The Use of Risk Assessment and Benefit-Cost Analysis in U.S. Risk-Management Decision Making

Richard. B. Belzer, Ph.D.(1)

I. Introduction

The practice of both risk assessment and benefit-cost analysis is highly advanced in the United States relative to many other nations. Both are used extensively for designing regulations involving health, safety and the environment, and they play significant roles in the political system as interest groups battle over the hearts and minds of the American people and their elected representatives. Indeed, risk assessment has become so important to politics that many observers believe that the imprimatur of science which it once had is now wearing thin.

In this paper I shall summarize the role which risk assessment and benefit-cost analysis play in making policy at the federal level in the United States. It is a story of confusion between risk assessment, an ostensibly scientific endeavor, and risk management, the establishment of policies, programs and regulations based on a political balancing of competing interests and concerns. If there is a single lesson to be learned from two decades of American experience, it is this: Unless these scientific and political elements are separated with care and determination, science will be corrupted by politics and the tool of risk assessment will become increasingly suspect.

Risk assessment can be an extremely valuable method of ascertaining the possible consequences of exposure to a substance, engaging in an activity, or exhibiting a behavior. Its careful use can help decision makers in government, industry, and even the individual household make more informed choices. However, risk assessment is extraordinarily easy to misuse and abuse. Misuse occurs when risk assessment is performed incorrectly or interpreted improperly, but without cognizance of the error. Abuse occurs when these errors are part of an intentional effort to mislead officials, confuse the public, or distort the truth.

Performed properly, risk assessment also is an essential ingredient in benefit-cost analysis. Whereas risk assessment is a tool for estimating consequences, benefit-cost analysis helps ascertain the values associated with these consequences and identify the tradeoffs implied by making choices. Just as few interesting questions have simple answers, complex choices always involve tradeoffs. The field of energy policy provides useful examples. The production of electricity by smashing atoms involves many risks. But electricity cannot be produced from burning coal and other fossil fuels without also generating risks. Wood stoves, which were quite fashionable in the United States during the 1970s because they "saved oil" and represented "Green" attitudes, actually generate greater pollution and environmental damage than nuclear power, coal, or oil. Finally, and most importantly, going without heat, light, and refrigeration may be the riskiest energy policy of all.

(1) Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President, Washington, DC 20503, USA. The views expressed in this paper do not necessarily reflect any official policies or positions taken by the Office of Management and Budget or the Executive Office of the President.

II. U.S. Health and Safety Legislation

Scanning the range of areas in which the U.S. Government promulgates regulations for the purpose of managing risk, one quickly discovers that risk assessment plays a varied but inconsistent role. In some instances, risk assessment is explicitly required and forms the fundamental basis for decision making. In other cases, however risk assessment is completely irrelevant as a practical consideration. Differences in the role played by risk assessment reflect many factors, including the identity of the interest groups participating in the political debate, public attitudes, and the irreproducible political microenvironment existing at the time a statute is enacted.

A. Constitutional Constraints

First, it is important to recognize certain constraints which attend federal policy making in the United States. Unlike some other nations, the federal government was created by the States, and the States at least theoretically have the power to dissolve it. Article II, Section 8 of the U.S. Constitution expressly delegates certain powers to the federal government, such as the regulation of interstate and international commerce, enactment of uniform laws of bankruptcy, the establishment of Post Offices. Section 10 prohibits the States from engaging in certain others, such as entering into treaties, coining money, and enacting laws impairing the obligation of contracts.

The U.S. Constitution also explicitly prohibits the federal government from interfering in State affairs. For example, the 10th Amendment reserves to the States and to the people all powers not delegated to the federal government by the Constitution nor prohibited to the States. Despite the breadth of this potential constraint, it has little relevance to policy making today because the States have become exceptionally weak governmental partners. Other significant constitutional constraints upon the federal government have fallen into disrepair as well. The 5th Amendment prohibits the government from taking private property for public use without just compensation, but governmental actions generally have not risen to a "taking", even if they rendered private property useless, as long as they were ostensibly intended to protect public health and safety. Recently, the U.S. Supreme Court breathed life back into the 5th Amendment by establishing a new common law test of governments' public health and safety rationales(2).

Second, it is important to recognize that the American policy making regime is intensely and intentionally adversarial. Our three branches of government have expressly different functions, but each branch seeks to expand its powers at the expense of the others. The President executes the laws enacted by the Congress, but the Congress objects when the President exercises discretion that is allowed under the law. The President objects when the Congress interferes in his execution of foreign policy, which it does frequently. Both the President and the Congress rail against the judiciary when it implicitly rewrites the laws and the Constitution rather than simply interpreting them.

(2) In the case of **Lucas vs. South Carolina Coastal Council** (91-453), the Court opined that a State law prohibiting the development of real estate violated the 5th Amendment because the State did not show that the owner's intended use would run afoul of common law nuisance principles. Absent such a showing, the Court determined the State's action to be a "taking" requiring just compensation.

B. Major Statutes Enacted to Reduce Risks to Health, Safety, or the Environment

Over the years, the list of agencies created to attend to a risk-related concern has become quite long. Table I below identifies the names of the major U.S. agencies charged with regulating risks, the years in which each agency was created, and its principal areas of regulatory responsibility. In many cases, agencies have overlapping responsibilities, which not surprisingly leads to conflict and confusion.

Another source of conflict and confusion is the number and diversity of statutes these agencies are charged with implementing. Table II below lists the major federal risk-management statutes and the agencies charged with implementing them. Even within a major area (e.g. environment), these statutes have very different goals, objectives and philosophies.

1. Example: environmental statutes

The original Clean Air Act Amendments of 1970 sought to protect public health from air pollution "with an ample margin of safety". Neither the law nor its legislative history clearly articulated how this "margin of safety" should be determined or how "ample" it should be. Consistent with the genre of the period, it was a "technology-forcing" statute. This means that compliance with its provisions was known to be technically impossible at the time that the law was enacted, but legislators generally believed that technological innovation could only be coaxed by government mandate.

In a similar fashion, the Congress established as the overriding objective of the Clean Water Act to eliminate all discharges into the navigable waters of the U.S. by the year 1985. Again, whether it was either technically feasible or socially desirable to eliminate *every* discharge was not debated intensively. Nor is there any evidence that the Congress actually intended for all U.S. waters to be made pristine. Rather, the law was motivated by pictures of America's streams, rivers, and lakes transformed into open sewers. The Congress simply directed that this shall not be so any longer.

