68 at 70.

[132] *Ibid.* at 74.

[133] Gregory, Brown & Knetsch, *supra* note 130 at 58.

[134] See Kelman, *supra* note 129 at 38.

[135] *Supra* note 96 at 118.

[136] *Ibid.* at 117. See also Matthew Adler, "Incommensurability and Cost-Benefit Analysis" (1998) 146 Univ. Pa. L. Rev. 1371.

[137] See *supra* note 129 at 39.

identify the net benefits and net costs of proposed regulatory options summed over the entire affected population. It is not primarily concerned with the distribution of these costs and benefits. In principle, then, it is possible that a cost-benefit analysis may lead to the adoption of a policy that imposes great costs on a few individuals or groups if the benefits to the community as a whole outweigh these costs.

Consider the case in which a factory is emitting a pollutant as a by-product of its manufacturing process. This pollutant, let us assume, causes minor irritation to most nearby residents, but leads to more serious and debilitating consequences in asthmatics and others with respiratory disorders, who comprise a small percentage of those within the ambit of the risk. Suppose that the following three courses of action are proposed: (1) do nothing, (2) alter the manufacturing process so that the pollution is cut by 50%, or (3) ban the manufacturing process altogether. Suppose further that the results of the cost-benefit analysis suggest that the most efficient course of action is option 1, followed by option 2, and then 3. In turn, the asthmatics most prefer option 3, followed by 2, then 1.

Adherence to a strict cost-benefit calculus would lead to the adoption of option 1. Leonard and Zeckhauser would likely defend such a move through the use of a contractarian argument similar to the argument from the original position used by John Rawls in *A Theory of Justice*.[138] They write: "What mechanisms for making decisions would individuals choose if they had to contract before they knew their identities in society or the kinds of problems they would confront? Our answer is that, on an expected-value basis, cost-benefit analysis would serve them best and hence would be chosen."[139]

It is ironic that Leonard and Zeckhauser would employ such an argument to justify the use of cost-benefit analysis without specifying the obvious limits to its application that individuals in such a hypothetical situation would insist on. As Rawls writes, "[J]ustice is the first virtue of social institutions"[140] — not efficiency. The parties in the original position, according to his argument, would only agree to principles of justice that guaranteed their basic liberties. Furthermore, they would endorse institutions and policies that worked to the greatest advantage of the least advantaged groups in society. The unconstrained use of cost-benefit analysis, though, as illustrated in the example above, raises the spectre of holding citizens' basic liberties and legitimate expectations hostage to the calculus of social interests, violating principles of justice and equity. Thus, the failure of cost-benefit analysis to account for distributional consequences adequately is one of its most serious flaws.[141]

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[138] J. Rawls, *A Theory of Justice* (Cambridge: Harvard University Press, 1971).

[139] *Supra* note 95 at 33.

[140] *Supra* note 138 at 3.

[141] See Royal Commission on Matters of Health and Safety Arising from the Use of Asbestos in Ontario, *Policy Options in the Regulation of Asbestos-Related Health Hazards* (Study No. 3) by C.J. Tuohy & M.J. Trebilcock (Toronto: Ontario Ministry of the Attorney General, 1982).

D. Discount Rate

Yet another difficulty encountered in the use of cost-benefit analysis is the determination of the correct rate through which future benefits and costs should be discounted to present values. As Gregory *et al.* point out, $100 compounded annually at 6% would be worth $1842 at the end of fifty years, and conversely, $1842 fifty years in the future would have a present value of $100.[142] In many risk regulations, decisions have to be made about whether to invest resources in precautionary measures to avoid future harms. As Arrow *et al.* note, "[b]oth economic efficiency and inter-generational equity require that benefits and costs experienced in future years be given less weight in decision-making than those experienced today."[143]

Gregory *et al.*, citing a number of studies, find that individuals do not use a constant and unvarying rate to discount all future outcomes, as it would seemingly be rational for them to do. The implications for risk valuations are that

> [i]ncurring present costs to avert potentially catastrophic losses far in the future, which would not appear to be worth undertaking using the constant discount rates of standard analyses, may well be economically worthwhile when account is taken of the lower time preference rates for losses, for longer time horizons, and for more important outcomes.[144]

Knetsch uses the examples of global climate change and reforestation to illustrate this point. "Nearly any conventional invariant positive discount rate would preclude an easy economic justification of precautionary efforts in many such cases."[145] Even acknowledging these points, how are we to decide on the correct rate? The choice is subject to serious uncertainty, and the results of analyses will be subject in many instances to legitimate doubts and challenges.[146]

E. Cost-Effectiveness Comparisons between Regulations

We have already noted the considerable difficulties associated with valuing goods such as human lives and the environment. To avoid some of these problems, a more limited use can be made of cost-benefit analysis: cost-effectiveness analysis of regulation.[147] On this approach, all that needs to be valued are the costs of alternative regulatory responses. Although making such a determination is itself problematic, it will

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[142] See *supra* note 130 at 59.

[143] Science, *supra* note 91 at 222.

[144] *Supra* note 130 at 60.

[145] *Supra* note 131 at 70.

[146] Arrow *et al.* suggest that "[t]he rate at which future benefits and costs should be discounted to present values will generally not equal the rate of return on private investment. The discount rate should instead be based on how individuals trade off current for future consumption." (*Benefit-Cost Analysis, supra* note 91 at 13-14). This suggestion may reduce uncertainty in determining rates but by no means eliminates it.

[147] See Fischhoff *et al.*, *supra* note 113 at 104; and Rescher, *supra* note 119 at c. 14. See also Graham & Vaupel, *supra* note 98 at 93.

typically be easier than valuing benefits of regulation since some of the more difficult valuation problems will be bypassed.[148] J.L. Regens notes that

> In practice, EPA has utilized cost-effectiveness analysis more frequently because the benefit-cost approach 'is often difficult to do, since the Agency is frequently concerned with protecting such things as human life and the stability of ecosystems, social values for which there is no market price, or for which current procedures for finding 'shadow prices' are bitterly controversial.'[149]

Although cost-effectiveness analysis "does not address the question of whether the outcome is worth having in the first place," it "can be used to allocate resources among several programs in order to achieve the greatest result per unit cost; or it can be used to project and compare the total costs (to industry, government and the consumer) of several alternative programs."[150] For example, without attaching any values to lives saved, the 1979 EPA trihalomethane drinking water standard cost approximately $200,000 per life saved, whereas EPA's 1990 hazardous waste listing for wood-preserving chemicals was estimated at $6.3 trillion per life saved.[151] (It bears pointing out that $6.3 trillion was not actually spent. The figure is the result of expenditures made divided by the expected number of lives saved given the expenditure.) Clearly, regardless of the value of the benefits of these regulations, this information is helpful. In comparing the costs of the two regulations, we know, for instance, if the opportunity presented itself, that as between the two, it would be more efficient to invest in the cheaper regulation.

While cost-effectiveness analysis is a valuable tool in promoting a more efficient allocation of resources, even this more limited use of cost-benefit analysis is subject to limitations. For example, consider the two following regulatory proposals. In proposal A, air bags will be made mandatory in all new cars sold. Assume that this regulation will save each statistical life at a cost of $2 million. Proposal B is a ban on the emission of certain toxic pollutants into the atmosphere, pollutants which affect a large number of people living in residential areas in the vicinity of the source. Suppose this regulation would save each statistical life at a cost of $10 million and that the deaths that would be averted are particularly dreaded.

On a straight-forward cost-effectiveness approach that seeks to maximize numbers of lives saved at least cost, it is clear that regulation A is preferable to regulation B. But this conclusion neglects some important differences between the two risks. In

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[148] But not completely. A thorough analysis of the costs of regulation will consider substitution effects as well, which may entail valuing lives and harms to the environment. We will return to this issue below.

[149] J.L. Regens, "Attitudes Toward Risk-Benefit Analysis for Managing Effects of Chemical Exposure" in H.M. Seip & A.B. Heiberg, eds., *Risk Management of Chemicals in the Environment* (New York: Plenum, 1989) 75 at 81 (quoting from U.S. Environmental Protection Agency, *Risk Assessment and Management: Framework for Decision Making* (Washington: U.S. Environmental Protection Agency, 1984) at 27).

[150] "Health-Risk Determination", *supra* note 40 at 33.

[151] See Arrow *et al.*, Science, *supra* note 91 at 221.

the case of the air bags, it is still possible for consumers who value safety highly to purchase cars with air bags without making them mandatory and thereby driving up the costs for everyone else. The situation is far different in the pollution case. The risk faced by the residents is an involuntary externality—risks are imposed upon them without their consent.[152] In addition to the involuntariness of the risk, there may be important distributive concerns, as those most affected are nearby residents, who will likely bear a disproportionate share of the risk. Finally, the deaths sought to be averted under proposal B are dreaded. Thus, in light of these differences, and recalling our discussion above of perceived risk factors and their effect on the acceptability of risk, it may make more sense to implement proposal B instead of or before proposal A, even though we will be spending more money to save each statistical life and will therefore appear not to be acting as cost-effectively as possible.[153]

F. Cost-Benefit Analysis and Substitution Effects

A well-conducted cost-benefit analysis should also take account of possible substitution effects of proposed regulations. Sunstein provides the following example: "A regulatory ban may result in independent health risks coming from ancillary 'replacement' risks. If we ban substance A, the replacement substance B may be dangerous too. If a carcinogenic substance is regulated, perhaps people will use a product that is not carcinogenic but that causes serious risks of heart disease."[154]

Government agencies frequently fail to take into account the replacement risks of proposed regulations. Cost-benefit analysis can therefore be of considerable help by pointing out, to the extent feasible, all possible costs and benefits, including the possibility of regulations simultaneously increasing new risks while reducing old ones. Of course, there are still the practical limitations referred to above: the difficulties of identifying all possible costs and benefits, and even if identified, problems in valuing them.

Sunstein notes that "there are many different mechanisms by which risk regulation may increase aggregate risks."[155] For the purposes of the discussion, this article focuses on recent research, which has indicated that regulatory expenditures of a cer-

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[152] Assume these people did not know of the risk when they purchased their homes.

[153] If a perfect cost-benefit analysis were conducted, the net benefits of B would exceed the net benefits of A. However, the use of cost-effectiveness analysis precludes reaching this conclusion, since cost-effectiveness analysis focuses exclusively on the relative costs of regulations, and not at all on their relative benefits. Recall that the rationale underlying the use of this technique is that the valuation of the benefits or regulations is generally more difficult than the valuation of costs. This is at once cost effectiveness analysis' greatest strength and weakness. Since the valuation of the benefits of regulations is fraught with difficulties, cost-effectiveness analysis is helpful because it enables decision-makers to bypass these valuations. However, bypassing the valuation of the benefits or regulations can lead to the implementation of suboptimal regulations, as illustrated in the example above.

[154] *Free Markets, supra* note 20 at 301.

[155] *Ibid.* See also *ibid.* at 279-81 for a number of examples.

tain magnitude, with their resultant effects on the economy, may actually lead to fatalities because of the "richer is safer" argument.[156] Sunstein summarizes the point well: "Regulations cost money—sometimes a great deal of money—and private expenditures on regulatory compliance may produce less employment and more poverty. People who are unemployed or poor tend to be in worse health and live shorter lives."[157]

Ralph Keeney has attempted to quantify the health effects of regulatory expenditures.[158] He writes that "several studies suggest that for every $2 million to $15 million spent on public programs one statistical life is lost."[159] He argues that "[t]he induced fatalities caused by the expenditures to satisfy regulations provide an upper bound for a reasonable value trade-off between statistical lives and statistical costs."[160] Viscusi echoes this sentiment when he says "[i]n effect, saving lives becomes a break even proposition where every time we are willing to spend money to save a life, we lose a life because we become poorer in doing so."[161] Courts in the United States have been receptive to this research. Easterbrook J. cited concerns about the income-mortality link in his dissenting judgment in *International Union* v. *Johnson Controls*,[162] as did Williams J. in *UAW* v. *OSHA*.[163]

Accepting in principle the "richer is safer" argument, there is still considerable uncertainty on how to measure the health effects of regulatory expenditures, as reflected in the large range of values in existing studies.[164] The "richer is safer" substitution effect is yet another instance of both the strengths and limitations of cost-benefit analysis.

G. Practical Difficulties

We note also two practical difficulties with the use of cost-benefit analysis. The first is what Sunstein refers to as "excessive proceduralism."[165] Conducting a thorough cost-benefit analysis and accounting for all possible costs and benefits requires considerable time and resources. In many cases, the costs of these studies may exceed the

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[156] See A. Wildavsky, "Richer is Safer" (1980) 60 Public Interest 23.

[157] *Supra* note 20 at 302.

[158] See R.L. Keeney, "Mortality Risks Induced by Economic Expenditures" (1990) 10 Risk Analysis 147.

[159] R.L. Keeney, "The Role of Values in Risk Management" (1996) 545 Annals 126 at 130; see also Viscusi, "The Dangers of Unbounded Commitments", *supra* note 92 at 161.

[160] Keeney, *ibid.* at 131.

[161] *Supra* note 92 at 160.

[162] 886 F.2d 871 (7th Cir. 1989), reversed by the U.S. Supreme Court (April 22, 1991).