Subsequently environmental statutes display an evolution away from these technology-based approaches toward strategies based more on balancing risks and benefits. For example, when the U.S. began to regulate pesticides in a serious way in 1972, the law directed the Government to write implementing regulations that take account of the public health and economic benefits associated with pesticides. Similarly, when toxic substances used in commerce were first subjected to regulatory control in 1976, the Congress recognized the economic value of these materials by directing regulators to concern themselves only with "unreasonable" risks – that is, substances whose use poses more danger to human health and the environment than they create in societal benefits.

This evolution was by no means uniform, however. When Congress enacted a law in 1976 to regulate the identification, generation, transport and disposal of hazardous wastes, it was silent on the question of whether regulators should strive to balance risks and benefits. Instead, it simply directed them to write regulations that "protect human health and the environment". When the U.S. Environmental Protection Agency (EPA) first promulgated rules implementing this new law in 1980, it chose to interpret Congress' *silence* on this question as equivalent to a statutory *prohibition* on balancing risks and benefits. And U.S. hazardous waste regulators have virtually ignored the costs of their actions ever since. As I will show later, many regulations

aimed at controlling risks from hazardous wastes easily impose costs in the billions and even trillions of U.S. dollars per statistical mortality prevented.

More recently, the pendulum of U.S. environmental legislation has swung back toward technology- rather than risk-based approaches. The 1986 amendments to the Safe Drinking Water Act directed the Environmental Protection Agency (EPA) to establish a list of potential drinking water pollutants by 1988, and to promulgate enforceable regulatory standards for at least 25 of these pollutants by 1991. In addition, the law directs EPA to promulgate standards for an additional 25 potential contaminants every three years indefinitely. The law simply assumes that there are more than 25 such contaminants, and that the list can grow without bound. Considerations about neither risk nor cost seem to matter; it is as if municipalities and privately-

Table I: Major U.S. Regulatory Agencies Charged with Risk Management Activities

Agency[a]	Year Established[b]	Major Regulatory Responsibilities
U.S. Coast Guard (USCG, Dept of Transportation (DOT))	1915	Tankers, other shipping in U.S. waters
Food and Drug Administration (FDA, Dept of Health and Human Services (HHS))	1931	Food (except containing meat and poultry), drugs, medical devices
Nuclear Regulatory Commission (NRC)	1946	Nuclear power and materials
Army Corps of Engineers (COE, Dept of the Army)	1949	Rivers, harbors, and waterways; wetlands
Federal Aviation Administration (FAA, Dept of Transportation (DOT))	1958	Air travel, transport and air-traffic control
National Highway Traffic Safety Administration (NHTSA, Dept of Transportation (DOT))	1966	Highway safety
Consumer Product Safety Commission (CPSC)	1970	Consumer products, flammable fabrics, hazardous substances
Environmental Protection Agency (EPA)	1970	Air and water pollution, pesticides, toxic substances, solid and hazardous wastes, drinking water
Occupational safety and Health Administration (OSHA, Dept of Labor (DOL))	1970	Occupational safety and health (except mines)
Mine Safety and Health Administration (MSHA, Dept of Labor (DOL))	1977	Mine safety and health
Research and Special Programs Administration (RSPA, Dept of Transportation (DOT))	1977	Hazardous materials transportation
Food Safety and Inspection Service (FSIS, Dept of Agriculture (USDA))	1981	Food containing meat or poultry

Notes: [a] Department name and acronym provided for agencies located within Executive departments.
[b] Regulatory functions may have been performed by a different agency, or the agency may have had non-regulatory authorities, prior to this date.

owned public water systems can draw funds from their bank accounts as easily as they draw ground water from deep aquifers.

The Clean Air Act Amendments of 1990 include a bizarre mixture of risk- and technology-based requirements. Regulations addressing "criteria pollutants" (e.g. ozone, nitrogen oxides, carbon monoxide, and particulate matter) must be set based on public health concerns. However, regulations concerning so-called "hazardous air pollutants" (a term of art meaning only that Congress expressly listed the substance in the Act) may consider risk, control cost, and a host of other factors *provided that* control levels are at least as stringent as an arbitrarily-defined technology standard.

Table II. Major U.S. Risk-Management Statutes, Year of Principal Enactment, and Responsible Agencies

Statute	Year	Responsible Agencies[a]
Environment		
Atomic Energy Act	1946	NRC
National Environmental Policy Act	1969	EPA
Clean Air Act Amendments	1970	EPA
Clean Water Act	1972	EPA, COE
Federal Insecticide, Fungicide, and Rodenticide Act	1972	EPA
Coastal Zone Management Act	1972	DOC
Endangered Species Act	1973	DOI, DOC
Resource Conservation and Recovery Act	1976	EPA
Toxic Substances Control Act	1976	EPA
Comprehensive Environmental Response, Compensation, and Liability Act	1980	EPA
Emergency Planning and Community Right-to-Know Act	1986	EPA
Oil Pollution Act	1990	EPA, DOT (USCG)
Food Safety		
Meat Inspection Act	1906	USDA (FSIS)
Food, Drug, and Cosmetic Act	1906	HHS (FDA), EPA
Poultry Products Inspection Act	1957	USDA (FSIS)
Safe Drinking Water Act	1974	EPA
Consumer Product Safety		
Consumer Product Safety Act	1972	CPSC
Transportation Safety		
Federal Aviation Act	1958	DOT (FAA)
Highway Safety Act	1966	DOT (NHTSA)
Hazardous Materials Transport Act	1975	DOT (RSPA, FAA)
Work Place Safety		
Atomic Energy Act	1946	NRC
Coal Mine Health and Safety Act	1969	DOL (MSHA)
Occupational Safety and Health Act	1970	DOL (OSHA)

Notes: [a]DOI = Dept of the Interior; DOC = Dept of Commerce; see Table 1 for interpretation of other agency acronyms.

2. Role of risk assessment in legislation

Across the gamut of U.S. efforts to manage risks, the prevalence and importance of risk assessment varies enormously. The discussion above suggests the extent of this variation in the environmental area. Public health regulation tends to rely more consistently on risk assessment, but in one particular area it does so only in a cursory fashion. Under the Delaney Clause of the Federal Food, Drug and Cosmetic Act, enacted in 1959, the Food and Drug Administration (FDA) must prohibit the use of any food additive shown to cause cancer in man or animals. There are many reasons for believing that the Delaney Clause should be abandoned. For example, advancements in detection have dramatically increased the domain to which Delaney applies. Substances which in 1959 could not be detected at all can now be readily quantified.