[163] 938 F.2d 1310 (D.C. Cir. 1991), remanded 37 F. 3d 665 (D.C. Cir. 1994). See *Free Markets*, *supra* note 20, for a brief discussion of these and other related cases.

[164] See Viscusi, *supra* note 92 at 162.

[165] "The Cost-Benefit State", *supra* note 6 at 27.

benefits, leading to the incongruous result that cost-benefit analysis may fail cost-benefit analysis.[166]

Failure, however, to conduct thorough analyses may result in other problems. Although time and money may be saved in the short term, the results of many agency analyses are of questionable quality. Lave dramatically presents these difficulties with the following example:

> [W]hat should EPA Administrator Carol Browner infer from a benefit-cost analysis of a new automobile emissions standard? Suppose she was informed that the analysis was done by a GS-9 with a B.A.—or even an M.B.A.—in six weeks with no supplementary budget. The analyses produced by government agencies often contain major flaws in theory, quantification, and analysis.[167]

Thus, there are difficult trade-offs agencies must make between the costs and benefits of cost-benefit analysis.

The second major difficulty is the use of value judgments by practitioners of cost-benefit analysis. Given the significant uncertainties we have noted above, analysts are forced to make value judgments in much the same way as scientists do in risk assessment. And just as scientists are vulnerable to influence from public opinion, friends, family, and their own personal points of view, so too are cost-benefit practitioners. Lave comments that this "recognition leads to a shocking assertion. The same economist might do quite different benefit-cost analyses of the same issue, depending on who the client is."[168]

IV. Regulatory Reform

This article began by pointing out that the current way in which institutions design and implement environmental, health and safety regulation is sub-optimal. To improve performance, we argue that it is necessary to make greater use of two technocratic tools — science and cost-benefit analysis. Science and cost-benefit analysis are systematic procedures which can discipline the politics of risk regulation. Both can help to achieve the goal of allocating society's scarce resources as efficiently as possible, leading to greater safety at the same cost as currently expended, or alternatively, the same amount of safety at less cost.

Science and cost-benefit analysis, however, are subject to serious limitations, many of which we have noted. In light of these uncertainties, the need to make value judgments is inescapable. These judgments are often a political matter, and experts are no better qualified than other members of the public to make them. Daniel Fiorino remarks that "[e]xperts must take part in these decisions, because they have the knowledge and methods to estimate the likely range of consequences. However, par-

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[166] See *ibid.*

[167] *Supra* note 96 at 120.

[168] *Ibid.* at 121.

ticipation by the lay public is necessary to 'represent societal values to the experts and to clarify necessary choices that the political process must make.'"[169] He goes on to argue that "a technological society can remain a democratic one only by remaining conscious of democratic values and by searching for institutional measures that will promote those values in social decision-making."[170]

Public involvement in both risk assessment and risk management decisions is essential. The challenge we address in this final section is straightforward: how can we design credible risk regulating institutions that incorporate these technocratic tools and make appropriate use of experts while still allowing room for the public to participate in a meaningful way? This article adopts Fiorino's view that "agencies will need to take the design of participating institutions as seriously as they take the design of their analytical documents."[171]

A. *Mandatory Scientific Risk Assessments*

Scientific risk assessments should be mandatory for all regulatory initiatives. The enabling legislation of all risk regulating institutions, both federal and provincial, should be amended to include this requirement. Since these studies are costly, both in terms of time and money, following Graham, whose recommendations have informed our thinking throughout this section, it is appropriate that "agencies ... tailor the complexity of the analysis to the importance of the rule."[172] Perhaps different categories of regulation should be defined, with the most extensive studies reserved for "major" regulatory initiatives. The term "major" will of course require elaboration, but similar language has been used in presidential executive orders in the United States.[173] Referring to the United States, Hahn notes that:

> While the definition of a "major" or "significant" rule has changed somewhat over time, it is generally a regulation that is expected to have one or more of the following characteristics: an annual impact on the economy of $100 million or more; a major increase in costs or prices for consumers or business; or significant effects on competition, employment, investment, productivity, or innovation.[174]

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[169] D.J. Fiorino, "Environmental Risk and Democratic Process" (1989) 14 Col. J. of Env'l L. 501 at 509, quoting Brooks, *supra* note 49.

[170] *Ibid.* at 523.

[171] *Ibid.* at 546. See also W.D. Ruckelshaus, "Science, Risk and Public Policy" (1983) 221 Science 1026 at 1028, where he writes "we should seek more imaginative ways to involve the various segments of the public."

[172] J.D. Graham, "Making Sense of Risk" in *Risks, Costs*, *supra* note 2, 183 at 199.

[173] Executive Order 12291, issued by President Reagan in 1981, as well as Executive Order 12866, issued by President Clinton in 1993 require cost-benefit analysis for major regulations. For more detailed discussion of Reagan's pioneering order, see D. Whittington & W. Norton Grubb, "Economic Analysis in Regulatory Decisions: The Implications of Executive Order 12291" (1984) 9:1 Science, Technology & Human Values 63.

[174] *Supra* note 32 at 244.

For the purposes of the discussion, this article assumes that the regulatory initiatives under review are "major" and therefore require the most extensive analysis. This is done to illustrate, in a limiting case, how science can best be used in risk regulation.

Agencies ought to conduct or commission one or more assessments using a variety of plausible assumptions, in order to provide risk managers with a balanced view of the uncertainties. William Leiss and Christina Chociolko, in *Risk and Responsibility*, wisely state that "there be a reasonable effort made ... to produce a truly disinterested risk assessment, that the nature of the uncertainties be described as fully as possible."[175] Graham says that "[s]ingle-point estimates, such as plausible upper bounds or worst-case scenarios, should generally be accompanied by lower-bound (optimistic) and realistic (or likely) estimates of risk."[176] He also urges the use of "distributional methods of variability analysis," since some citizens may be more sensitive to certain kinds of risk than others. For instance, asthmatics incur a disproportionate share of the adverse effects of air pollution. "Without that kind of information, risk managers are in a poor position to incorporate equity and justice considerations into their decision."[177] With the information provided, the agency should make a *preliminary* determination of which numbers it plans to use, publishing the results and the reasons for its choice.

B. Notice and Comment Period

Following mandatory scientific risk assessment, there should be a mandatory notice and comment period in which various stakeholders can challenge or confirm the agency's scientific findings if they choose by conducting or commissioning studies of their own. Since uncertainties in the agency's assessments will be clearly identified, stakeholder groups can take issue directly with controversial assumptions. In doing so, stakeholders' studies should also clearly identify the assumptions they are making and offer reasons for them. Including the public in this way, Jasanoff argues, is "an essential counterweight to biases that scientists might bring to policymaking, individually or as a professional class."[178]

Of course, the financial hurdles associated with conducting these kinds of studies may prove an insurmountable obstacle for some stakeholder groups, particularly citizen groups, who, compared with industry, will typically comprise more diffuse interests and have fewer resources with which to undertake studies of their own. To redress these possible financial and collective action problems, it may be appropriate to provide funding for certain recognized stakeholder groups to conduct studies of their own

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[175] W. Leiss & C. Chociolko, *Risk and Responsibility* (Montreal: McGill-Queen's University Press, 1994) at 261.