Furthermore, the quantitative measurement of risk is irrelevant in this debate. Once a food additive is "shown" to cause cancer in man or animal, that substance must be prohibited irrespective of the risk involved. A risk of 10^{-1} is treated the same as a risk of 10^{-12}. Most risk assessment practitioners and risk management professionals will agree that this is a nonsensical result. Both the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have tried in recent years to establish administratively the notion that the Delaney Clause does not apply to additives that pose potential upper-bound excess lifetime cancer risks of less than one in one million. Both agencies have had these policies overturned by the federal courts. The unpleasant fact is that the Delaney Clause remains the law of the land, and efforts to repeal or modify it have not coalesced into a sufficiently powerful political force. Consequently, problems such as the procymidone crisis in 1991 are virtually guaranteed to recur.

Risk assessment plays a less visible but still significant role in other areas of U.S. regulatory decision making. For example, regulations addressing transportation risks are based implicitly on risk assessments because estimates of societal benefits from regulation often figure prominently in the selection of regulatory alternatives. Agencies within the U.S. Department of Transportation (DOT) set safety standards for motor vehicles and aircraft. Before promulgating new standards, these agencies examine and quantify the potential societal benefits associated with reducing transportation risks, because the statutory authorities underlying these regulatory activities requires them to take costs into account.

Finally, risk assessment appears to have little relevance to policy making in certain highly-charged issues. While the U.S. has imposed fuel economy standards on automobiles since 1974, the safety-related consequences of these standards have entered this debate only recently. Credible estimates indicate that 2,200 to 3,900 lives are lost each year due to current Corporate Average Fuel Economy (CAFE) standards. Nevertheless, Congressional attention toward these estimates appears to correlate only with pre-existing views on the desirability of CAFE; few policy makers, if any, appear to have been persuaded that the risk-related consequences of fuel economy standards are relevant and should be considered in the establishment (or repeal) of CAFE standards.

Similarly, the acid rain provisions of the Clean Air Act Amendments appear to have little scientific basis. The U.S. government devoted over one-half billion dollars to carefully study the potential environmental problems associated with acid rain, then proceeded to ignore the results of this effort. Instead of using risk assessment to ascertain the risks associated with acid rain, the Congress simply mandated that aggregate sulfur dioxide (SO_2) emissions be reduced 10 million tons annually by the year 2006.

The latest phenomenon in environmental legislation involves the establishment of extremely detailed "toxic release reporting" and disclosure requirements. This began with the Emergency Planning and Community Right-to-Know Act of 1986, and was recently expanded upon by the Pollution Prevention Act of 1990. Rather than directly mandate specific changes in the production processes of American industry, these laws do so indirectly (and probably more effectively) by simply mandating the collection, reporting and public disclosure of certain data. These reporting requirements cost billions of dollars each year. They also provide domestic and foreign competitors extensive information concerning production technology and market strategy that cannot be legally obtained any other way. Finally, there is no clear correlation between the number of pounds of a chemical "released" into the air and risk to human health and the environment. Nevertheless, the threat of public disclosure of such data *suggest* the presence of risk and thus motivate firms to invest substantial sums in changes to their production processes to avoid the negative publicity.

Risk assessment is irrelevant to decision making under reporting schemes such as "toxic release reporting". Quantity replaces hazard and dose in the implicit equation of risk. The fact that the Congress is increasingly relying upon such approaches suggests that at least some Members of Congress do not have much confidence in risk assessment.

3. Role of benefit-cost analysis in legislation

Similar variation in legislative attitudes exist with respect to the use of benefit-cost analysis (BCA), both as an analytic tool for understanding the implications of policy choice and as a methodological device for decison making. BCA is required in some cases, explicitly prohibited in others, and generally tolerated elsewhere.

The U.S. environmental statutes related to pesticides and toxic substances require both the application of and reliance upon BCA for regulatory decision making. These requirements do not appear to have hindered the promulgation of pesticide regulations, but may have stifled the promulgation of regulations concerning so-called "toxic substances". The explanation for this apparent discrepancy may be that, unlike substances which *may* have toxic effects under certain circumstances, pesticides are expressly intended to be toxic to certain life forms. Thus, it is not at all surprising to discover that the administration of high doses of certain pesticides may have significant human health consequences. In contrast, analyses of so-called "toxic substances" generally show that they pose little or no risk except under highly unusual circumstances.

Regulatory decision making in these areas must take account of the economic benefits associated with continued use. Regulatory agencies attempt to estimate the losses of both consumers' and producers' surplus associated with use restrictions or prohibitions. Risk assessment, in turn, is an essential ingredient in the estimation of the potential benefits associated with regulation.

On the other hand, the Environmental Protection Agency Administrator is forbidden to consider costs when setting air quality standards for criteria pollutants. By law, the sole criterion for standard setting must be the protection of human health "with an ample margin of safety". This requirement is apparently based on one of two incorrect but widely-held notions: (1) that there is a precise, quantitative non-zero level of air pollution that can be shown to be "safe"; or (2) zero pollution is a technically feasible and economically reasonable objective. Similar extremism characterizes standard-setting under the "zero discharge" objective of the Clean Water Act,

and as indicated earlier, the zero cancer risk threshold for food additives under the Delaney Clause of the Federal Food, Drug and Cosmetic Act.

In between lie the remainder of U.S. statutes addressing risks to human health and the environment. Closely approximating the Clean Air Act extremum is the requirement under the Occupational Safety and Health Act that "no employee (should) suffer material impairment of health or functional capacity" over an entire working lifetime. The Occupational Safety and Health Administration (OSHA), which administers this law, interprets it to mean that once it identifies a "significant risk", the Agency can only consider whether meeting the necessary standards is "feasible". Generally, OSHA has not been constrained by the test of "feasibility". In 1989, OSHA promulgated standards for exposure to lead which, according to the Agency's own analysis, would impose compliance costs in excess of net profits for over half of all firms in 38 industries covered by the standard. These standards have not been successfully challenged in court.

Similarly negative legislative attitudes with respect to BCA can be found in the U.S. food safety statutes (e.g. The Federal Food, Drug, and Cosmetic Act), which as indicated earlier with respect to the Delaney Clause, simply prohibits the use of any new food additive "shown" to cause cancer in man or animals. This prohibition applies irrespective of the magnitude of the cancer risk involved, and irrespective of the potential gains associated with use of the additive – including gains to human health.

To illustrate, suppose that I had invented a miracle preservative that could prevent spoilage indefinitely, and eliminate the need for both pesticides and refrigeration. Clearly, this product would be extremely valuable, both in less developed countries where food spoilage and shortages represent daily public health crises, and in the developed countries where the public worries instead about low-level exposure to pesticides. Hundreds of thousands of lives could be saved thanks to my inventiveness. Suppose also that a well-conducted laboratory bioassay reveals that it causes cancer in rats. Using conventional methods of high- to low-dose extrapolation and interspecies scaling, regulatory scientists estimate that the excess lifetime cancer risk to an individual due to my additive is one in one million (10^{-6}). (This is, of course, the *upper-bound* estimate; the *lower-bound* risk estimate is zero.)

Under the Delaney Clause, my additive cannot be used on foods sold in the U.S.

A useful and revealing exercise would be to estimate the social benefits which American consumers (never mind the rest of the world) would have to forego because of this statutory constraint. Such estimates are rarely generated. It is extremely difficult to motivate regulatory agencies to focus on the consequences of actions they take with regret because of legislative constraints. Agencies resist expending the resources on analysis when it cannot legally influence decisions.

The U.S. Food and Drug Administration (FDA) also regulates pharmaceuticals and medical devices, and tends to place greater weight on avoiding risks associated with its approvals (i.e. false positives) and little if any weight on avoiding risks associated with delays in the approval process and risks associated with decisions to deny such approvals (i.e. false negatives). This behavior appears to be rooted in the extreme risk-aversion associated with FDA's bureaucratic mindset combined with the paternalistic attitude of the public health profession, which is uncomfortable with the notion that individuals should be empowered to make their own risk management decisions. An important initiative of Vice President Dan Quayle's Council on

Competitiveness has been to break down these barriers, reduce the FDA's review time, and enhance the ability of patients to make these decisions themselves. Nevertheless, the capacity of the bureaucracy to stifle innovation and resist change should not be underestimated.

Elsewhere, regulatory agencies are routinely required by law to at least consider the economic consequences of their decisions. For example, the regulatory agencies charged with aircraft and highway safety routinely examine the costs associated with proposed regulatory actions(3) During our reviews of these proposals (a process described in more detail below), we generally focus on whether the analyses were performed properly and do not get into extensive debates over whether such analysis is necessary, appropriate or desirable.

4. Structural impediments to strengthening the use of risk assessment and benefit-cost analysis

Most U.S. health and safety legislation is revised by the Congress in a relatively predictable cycle. This occurs because typically "authorizes" an agency to regulate in a particular area for a fixed period of time – perhaps five years. The Congress takes up the question again when this "authorization" nears its end. In the event that an authorization expires, agencies continue to implement the authorities conferred upon it so long as the funds for doing so are appropriated. This distinction between authorization and appropriation leads to considerable confusion, even within Washington. It is critically important, however, because different Congressmen and Senators chair the relevant authorization and appropriation committees and subcommittees, and they may agree.

For a new regulatory program to be enacted, the relevant authorization committees must first identify (or create if necessary) the organic authority under which a department or agency will operate. The committees will write a bill directing the department or agency to promulgate the necessary regulations, giving it as little or as much guidance as it sees fit. Once the bill receives the approval of both houses of Congress and is signed by the President (a tortuous process in itself), the department or agency now possesses the *authority* to implement the new regulatory program.

This does not mean that the agency will have an *appropriation* to implement it, however. Getting the money requires successfully passing through another gauntlet, this one under the control of the appropriations committees. Depending on a host of factors, the department or agency may be appropriated the full amount necessary, nothing at all, or something in between.

With this background, it is easy to see that changes in statutory requirements can arise either through the authorization process or through the appropriation process. The authorization committees hate it when the appropriations committees "meddle" by either limiting the amount of funds appropriated or placing conditions on the expenditure of such funds. In turn, the appropriation committees often "meddle" because the authorization committees never worry about competing claims upon the budget, or because they want to steer funds toward constituents

(3) The Federal Aviation Administration (and its companion agency charged with regulating railroad safety) often face resistance to cost concerns, especially in cases where they are responding to "suggestions" made by the National Traffic Safety Board (NTSB). The NTSB is charged with investigating air and rail accidents and is independent of the Department, and it does not consider costs when making such suggestions.

in their own States or districts, or perhaps because they fundamentally disagree with what the authorization committees are trying to accomplish. This process often leads to incompatible demands upon the agency.

Once any statute has been enacted, this system is highly protective of the status quo. There are high hurdles to change, irrespective of its motive or merits. Efforts to enact meaningful reforms that would impose greater rigor on agency decision making, either involving risk assessment or benefit-cost analysis, thus encountered severe barriers. Conversely, efforts to remove risk assessment or benefit-cost analysis requirements where they now exist also face great difficulty.

5. Political impediments to strengthening the use of risk assessment and benefit-cost analysis

In addition to these structural problems, reform efforts encounter entrenched political and economic interests for whom the status quo constitutes a valuable political or economic asset. Members of Congress who are responsible for or benefit from the status quo are naturally loath to recognize the need for reform. Special interest groups, who may have been important players in the development of a statute and gain politically and financially from its unfettered implementation, recognize reform efforts as direct attacks upon these assets and virulently resist.

Risk assessment is now under attack in the U.S. because it has become a political tool of special interest groups whose interests are coterminous with exaggerated estimates of risk. High estimates of risk, no matter how implausible, have been successfully used as the basis for extensive government intervention. Efforts to restore credibility to risk assessment are met with scathing attacks on the motives of the putative reformers, some of whom stand to reap substantial political and economic gains from reform. Science has become just another weapon in the perpetual war of politics. Because of these constraints, prospects for reforming legislatively the use and application of risk assessment appear exceedingly dim.

A significant opportunity for reform is available pursuant to the Clean Air Act Amendments of 1990. Section 301 directed the Environmental Protection Agency to fund a study of risk assessment methods to be performed by the National Academy of Sciences. This report is due no later than May 1993(4). In addition, Section 303 established a bipartisan Risk Assessment and Management Commission to:

> make a full investigation of the policy implications and appropriate uses of risk assessment and risk management in regulatory programs under various Federal laws to prevent cancer and other chronic human health effects which may result from exposure to hazardous substances(5).

Despite the apparent breadth of this charge, the Commission faces an even more Herculean task than can be gleaned from this short passage. First, the Commission will be composed of members appointed by the president and the majority and minority leaders of both Houses of Congress;

(4) New Clean Air Act §112(o) at 104 Stat. 2560, codified at 42 U.S.C. 7412.