[176] *Supra* note 172 at 190.

[177] *Ibid.* at 191. See also F.D. Hoerger, "Presentation of Risk Assessments" (1990) 10 Risk Analysis 359.

[178] S. Jasanoff, "Peer Review in the Regulatory Process" (1985) 10 Science, Technology and Human Values 20 at 23-24.

in cases of major regulatory importance.[179] This will no doubt result in increased government expenditures, but these may be justified as promoting democratic values, a greater likelihood of arriving at a consensus, and increased trust in the regulatory process. The effects of greater trust in the regulatory process are not to be underestimated, as is argued later in this section.

Once all studies have been submitted, an opportunity for discussion and negotiation among various constituencies and the government agency presents itself.[180] Perhaps a consensus can be reached as to what numbers are most appropriate. Brooks notes that even in the absence of consensus, "[i]f the parties to a controversy could actually agree on the specifications for the research needed to resolve their technical differences (or at least narrow them appreciably), it might spur a research program focused on critical issues and thus accelerate the resolution of controversies through research."[181]

C. Peer Review

If there is still substantial disagreement at the end of the notice and comment period between the agency's risk assessment and those submitted by stakeholder groups, how should the controversy be resolved? The agency which produced the assessment that sparked the controversy may be subject to charges of bias if it is responsible for resolving the dispute.

One possible solution is the use of independent scientific peer review committees, in which the various studies (both the agency's and the public's) are submitted to a blue ribbon panel of disinterested scientific experts.[182] The composition of these panels will of course be of fundamental importance, and serious thought must be given to how members are selected. Professional reputation and no direct interest in the outcome of the dispute would clearly be pre-requisites. The scientific profession currently has well developed methods for making peer review selections, and should be consulted by government when creating panels for regulatory review.

The peer review committee would be charged with determining the most accurate assessment of the risk and reporting back to the agency, operating as a science court.[183] In making this determination, it is possible that the committee will support a particular

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[179] Shrader-Frechette makes a similar suggestion, *supra* note 80 at c. 12.

[180] See *ibid.* For an overview of multistakeholder consultation in Canada, see G. Hoberg, "Environmental Policy: Alternative Styles" in M.M. Atkinson, ed., *Governing Canada: Institutions and Public Policy* (Toronto: Harcourt Brace Jovanovich, 1993) 307.

[181] *Supra* note 49 at 43.

[182] See L. Salter, "Science and Peer Review: The Canadian Standard-Setting Experience" (1985) 10:4 Science, Technology & Human Values 37.

[183] Arthur Kantrowitz is a proponent of this view. He writes "if the making of mixed judgments is meticulously separated into scientific and nonscientific parts, then a system can be devised by which the experts can make objective judgments regarding the scientific parts of the question." See A. Kantrowitz, "Controlling Technology Democratically" (1975) 63 American Scientist 505 at 509.

group's study, or that it will issue a new set of results based on the synthesis of the best data and assumptions from each study under review. A range of values, including the mean estimate, plausible upper and lower bounds and worst-case scenario, as well as the distributional impacts, should be reported back to the agency. The agency would then be bound by these figures, and risk management decisions would be based upon them. Creating similar or overlapping peer review committees for families of regulatory agencies, or at least generic classes of risks, would promote consistency of treatment across agencies.

D. Mandatory Cost-Benefit Analyses

Just as scientific risk assessment should be mandatory for all major regulatory initiatives, so too should cost-benefit analysis. The enabling legislation of risk regulating agencies should be amended to include this requirement, and, acknowledging that cost-benefit analysis may sometimes fail cost-benefit analysis, "the intensity of the analysis 'should be tailored' to the importance and complexity of the specific problem."[184] An initial cost-benefit analysis should be conducted by the agency after it has completed its preliminary risk assessment. Without data from this assessment, it would be impossible to conduct such an analysis.

All possible costs and benefits, including substitution effects, should be valued for a range of regulatory proposals. For example, consider a case of air pollution arising from an industry's manufacturing process. Many policy options could be implemented, *e.g.*, do nothing, tax the industry, modify the manufacturing process through standards, or ban the process altogether. There are various costs and benefits associated with each proposal, all of which should be calculated.[185]

As we have recognized earlier, valuing costs and benefits is fraught with uncertainty. Consequently, agencies should explicitly identify the values used and the reasons for using them. Arrow *et al.* suggest that "a core set of economic assumptions should be used in calculating benefits and costs. Key variables include the social discount rate, the value of reducing risks of premature death and accidents, and the values associated with other improvements in health."[186] Two main arguments underlie this suggestion. First, using such a core set of assumptions promotes consistency among agencies, allows for the comparison of different agencies' cost-effectiveness, and makes the analyses easier to perform. Second, although there are obstacles to valuation, some figures are clearly more plausible than others, and a degree of consensus has emerged around certain bounded values given revealed preferences in the market place and other data from research on expressed preferences.

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[184] Graham, *supra* note 172 at 184.

[185] For a discussion of policy options in regulation, see Dewees, Mathewson & Trebilcock, *supra* note 12 at c. 2.

[186] Science, *supra* note 91 at 222.

Some goods, however, such as distributive justice, defy monetization. A responsible cost-benefit analysis should acknowledge the difficulties in valuation and indicate that these goods, in so far as they are implicated in the analysis, are to be given a qualitative as opposed to a quantitative description. If valuations of these goods is attempted, then special care should be taken to note their highly speculative nature.[187]

After a preliminary analysis is completed, with all uncertainties and assumptions clearly identified, it should be published and submitted for public scrutiny and criticism. Although we have discussed the proposals for scientific risk assessment and cost-benefit analysis sequentially, in practice the preliminary risk assessment and the preliminary cost-benefit analysis based upon it should be published and released to the public at the same time. The only reason the two proposals were discussed sequentially is that risk assessment is logically prior to a cost-benefit analysis.

The notice and comment period for the cost-benefit analysis should occur simultaneously with the notice and comment period for the risk assessment. Stakeholders, in addition to commissioning scientific risk assessments, should also be free to conduct cost-benefit analyses and submit the results for consideration. Funding should be provided for these studies as discussed above.