(5) Clean Air Act Amendments of 1990 §303 at 104 Stat. 2574, codified at 42 U.S.C. 7412 (note).

reaching a consensus will be extremely difficult(6). Second, most of the significant and costly regulatory actions which involve risk and are required under the new amendments will have been promulgated before the Commission completes its work at the end of 1994(7).

It is unlikely that there will be an increased propensity for Congress to mandate (or expressly permit) benefit-cost analysis. The explanation is analogous. Some politicians and special interest groups benefit handsomely from the status quo and will expend significant resources to preserve it. Efforts to require Congress to quantify and consider the social costs of its actions are attacked as representing base material concerns rather than the enlightened "public interest".

To give just one example, the Delaney Clause resists reform in part because its consequences are generally hidden from view. The U.S. public is completely unaware of the real cost of prohibiting food additives that pose trivial cancer risks. Agencies do not quantify these costs, and the Congress does not want to acknowledge them. Ironically, there is one major instance in which Delaney was explicitly overridden, and it was widespread public recognition of the costs that motivated the override. This occurred when the Food and Drug Administration proposed to ban saccharin because a high-dose laboratory study found bladder cancer in animals. Faced with the threat of losing all diet products from the marketplace, the Congress responded by legislatively exempting saccharin from Delaney.

A potentially analogous situation occurred in 1990 when the fungicide procymidone turned up at previously undetectable levels in French wine. The Evironmental Protection Agency (EPA) hurriedly promulgated a tolerance level to ensure that Americans' access to Bordeaux was not interrupted. Had studies shown that procymidone concentrated in grape juice or wine, EPA would have been compelled under the law to prohibit the importation of "contaminated" French wine.

III. The Exercise of Administrative Discretion in Regulatory Decision Making

Regulatory agencies charged with implementing a law generally have discretion to make certain determinations in the process. The amount of discretion varies considerably across statutes, however. Risk-management statutes have historically delegated substantial discretion in certain areas but placed very severe constraints in others. In the environmental area, agency discretion reached a low-water mark with the 1984 amendments to the Resource Conservation and Recovery Act, the law governing the management of hazardous wastes, when Congress mandated an extremely severe regulatory system with very tight implementation deadlines. These deadlines were called "hammers" because certain Draconian restrictions would have been imposed automatically if the Environmental Protection Agency (EPA) had not taken action prior to specified dates. Despite heroic efforts by EPA to meet these deadlines, many significant and complex hazardous waste regulations were promulgated without adequate support and careful analysis because the Congress did not provide EPA with enough time to do the job right.

(6) The president and the minority (i.e. Republican) leaders of the House and Senate have five of the ten appointments. The majority leaders of both houses appoint four members. The tenth member is appointed by the president of the National Academy of Sciences.

(7) Given the Commission's composition, it seems likely that it will produce majority and minority reports. Each side will have something they can point to in support of its own views and to condemn the views of its opponents.

In the Clean Air Act Amendments of 1990, Congress resumed its earlier pattern in which certain provisions allow for substantial administrative discretion but others are extremely inflexible, severe, and lack any discretion whatsoever. As an example of the latter genus, Congress' list of so-called "hazardous air pollutants" actually contains Chemical Abstract Service numbers and matrix notation for certain chemical compounds.

A. Administrative procedure

In the midst of this is a governmental system that emphasizes administrative procedure above all other things. There is no room for an autocrat, even if his every action were guaranteed to be correct. The process of regulatory decision making must be consistent with the law, and based on an extensive administrative record that was amassed in accordance with specified procedures of public notice, hearing and comment. This means that virtually every regulatory action must be published in the *Federal Register* as a "proposed rulemaking" to be subjected to the rigors of public comment on all of its salient features, supporting data, and analysis. In its final action promulgating the regulation, the agency must respond to all significant comments it received during the public comment period. The agency may change directions so long as the change is supported by these comments, or is otherwise a "logical outgrowth" of the proposed rule.

To support a final regulation from legal challenge (a routine phenomenon for both the Environmental Protection Agency and the Occupational Safety and Health Administration), the regulatory agency must have amassed an administrative record which, when taken as a whole, supports or at least does not refute the agency's chosen action. For even the most minor regulation, this can be a convoluted and time-consuming process. Nevertheless, current doctrine in U.S. administrative law requires the federal courts to give substantial deference to the implementing agency's interpretation of the statute where the statute gives the agency administration discretion.

The real battle thus occurs on the inside, where a variety of interests converge upon the agency head, who has the ultimate authority to exercise this discretion. First, there is the agency staff, who are often captured by special interest groups or in some cases have their own independent political objectives. Second, there are Members of Congress, who seek to persuade agency heads to interpret ambiguous provisions of the law in certain ways. Sometimes, Congressmen are merely forwarding the concerns of their constituents; other times, they have a special interest in the issue at hand. There is also the Congressional staff, a huge body 20,000 strong and growing, who actually write the bills and negotiate compromises among the Members that are necessary to make the system work. Many Congressional staffers are ardent advocates themselves and have interests independent of the Members who employ them. Third, there are the usual external interest groups – the regulated community, "public interest groups", etc. – who lobbied for (or against) the law in the first place and have their own visions concerning how the law should (or should not) be implemented. American high school students learn in their government courses about the so-called "iron triangle" – the unholy alliance between a government agency, the special interest groups whose interests it serves, and the relevant Congressional committees who control the agency's authorization and appropriations.

Finally, there is the President of the United States.

Under Article II, Section 3 of the U.S. Constitution, it is the President who must "take Care that the Laws be faithfully executed, and shall Commission all the Officers of the United States".

Agency heads thus are supposed to be accountable to the President, who himself may be held accountable for failing to obey his oath of office.

Like many other laws, most risk-management statutes are written with a somewhat different reporting arrangement in mind. Instead of directing the President to execute the policies and programs it enacts, the Congress is fond of vesting these powers directly in the relevant agency heads themselves. The intent of this subterfuge is to make agency heads accountable *directly* to the Congress rather than indirectly through the President. Unsurprisingly, this has the effect of reducing the powers of the President relative to the Congress, and strengthening the "iron triangle".

B. Presidential Oversight of Agency Decision Making

Presidents of both political parties have made numerous attempts to restore Presidential power by establishing White House coordination and review mechanisms. Among the review mechanisms have been several focused on regulatory decision making. In modern times this began with the Nixon Administration's "Quality of Life" reviews. Reflecting the concerns of the era, President Ford ordered "Inflation Impact Statements" to be performed. President Carter established the Regulatory Analysis Review Group (RARG) within the Council on Wage and Price Stability (COWPS). Whereas the principal focus of the COWPS was the implementation of wage-and-price controls, the purpose of the RARG was to weed out regulatory initiatives that failed the benefit-cost test.

A new process was formalized in 1981 after President Reagan signed Executive Order No. 12291. This Order invigorated White House regulatory review by establishing both a process for all Executive department agencies to follow and specific performance standards by which their regulatory proposals would be judged. Simply put, Executive Order No. 12291 established a formalized benefit-cost test: to the extent permitted by law, agencies were to foreswear regulatory actions that provided less in social benefits than they imposed in social costs. Furthermore, agency heads were directed to exercise their administration discretion to select regulatory alternatives which *maximise* net social benefits.

My office implements this executive Order. While our record is mixed with both successes and failures, there is no doubt that the Order provides an extremely powerful tool for establishing presidential oversight over agencies and providing presidential guidance to agency heads. Each year, we review well over 2,000 individual draft proposed and final regulations before they are published or promulgated. Although many of these draft regulations comply with the substantive provisions of the Order, a substantial share do not(8).

IV. Improving Risk Assessment and Risk Management

Over the years, we have developed certain insights and expectations and have reached certain conclusions about the use of risk assessment and benefit-cost analysis in U.S. agency risk-management regulations. First, there are significant problems attending the way in which U.S.

(8) In 1990, the last year for which complete data are available, at least 30 percent of these draft regulations failed to comply with the provisions of the Order or required significant changes to achieve compliance. Because of inherent features of our data base, the proportion of draft rules failing to comply with the terms of the Order is probably much higher than 30 percent.

agencies perform risk assessment and benefit-cost analysis. Many risk assessments are fraught with huge biases that result in highly exaggerated estimates of risk and inflated estimates of the social benefits of regulation. Benefit-cost analyses performed by federal agencies in support of these regulations routinely suffer from serious methodological errors that would render them unacceptable student papers in most American universities. Very few would survive peer review if their authors sought publication in professional journals. These problems persist because the adversarial nature of administrative decision making has converted risk assessments and benefit-cost analyses into political weapons rather than instruments of informed decision making.

Second, the solution is not to abandon risk assessment or benefit-cost analysis, but to reinvigorate review procedures so that rigorous, high-quality analysis becomes a *prerequisite* for decision making rather than an exercise in *ex post* justification. It is in this spirit that we have embarked on a three-part program aimed at improving agencies' analytic capacity and performance, and educating the American public concerning the opportunity costs of regulatory decisions. This program involves (1) reforming risk assessment methodology and applications, (2) publicizing the opportunity costs of risk-management decisions, and (3) developing new analytic methods to deal with those policy areas in which the Congress has forbidden the use of benefit-cost analysis in the mistaken belief that if tradeoffs are not made explicit they can be safely ignored.

A. Conservatism in Risk Assessment: Benign or Maligant?

In the United States, there is currently underway a vibrant debate concerning the methods of risk assessment, particularly those methods used to estimate cancer and non-cancer risks from man-made chemicals. This debate could profoundly affect the use and practice of risk assessment as we approach the next century.

Risk assessment is in the grip of crisis. Although it is widely believed that risk assessment constitutes an interdisciplinary scientific methodology, it is in fact brimming with value judgments, political concerns and other non-scientific ingredients, all of which masquerade as science. In the process, the pursuit of objective truth has become a quasi-scientific tool for the achievement of non-scientific political and economic objectives. This is not to suggest or imply that the political and economic objectives served by risk assessment are illegitimate. Rather, the point is that it has become extremely difficult to distinguish between "science" as a value-neutral exercise in understanding that which was unknown, and "science politics" as a device for motivating political systems toward goals which were established based on principles and concerns other than science.

Many of us who are strident in our criticism of current risk assessment methods are economists. One reason for this is that years ago we experienced the political corruption of another extremely useful analytic method – benefit-cost analysis. Instead of applying benefit-cost analysis properly to ascertain reliable estimates of net social benefits from various development projects, some governmental practitioners used it as a tool for justifying projects that had been approved on political grounds. During the 1950s and 1960s, for example, it was not unusual to see a government benefit-cost analysis "support" a proposed hydroelectric dam, where benefit/cost ratio was something like 1.001. Upon further examination, a competent independent reviewer

would quickly discover that costs were grossly underestimated and benefits were highly exaggerated(9).

The effect of these biased applications was that benefit-cost analysis developed a shady reputation, particularly among environmentalists who opposed these projects. Their opposition typically derived from non-economic considerations, but observing that benefit-cost analysis was apparently the analytical basis for justifying a project they despised, they learned also to hate benefit-cost analysis as well. One can only speculate as to whether environmentalists would have incubated this attitude had they realized that benefit-cost analysis was being employed in an abusive way, and that proper application would have shown the projects they opposed on environmental grounds to be without economic merit as well.

Risk assessment is now suffering the same sort of "credibility gap" that afflicted benefit-cost analysis two decades ago. The good news, of course, is that benefit-cost analysis has survived and prospered. The bad news is that environmentalists (and others) are still leery of it, in part because they fear that it will be manipulated for political purposes rather than used in a reasonably objective manner.

With this background, it is important at an international conference on risk assessment to catalog the problems which plague the practice of risk assessment, point out areas where improvements can be made now, and identify areas in which further research is needed. Table III below does this in a compact form. It lists the types of biases in current risk assessment methodology, the direction of these biases, and an indication as to whether reform is possible now or must be delayed pending additional research.

Except for a handful of very difficult issues where significant research is necessary before major methodological improvements can be made, there are plenty of ways to fix many of these technical problems. The real barriers to reform are bureaucratic and political. Government bureaucracies despise change, and like other organisms, react to perceived threats by throwing up a variety of defense mechanisms. Given the limited amount of reform which has occurred over the last decade during which risk assessment has been subjected to increasingly intense criticism, one must conclude that U.S. risk assessment bureaucracies have powerful antibodies.

The most important reform that can be implemented today is the proper characterization of uncertainty surrounding quantitative risk assessments. U.S. regulatory agencies routinely estimate and report point estimates of individuals that appear to have two or three significant figures, while at the same time acknowledging that uncertainties in these estimates span orders of magnitude. It is rather common to observe a so-called "verified potency estimate" for a putative carcinogen such as 6.27 mg/kg/day, but the left-most digit (6) is probably not meaningful, never mind the digits which follow. In virtually every instance, such an estimate refers to some amorphous "upper bound", and the analogous lower-bound risk estimate is zero.