Assuming that no consensus emerges after a mediated discussion among the various constituencies, the studies should be sent for peer review. The same principles of selection should apply to the peer review committees responsible for the cost-benefit analyses as for scientific analyses. The experts should have excellent professional credentials and no conflicts of interest. They would be charged with evaluating the quality and accuracy of competing studies, in the same way as the scientific peer review committee would evaluate the competing risk assessments. The cost-benefit peer review committee, however, will have to await the scientific review committee's report on its findings before issuing its final report, because the outcomes of the cost-benefit analysis will be affected by modifications to the assessment of the magnitude of the risk. Again, creating similar or overlapping cost-benefit peer review committees for families of regulatory agencies, or at least generic classes of risks, would promote consistency of treatment.

E. Emergency Situations

In certain emergency situations, it may be appropriate for the government to make regulatory decisions without following the proposed procedures. Consider the recent "mad cow" crisis in Britain. Little was known about the cause of the outbreak of CJD. There was a presumed link with BSE, but no conclusive data to that effect. Even if there were a correlation, no accurate dose-response relationship could be established, and therefore the dangers of consuming beef could not be estimated with a high degree of accuracy. A frightened public and alarmist media demanded that some action be taken. What should the government do?

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[187] See Arrow *et al.*, *Benefit-Cost Analysis*, *supra* note 91 at 10.

Under such circumstances, the government should be given the power to regulate through a Quick Response Mechanism ("QRM"). This article does not outline the procedures of such a mechanism in any detail. However, this power should be exercised by government through formal cabinet directives to a regulatory agency tabled in Parliament. Its exercise would be conditional upon meeting the requirements relating to risk assessment and cost-benefit analysis (as laid out above) in the future, say within six months of the emergency enactments, and sustaining, modifying or withdrawing the regulations accordingly. It is of interest to note that the new WTO *Agreement on the Application of Sanitary and Phytosanitary Measures*[188] envisages a similar procedure.

For example, a QRM could authorize regulators, on apprehension by government of a serious product hazard, to temporarily ban goods from sale and if necessary to seize them, and in appropriate cases to recall them from retailers, pending fuller evaluation of the risks apprehended. This would require a subsequent systematic review of the evidence and appropriate weighing of costs and benefits of continued intervention, which would need to be performed and completed within a prescribed limited time in order not to unfairly prejudice manufacturers, importers and retailers of the product. Perhaps if the product in question were found to be safe at the conclusion of this process, the government should compensate manufacturers or suppliers at least for out-of-pocket losses incurred during the period of its removal from the market. The risk of such compensation would provide an incentive for the government to use the QRM judiciously.[189]

F. Decision Criteria and Judgmental Inputs

Now that the agency has conducted its scientific risk assessments and cost-benefit analyses, published its preliminary reports, subjected them to public scrutiny in a notice and comment period, and submitted the competing studies for peer review, what is it to do? The report of the scientific peer review committee on risk assessment has provided the agency with a range of values reflecting the magnitude of the risk, while the cost-benefit panel has provided the agency with the expected values—net benefits or costs—associated with various policy options. With respect to (1) the risk assessment data, should the mean estimates of the risk always be utilized? Or, given the uncertainties, ought more conservative figures be employed in some circumstances, and if so, when? With respect to (2) the results of the cost-benefit analysis, should the policy option with the greatest expected value, that is, the greatest net benefits, always be implemented? Or are there occasions when agencies should implement regulations even if they are not cost-justified, or when there are greater efficiencies to be realized through the implementation of other regulations? This article considers each of these two questions in turn.

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[188] *Supra* note 41.

[189] See Hadfield, Howse & Trebilcock, *supra* note 28 at 74.

Rescher notes three cardinal rules in risk management decision-making. They are (1) maximize expected values; (2) avoid catastrophes; and (3) dismiss extremely remote possibilities.[190] What do these rules mean, and how do they inform the two questions we are seeking to answer?

Maximizing expected values is essentially a call on decision-makers to maximize net benefits. This simple, intuitive idea lies at the heart of the calls for increased use of cost-benefit analysis. There are, however, limits to this principle of practical reason. One of them is the second cardinal rule: avoid catastrophes. There are circumstances where the materialization of a risk may produce consequences that are so awful and dreaded that we may rationally choose to avoid it, even if running the risk, despite its catastrophic potential, yields greater benefits (according to the results of a cost-benefit analysis) than avoiding it.

Suppose nuclear fusion becomes a viable energy source. Assume that in building a fusion power plant, there is a slim chance, say 1%, of a catastrophic accident leading to 20,000 deaths. Let us assume that the energy savings are so dramatic, however, that the benefits of the technology significantly outweigh the costs. One may quite rationally insist that such a plant not be built because of the slim chance of a catastrophic accident. In principle, it is argueable that a suitably conducted cost-benefit analysis should be able to capture this "dread factor", but in recognizing the limitations of this formal method, it is more accurate to say that given the potential for a catastrophe, the risk faced is simply unacceptable.[191] A judgment is made that the risk is too great to bear. This is often referred to as the "precautionary principle" which holds that "if an action or a policy potentially has catastrophic effects, then we should refrain from undertaking it even if the probabilities are uncertain."[192] The minimax rule in decision theory is intimately related to the avoid catastrophes rule and the precautionary principle. The minimax rule "tells us to identify the worst outcome of each available alternative and then to adopt the alternative whose worst outcome is better than the worst outcomes of all the other alternatives."[193] The question is, when should the minimax rule be applied? The answer seems to be where there is either considerable uncertainty as to the magnitude of the risk and the worst possible outcome is potentially catastrophic, or alternatively in situations where even if the probabilities of a risk are known with certainty, a non-trivial potential for a catastrophe is known to exist.

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[190] See *supra* note 119 at 114.

[191] As a means of capturing this dread factor, Shrader-Frechette notes that "[s]everal authors have proposed that n lives lost simultaneously in a catastrophic accident should be assessed by a loss of n^2 lives. They argue that the risk-conversion factor for catastrophic accidents should be exponential" (*supra* note 80 at 94). We believe that an adoption of the avoid catastrophes rule is superior to this *ad hoc* manipulation to the cost-benefit analysis.

[192] See D. Jamieson, "Scientific Uncertainty and the Political Process" (1996) 545 Annals 35 at 40.

[193] J. Rawls, *Justice as Fairness: A Briefer Restatement* (Cambridge: Harvard University, 1990) at 80 [unpublished].