Despite the obviously misleading features of such numbers, they are usually combined with upper-bound estimates of exposure to derive estimates of "individual risk". Oftentimes, there is no individual anywhere for whom this estimate of "individual risk" is accurate. Even where

(9) Benefit-cost ratios are not acceptable summary measures because they do not reveal the scale of a project. Economists agree that the net benefit criterion (i.e. benefits minus costs) provides the appropriate summary statistic for benefit-cost analysis.

Table III: Biases in Current Risk Assessment Methodology and Opportunities for Reform

Identity of Bias	Direction	Reform Now/*Research Needed*
Sensitive test species in animal bioassay	Overstates risk	Use weight-of-evidence approach; carry forward uncertainty
Selective use of alternative studies	Overstates risk	Use weight-of-evidence approach; carry forward uncertainty
Selective interpretation of results	Overstates risk	Use weight-of-evidence approach; carry forward uncertainty
Severe testing conditions ("Maximally-Tolerated Dose", or MTD)	Overstates risk	Use weight-of-evidence approach; carry forward uncertainty. *Research mechanisms of action*
Benign tumors counted as malignant	Overstates risk	Aggregate benign and malignant tumors only when there is a persuasive scientific basis
Pooling tumors across sites	Overstates risk	Pool tumors only where they are clearly independent
(Linearized) multistage dose-response model for carcinogens	Overstates risk more often than understates risk	Use unbiased estimate of MS rather than upper bound; estimate using variety of plausible dose-response models; apply explicit subjective weights; carry forward uncertainty
LOAEL/NOAEL approach with "uncertainty factors" for non-carcinogens	Overstates risk	Estimate population risk by simulation the distribution of individual thresholds
Interspecies scaling factor	Unknown	Select factor where scientifically defensible, otherwise carry forward uncertainty
Failure to capture all exposure pathways	Understates risk	Estimate risks for all significant pathways
Synergistic effects not considered	Understates risk	Take account of synergisms where known or suspected (e.g. smoking and inhalation lung carcinogens)
Antagonistic effects not considered	Overstates risk	Take account of antagonisms where known or suspected (e.g. antioxidants)
Zero risk assumed where results are inconclusive or nonsignificant	Understates risk	*Research needed to develop alternative to zero risk default*
Non-carcinogen risks often ignored for suspected carcinogens	May understate risk	Perform screening analysis to determine whether non-carcinogenic effects are plausible at doses of concern
Worst-case environmental conditions for exposure	Overstates risk	Use available distributions to capture likelihood of each exposure scenario; simulate unavailable distributions. *Research other distributions*
Maximum Exposed Individual (MEI) used as proxy for individual exposure	Overstates risk	Use available distributions to capture likelihood of each exposure scenario; simulate unavailable distributions. *Research other distributions*
Default exposure assumptions used instead of real-world data	Overstates risk	Use available distributions to capture likelihood of each exposure scenario; simulate unavailable distributions. *Research other distributions*
Point estimates of risk	Overstate risk	Characterize risk as distribution rather than point estimate

it potentially represents a real person, it is likely to be someone at the extreme high end of the exposure distribution.

Finally, these estimates of "individual risk" are often aggregated to produce estimates of population incidence. Because these estimates are the product of a series of cascading conservative assumptions, they have no scientific, statistical, or practical meaning. Nevertheless, agencies use them as measures of baseline risks in the benefit-cost analyses they perform as required under Executive Order No. 12291.

The entire process is a manifestation of the Lotus Theory: If Lotus 1-2-3 can generate the number, then it must be right.

The role of my office in reforming risk assessment is necessarily quite limited. We are economists and policy analysts, not physical or biological scientists. Nevertheless, we can tell when sound scientific and analytic methods are being abused to achieve non-scientific political objectives. If in the course of our review of draft proposed and final regulations we discover significant flaws in quantitative risk assessment, we challenge the responsible regulatory agency to defend its work. This process is highly adversarial, intensely controversial, and probably minimally effective.

What is needed is another review process running parallel to ours which focuses solely on ensuring the quality of science used to justify decision making. Such a process does not now exist, although this spring and summer there were some efforts within the Administration to create one. It has been delayed indefinitely because of well-founded concerns that the bureaucratic and political enemies of reform would successfully mischaracterize it as a partisan attack upon the *results* of risk assessment rather than an attempt to reform the *process* to make these results more credible and accountable.

Improperly performed risk assessment has important and undesirable side-effects. First, it distorts the priorities of the Government by directing resources toward the reduction of risks which are likely to be considerably smaller than they appear. These distortions are probably most severe with respect to cancer risks, least apparent with respect to safety risks(10). In any event, it is virtually certain that resources devoted to risk reduction could be reallocated so as to provide substantially more reduction of risk at much less cost.

Second, the results of current risk assessment practice are occasionally perverse. Sometimes we eliminate a trivial risk only to increase risks elsewhere. Sometimes we eliminate a risk faced by a hypothetical Maximum Exposed Individual (MEI), only to discover that we have increased risks to the rest of the population.

In 1983, the U.S. National Academy of Sciences published a report on risk assessment in which it strongly recommended heroic efforts to separate science (i.e. risk assessment) from policy (i.e. risk management). We are a long way from achieving the Academy's recommendations. That very year, William D. Ruckelshaus, twice Administrator of the U.S. Environmental Protection Agency, sounded a warning about the future of risk assessment if it failed to follow the Academy's advice:

(10) One reason why safety risks tend to suffer less from these biases is that safety risk assessment is generally based on real-world human data rather than extrapolations based on laboratory experiments.

> Risk assessment...must be based on scientific evidence and scientific consensus *only*. Nothing will erode public confidence faster than the suspicion that policy considerations have been allowed to influence the assessment of risk.

Biases resulting from such political considerations are like a benign tumor in the organism. Unless this tumor is attacked with vigor, there is considerable risk that this tumor may turn malignant.

B. The Cost-Effectiveness of U.S. Risk Management Regulation

A few years ago we began to keep a database of the cost-effectiveness of federal risk-management regulations. We published a summary of the available data last year, and it is reproduced in Table IV opposite.

The table lists about 50 major federal risk-management regulations which were primarily intended to reduce risks to life. For each regulation, we provide (1) the year in which it was promulgated, (2) whether it was a health or safety risk involved, (3) the agency responsible for the regulation, (4) the mortality risk per million persons exposed prior to promulgation, and (5) the cost per premature death averted in millions of 1990 U.S. dollars. Regulations are ranked from the most cost-effective (i.e. lowest cost per premature death averted) to least cost-effective (i.e. highest cost per premature death averted).