It bears pointing out that there is a difference between risk and uncertainty, and the application of the minimax rule, as well as the avoid catastrophe rule and the precautionary principle, ought to be sensitive to this distinction.[194] Under conditions of risk, there are known probabilities of future contingencies, whereas under conditions of uncertainty, these probabilities are not well defined. There is the greatest need to apply the minimax rule under conditions of serious uncertainty, since the outcomes of a cost-benefit analysis will be impossible to determine. One could argue that its application under conditions of risk, even where benefits from the risks are expected to exceed the costs, is unnecessarily risk averse, irrational and inefficient. In response to this claim, this article responds that the minimax rule should nevertheless still be applied where potentially catastrophic outcomes with a known probability exist, for the reasons offered above, although perhaps more judiciously than under conditions of uncertainty, where it should be applied more readily.

The use of the minimax decision rule, however, presupposes that judgments should be made about the likelihood of a catastrophic event. Suppose the risk of a catastrophic accident at the fusion plant, instead of being 1%, were only 0.0000001%? The third rule, dismiss extremely remote possibilities, holds that infinitesimal risks can be ignored. For example, the U.S. FDA has used a *de minimis* threshold of one in a million individual lifetime risk.[195] Any risk that has a one in a million lifetime chance or less of occurring may be discounted.

Each rule, Rescher argues, is limited by the subsequent rule. That is, the rule about maximizing expected values is limited by the avoidance of catastrophes, while the avoidance of catastrophes is limited by the rule about discounting effectively zero probabilities.

This article proposes the addition of a fourth rule to Rescher's list of three: (4) adopt equitable regulations. This rule recognizes another instance, besides avoiding catastrophes, where the rule of maximizing expected values should yield to other considerations. As argued above, regulations that would otherwise fail a cost-benefit analysis should nevertheless still be adopted in circumstances where failing to do so would lead to the inequitable treatment of certain groups. This is due to the fact that our considered judgments about justice are often incapable of being adequately captured in a cost-benefit analysis.

The differential imposition of risks on citizens threatens to violate both their basic liberties and their legitimate expectation that the government fashion policies and institutions that work to the greatest advantage of the least advantaged groups in society. Consider the regulation of blood in Canada. In choosing to adopt suitable policies, the preferences of hemophiliacs, a disadvantaged group, should be given additional weight. A cost-benefit analysis may suggest that certain policies are warranted under

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[194] See further on the distinction between risk and uncertainty, F.H. Knight, *Risk, Uncertainty and Profit* (Chicago: University of Chicago Press, 1985).

[195] See J. Fiksel in *De Minimis Risk*, *supra* note 25, 3.

circumstances where the vast majority of citizens face minimal risk of contracting HIV or hepatitis, even though these policies subject relatively more frequent users of the blood system such as hemophiliacs to risks that most would intuitively judge as unacceptable.

Hemophiliacs could argue that their basic liberties are violated by these proposed regulations since they have a right, as citizens, to the provision of certain primary goods (such as a safe blood system) in a manner which does not expose them to grave risks of morbidity and mortality. Alternatively, as an already disadvantaged group, they could argue that they have a legitimate expectation based on justice that policies operating to the greatest advantage of the least advantaged groups in society be adopted.

A strict adherent of cost-benefit analysis may counter that a suitably conducted analysis ought to capture our intuitions about the unacceptability of this risk. Since hemophiliacs are subject to greater risks, they would be willing to pay much more to avoid them than those without the condition. Whereas the risks of mortality and morbidity for an average citizen may be one in a million, the risks faced by hemophiliacs may be orders of higher magnitude. Thus, a cost-benefit analysis should reflect this by, perhaps, using a higher value of life figure for hemophiliacs than for average citizens. Consequently, the results of the cost-benefit analysis will become more congruent with our intuitions.

This argument presupposes the ability to accurately measure citizens' increased willingness to pay to avoid risks of increasing probability. However, the most reliable market data available to measure how much people are willing to pay to avoid risk, or conversely, are willing to accept for the imposition of additional risk is based on responses to risks of low probability. This data, as noted above, is subject to significant uncertainty. The uncertainty becomes even greater when looking to market data to measure willingness to pay or willingness to accept responses to the types of higher probability risks that are at issue in the example under consideration. Simply put, there is little reliable data for measuring the benefits of avoiding risks above a certain size. In the absence of such data, our collective intuitions and considered judgments are preferable to a cost-benefit analysis. Doctoring the analysis to suit these intuitions, which could be done, is superfluous. It is more straightforward merely to rely on intuitions about justice directly.

Even if reliable market data were available to measure the benefits of high-risk avoidance, the cost-benefit analysis would nevertheless be unable to measure the instinctive aversion most people have to placing certain groups under high risks for the benefit of other groups — treating those at higher risk as means rather than ends in themselves — even when one is a member of the group that benefits. This aversion is heightened when those at risk are among society's already disadvantaged. Average citizens, considering proposed blood policies under which their safety is not in jeopardy, may still find the policies unacceptable since their preferences may also include the altruistic desire to see that others such as hemophiliacs who have been traditionally disadvantaged are not subject to dangerously high risks.

For the foregoing reasons, strict adherence to the results of cost-benefit analyses is not warranted when there are significant distributional inequalities. In seeking to adopt equitable regulations, decision-makers should be attentive to a number of factors. First, they should look to the results of the scientific risk assessment, which, as noted above, ought to include the distributional consequences of the risk. Second, if the risks are not distributed equally, regulators should turn their minds to the severity of the risk at issue. Differences in the severity of the risk should inform judgments as to whether deviating from the cost-benefit analysis is warranted. If the risks are life-threatening as opposed to merely debilitating, there is greater reason to reject the findings of the cost-benefit analysis. Third, the question of who bears the brunt of the risk ought to be taken into account. Even if the severity of the risk at issue is not great, if it is borne by traditionally disadvantaged groups there may still be good reason for regulators to depart from maximizing expected values. This is because considerations of justice discussed above may militate against the imposition of yet another burden on groups that are already subject to disproportionate burdens. Fourth, decision-makers should be sensitive to whether those who bear the brunt of the risk are also those who derive the greatest benefits. For example, if an industry of national importance creates health risks that are concentrated in a small area, members of the affected community may be willing to bear those risks if they result in increased economic prosperity for those within their ambit. Under such circumstances, decision-makers may see the differential benefits to those at higher risk as a mitigating factor, and therefore choose to follow the cost-benefit analysis, notwithstanding the distributional inequality.

This last point raises the possibility that government compensate, either *ex ante* or *ex post*, those groups who suffer a disproportionate share of the risk in question, rather than foregoing the activity or proposed regulatory policies which yield net benefits to others in society. While it is true that awarding compensation will alter the cost-benefit ratios, such awards may nevertheless be worthwhile if they still allow for efficiency gains in an ethically acceptable fashion. Agencies, however, should not be given the power to award such compensation. Rather, at the end of the regulatory process and discussions with the affected constituencies, through which a sense of the viability of such a compensation scheme can be gauged, a report to the relevant government should be made suggesting a plausible course of action. It would then be left to elected representatives to make a final decision, informed by the agency's findings.

We note that decision-makers can only be guided by the factors listed above if they are presented with the requisite information. Given the above proposals to include distributional consequences in the scientific risk assessment and to fund various stakeholder groups so that they may participate in the decision-making process, the information necessary to make these kinds of decisions will hopefully become more readily available.

Having now presented four decision rules, it is important to note that rules two through four require judgmental inputs that are different in kind from the formal rules associated with rule one. That is, when maximizing expected values, costs and benefits are plugged into a calculus which yield a result in a relatively mechanistic way. Of course, judgments are made in valuing the costs and benefits, but these judgments are

of a different kind from the judgments in two through four. What is a catastrophe? What is an extremely remote possibility? What are equitable regulations? Unlike cost-benefit analysis in rule one, there is no formal method for making these judgments, and agencies should be given some latitude in making decisions of this nature. Over time, guidelines and precedents should develop to constrain decision-makers' discretion. Nevertheless, given the subjective nature of the judgments involved, the backgrounds, qualifications and perspectives of members of regulatory agencies are an important issue. While formal stakeholder or constituency representation may not be desirable out of concern for political paralysis and unprincipled decision-making, governments could commit themselves in the legislative mandates of regulatory agencies to appointing members in their individual capacities to reflect a balanced range of qualifications and perspectives, which should not be exclusively technocratic in nature but include members with, for example, industry, consumer, environmental or other perspectives (depending upon the risks being regulated). In a Canadian context, where much risk regulation occurs within executive branches of government rather than by quasi-independent regulatory agencies (as in the U.S.), the above proposals imply a somewhat less anonymous, more structured, transparent and accessible regulatory process than the traditional Canadian risk regulation process has entailed.

In light of the four decision rules presented, it is now possible to attempt to answer the questions posed at the beginning of this section. With respect to what figures should be taken from the risk assessments, the default assumption ought to be the mean risk estimates provided by the peer review committee.[196] However, if it can be shown that the upper bound estimates are potentially catastrophic, then it may make sense for risk managers to use those figures in the cost-benefit analysis. Of course, a judgment needs to be made about whether the risk is potentially catastrophic, and if so, whether or not the risk is small enough to discount completely. Some criteria for judging the catastrophic nature of the risk are the potential number of fatalities, the voluntariness of the risk, the type of death, and whether the deaths will occur simultaneously or not. Viscusi and Zeckhauser, however, properly caution that conservative figures are used far too often and lead to more costly regulations than might be necessary, as risks are frequently overestimated, and hence so too are the benefits of risk avoidance.[197]

With respect to whether the policy option with the highest expected value should always be implemented, there should be a default presumption in favour of maximizing expected benefits, save for two instances. The first is in a situation such as the hypothetical example given above about the fusion plant. If there is a non-trivial risk of a catastrophe, then the option that best avoids the catastrophic risk should be imple-

[196] Viscusi states "[f]rom a statistical decision theory standpoint, if we are concerned with maximizing the expected benefits of government efforts, we should rely upon the mean risk values in making these assessments rather than some other value along the risk distribution" ("Economic Foundations", *supra* note 10 at 131).

[197] See "Risk Within Reason", *supra* note 7.

mented, even if that means rejecting the results of a cost-benefit analysis. The second is when a regulatory decision, although cost-justified, has distributional consequences which are inequitable, for example because the rights or legitimate expectations of already seriously disadvantaged citizens are violated. Again, it is important to stress that making these decisions requires the exercise of judgment by agencies. Guidelines should be developed to help ensure consistency in making them.

G. Risk Communication, Risk Perception, and Trust

One of the main benefits of the proposals we are considering is the development of increased public trust. A trusting public is much more likely to tolerate the imposition of certain risks than a mistrustful one. A patient who trusts a doctor is more likely to submit to a risky surgical procedure recommended by the physician. Similarly, the public will be more willing to submit to certain regulatory policies, including the decision to forego regulation in some instances where it is initially demanded, if there is trust in both the decision-makers and the decision-making process.

Good risk communication, "defined as the flow of information and risk evaluation back and forth between academic experts, regulatory practitioners, interest groups, and the general public"[198] is essential for increasing public trust. Leiss poses the following challenge: "[H]ow can we improve the quality of the dialogue about risk ... that separates experts from the general public? Second, how can we apply this improved dialogue to achieving a higher degree of social consensus on the inherently controversial aspects of managing environmental and health risks?"[199]

The institutional reforms proposed herein will help to improve the dialogue between government experts and the public, and afford an opportunity for greater consensus.[200] By publishing the results of risk assessments and cost-benefit analyses and allowing the public to participate meaningfully in the shaping of policy, and by being attentive to balanced membership composition of regulatory agencies, a strong message is sent that government is receptive to the concerns of its citizens.

For example, increased citizen participation in the regulatory process can help to make use of the best aspects of both expert and public perceptions of risk. As discussed above, public perceptions of risk are often based on poor information. If careful scientific risk assessments and cost-benefit analyses are performed and the results are communicated to the public in an open setting, it is likely that on some occasions citizens' risk perceptions will become more congruent with the scientific state of

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[198] W. Leiss, "Three Phases in the Evolution of Risk Communication Practice" (1996) 545 Annals 85 at 86.

[199] *Ibid.* See further on risk communication, see B. Fischhoff, "Risk Perception and Communication Unplugged: Twenty Years of Process" (1995) 15 Risk Analysis 137. See also Slovic, "Perceived Risk", *supra* note 22.

[200] National Research Council, Committee on Risk Perception and Communication, *Improving Risk Communication* (Washington, D.C.: National Academy Press, 1989).

knowledge and thus citizens will be more accepting of expert judgments. This process is likely to be facilitated by agencies relating the risks at issue to commonly assumed risks so that the public has some readily understood comparators to relate to. On the other hand, there may be times when regulatory decision-makers will change their view to one more in line with public risk perceptions. Consider a situation in which the public, although fully appraised of the probabilities of fatality, demands a regulation that, according to standard value of life figures, would not be cost justified. After consulting with the public and learning more about how dreaded the risks are perceived to be, regulators may decide to modify their assessments accordingly.

H. The Role of the Courts

Despite the opportunities for participation and independent peer review, various stakeholders are likely to be unaccepting of the decisions that regulators reach. There will always be winners and losers. What options are available to the losers to appeal decisions that they feel are unjustified? There are two main avenues: the courts and the political process.

Canadian courts have traditionally been deferential to the decisions of regulatory agencies, particularly with respect to expert judgmeuts.[201] This deference stands in marked contrast to activist courts in the United States which have overruled risk regulatory decisions on numerous occasions.[202]

Under our proposed regulatory changes, however, citizens would be able to launch judicial review applications only on due process grounds. For instance, if there is insufficient public consultation before a decision is made, a court could hold a regulation invalid until such time as proper procedures are followed. The courts in such a case would serve to enforce the proposed rules, which are aimed at a more participatory and transparent process, a goal which Hoberg and Harrison, in their comparative study of Canadian and U.S. regulatory styles, argue would be a welcome development.[203] Jasanoff echoes this sentiment, as does Salter.[204]

Canada currently has less citizen participation and a more closed regulatory style than the United States.[205] The offsetting benefit would appear to be the ability to enact

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[201] See *Canadian Union of Public Employees, Local 963* v. *New Brunswick Liquor Corporation* [1979] 2 S.C.R. 227, 97 D.L.R. (3d) 417 [hereinafter *CUPE*].

[202] See, for example, T.O. McGarity, "Judicial Review of Scientific Rulemaking" (1984) 9:1 Science, Technology & Human Values 97. See also R.A. Merrill, "The Legal System's Response to Scientific Uncertainty: The Role of Judicial Review" (1984) 4 Fundamental and Applied Toxicology S418.

[203] See *supra* note 19 at 168-84.

[204] See *supra* note 36, and note 182 at 42-43.

[205] See A.J. Green, "Institutional Structures and Policy Outcomes: The 'Americanization' of Environmental Regulation in Canada" (Working Paper #26) (Centre for the Study of State & Market, November 1996). See also P. Nemetz, W.T. Stanbury & F. Thompson, "Social Regulation in Canada: An Overview and Comparison with the American Model" (1986) 14 Policy Studies J. 580.

regulations more expeditiously, but Harrison and Hoberg find that there is no evidence to support this claim. In actuality, there are few practical advantages to the current system. In urging a more participatory and transparent Canadian system, we are not advocating the rampant litigiousness and judicial activism that marks the U.S. regulatory process. Judicial review should be restricted to policing procedural irregularities. Courts should not engage in substantive second-guessing, unless decisions are patently unreasonable[206] — for example, a patently unreasonable determination of an effectively zero probability based on no credible evidence at all — a highly unlikely eventuality, given the peer review processes envisaged. One possible caveat to this strong presumption of judicial deference relates to the fourth (distributive justice) decision criterion which qualifies utilitarian judgments out of concern for individual or minority rights. Here, more intensive judicial scrutiny of agency decisions may be warranted, paralleling the judicial role played in protecting constitutional or civil rights.

I. The Role of the Political Process

The second avenue for aggrieved citizens to pursue their complaints with regulatory policies is in the political arena. This article has argued that regulatory bodies should make their decisions in accordance with the procedures outlined above. This process, although better than that which currently exists in Canada, is still not perfect. It is merely an attempt to yield welfare maximizing results. Sometimes it may fail or be perceived as failing in this task.

In cases of such failure, at least from the standpoint of aggrieved citizens, lobbying can be undertaken to prompt legislative or ministerial action to override regulatory decisions. Political rallies can be organized, contributions withheld, politicians punished at the polls. When these pressures are brought to bear on politicians, they may eventually yield to public demands and overturn the regulatory decision in question. Doing so will not be costless, however. Politicians will be acting against the findings of a detailed and well-documented regulatory procedure, and will have to justify their actions, presumably by arguing that the valuations employed in the cost-benefit analysis were flawed or that an error in judgment was made in applying one of the decision rules discussed above.

Political override has occurred in the past. A notable example was the lifting of the saccharin ban in the United States after an enormous public outcry and letter writing campaign, orchestrated by concerned citizens and industry members, bombarded Congress until they finally relented.[207] Another was Congress' decision, by an overwhelming majority, to repeal an ignition interlock standard which prevented an automobile from being started unless seatbelts were attached, despite highly favorable

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[206] See *CUPE*, *supra* note 201.

[207] See Harrison & Hoberg, *supra* note 19 at c. 5.

cost-benefit ratios associated with that standard.[208] Such political action is not to be lamented. If the public demands an overturning of a regulatory decision, so be it. Democratic societies must, in the end, yield to the will of the citizenry, provided rights are not violated. The public has the ultimate decision-making prerogative. It is crucial, however, that political override be public, *e.g.* by a formal Cabinet or Presidential directive to an agency, tabled in Parliament or Congress, and subject to open debate and criticism (and perhaps in turn legislative override by a super-majority, *e.g.* a two-thirds vote of the legislative body), so that the government is fully accountable, politically and publicly, for exceptionalist decisions.

Designing an appropriate institutional division of labour between regulatory agencies, courts, and the political process is an important challenge. Different analytical currencies or discourses will be relevant in different institutional fora. Just as distributional equities are not relevant, as a general matter, in private law tort or breach of contract actions, but may be relevant in other fora, structuring the mandate of institutions in the risk regulation field so as to clarify what kinds of analysis, arguments and evidence are relevant in what fora should serve to maximize institutional complementaries and comparative advantages.

Conclusion

The democratic political process must be disciplined by the introduction of technocratic tools such as the use of science in risk assessment and cost-benefit analysis in risk management. If not, misallocation of scarce resources will continue. The use of these technocratic tools, however, must also be disciplined by the democratic process. Key social decisions cannot be made solely by unaccountable experts. Not only would the results be anti-democratic, they may be inefficient or inequitable as well. By implementing the regulatory proposals outlined above, which address these two concerns, it will be possible to move closer to achieving the goal of a safer, more efficient, and more democratic society. International trade obligations under the GATT/WTO and NAFTA, as exemplified by the recent GATT/WTO Panel ruling striking down EU Beef Hormone regulations *inter alia* for lack of scientific justification,[209] and the potential application of the proportionality test to such regulations, will increasingly require domestic risk regulation regimes to move in the directions proposed in this paper.

As noted at the outset, this article has been largely cast at a conceptual level. In a Canadian context at least, much less is known empirically about the structure and processes of risk regulating institutions, both federal and provincial, than is required to

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[208] See M.J. Trebilcock, "Requiem for Regulators: The Passing of a Counter-Culture?" (1991) 8 Yale J. on Reg. 497 at 500.

[209] The GATT/WTO Panel Decision in the Beef Hormone Case, *supra* note 41; see further M.J. Trebilcock & R. Howse, "Trade Liberalization and Regulatory Diversity: Reconciling Competitive Markets with Competitive Politics" (1998) 6 Eur. J. L. & Econ. 5.

inform concrete policy prescriptions. More detailed empirical research is required with this institutional focus (perhaps by way of case-study) to establish the extent to which, and ways in which, Canadian risk regulating institutions in practice conform to, or diverge from, the ideal risk regulation regime that this article has attempted to develop and defend.