Self-evident from this table is the fact that cost-effectiveness varies by almost eight orders of magnitude. Some regulatory actions, such as the Consumer Product Safety Commission's ban on unvented space heaters, cost very little per life saved. Others, however, cost tens of millions or even billions of dollars for every statistical life saved. So far, the worst we have found is a recent regulation that classified spent wood preserving chemicals as "hazardous wastes". This rule imposed costs of at least $5.7 trillion per statistical cancer case prevented.

It is useful to put this cost-effectiveness ratio in perspective. To save just one life, we would have to spend the entire gross domestic product of the United States. Put another way, if we devoted $10 million per year to life-saving projects like this, it would take 570,000 years before we had saved just one statistical life.

There is an extensive literature in which economists have estimated the implicit value of life-saving, based on the willingness-to-pay of individuals to reduce small risks. The consensus of this literature is that individuals are willing to pay between $2 million and $10 million to save a statistical life, with greater confidence in estimates near the low end of this range. The shaded region in Table IV covers all rules with cost-effectiveness ratios within this range. Rules above the shaded region are unambiguously cost-effective; rules below it are clearly *not* cost-effective and reflect an inefficient allocation of resources. We cannot be sure about the merits of rules that lie within the shaded region.

For most (but not all) of the rules that are cost-effective, cost was taken into account by the agency when it decided to regulate. For most (but not all) of the rules that are not cost-effective, compliance costs were not a factor in decision making. Benefit-cost analyses were performed in most cases to comply with the process established by Executive Order No. 12291, but agency heads apparently did not utilize these analyses in decision making.

Table IV. Baseline Risks and Cost-Effectiveness of Selected Federal Risk-Management Regulations

Regulations[a]	Cost a Factor in Decision Making?	Year Issued	Health or Safety?	Agency	Baseline Mortality Risk per Million Exposed	Cost Per Premature Death Averted ($M 1990)
Unvented Space Heater Ban		1980	S	CPSC	1,890	0.1
Aircraft Cabin Fire Protection Standard	Yes	1985	S	FAA	5	0.1
Auto Passive Restraint Seat Belt Standards	Yes	1984	S	NHTSA	6,370	0.1
Steering Column Protection Standards[b]	Yes	1967	S	NHTSA	385	0.1
Underground Construction Standards[c]		1989	S	OSHA-S	38,700	0.1
Trihalomethane Drinking Water Standards		1979	H	EPA	420	0.2
Aircraft Seat Cushion Flammability Standard	Yes	1984	S	FAA	11	0.4
Alcohol and Drug Control Standards[c]		1985	H	FRA	81	0.4
Auto Fuel-System Integrity Standard	Yes	1975	S	NHTSA	343	0.4
Standards for Servicing Auto Wheel Rims[c]		1984	S	OSHA-S	630	0.4
Aircraft Floor Emergency Lighting Standard	Yes	1984	S	FAA	2	0.6
Concrete and Masonry Construction Standards[c]		1988	S	OHSA-S	630	0.6
Crane Suspended Personnel Platform Standard[c]		1988	S	OHSA-S	81,000	0.7
Passive Restraints for Trucks and Buses; Proposed	Yes	1989	S	NHTSA	6,370	0.7
Dynamic Side-Impact Standards for Autos	Yes	1990	S	NHTSA	NA	0.8
Children's Sleepwear Flammability Ban[c]		1973	S	CPSC	29	0.8
Auto Side Door Support Standards[c]	Yes	1970	S	NHTSA	2,520	0.8
Low Altitude Windshear Equipment and Training Standards	Yes	1988	S	FAA	NA	1.3
Electrical Equipment Standards – Metal Mines		1970	S	MSHA	NA	1.4
Trenching and Excavation Standards[c]		1989	S	OSHA-S	14,310	1.5
Traffic Alert and Collision Avoidance Systems	Yes	1988	S	FAA	NA	1.5
Hazard Communication Standard[c]		1983	S	OSHA-S	1,800	1.6
Lockout/Tagout[c]		**1989**	**S**	**OSHA-S**	**4**	**2.1**
Side-Impact Standards for Trucks, Buses and MPVs; Proposed	**Yes**	**1989**	**S**	**NHTSA**	**NA**	**2.2**
Grain Dust Explosion Prevention Standards[c]		**1987**	**S**	**OSHA-S**	**9,450**	**2.8**
Rear Lap/Shoulder Belts for Autos	**Yes**	**1989**	**S**	**NHTSA**	**NA**	**3.2**
Benzene NESHAP (Original: Fugitive Emissions)		**1984**	**H**	**EPA**	**1,470**	**3.4**
Standards for Radionuclides in Uranium Mines[c]		**1984**	**H**	**EPA**	**6,300**	**3.4**
Ethylene Dibromide Drinking Water Standard		**1991**	**H**	**EPA**	**NA**	**5.7**
Benzene NESHAP (Revised: Coke By-Products)[c]		**1988**	**H**	**EPA**	**NA**	**6.1**
Asbestos Occupational Exposure Limit[c]		**1972**	**H**	**OSHA-H**	**3,015**	**8.3**
Benzene Occupational Exposure Limit[c]		**1987**	**H**	**OSHA-H**	**39,600**	**8.9**
Electrical Equipment Standards – Coal Mines[c]		**1970**	**S**	**MSHA**	**NA**	**9.2**
Arsenic Emission Standards for Glass Plants		1986	H	EPA	2,660	13.5
Ethylene Oxide Occupational Exposure Limit		1984	H	OSHA-H	1,980	20.5
Arsenic Copper NESHAP		1986	H	EPA	63,000	23.0
Hazardous Waste Listing for Petroleum Refining Sludge		1990	H	EPA	210	27.6
Cover Move Uranium Mill Tailings, Inactive Sites		1983	H	EPA	30,100	31.7
Benzene NESHAP (Revised: Transfer Operations)		1990	H	EPA	NA	32.9
Cover Move Uranium Mill Tailings, Active Sites		1983	H	EPA	30,100	35.0
Acrylonitrile Occupational Exposure Limit[c]		1978	H	OSHA-H	12,300	51.5
Coke Ovens Occupational Exposure Limit[c]		1976	H	OSHA-H	7,200	63.5
Asbestos Occupational Exposure Limit[c]		1986	H	OSHA-H	3,015	74.0
Arsenic Occupational Exposure Limit[c]		1978	H	OSHA-H	14,800	106.9
Asbestos Ban	Yes	1989	H	EPA	NA	110.7
Diethylstilbestrol (DES) Cattlefeed Ban		1979	H	FDA	22	124.8
Benzene NESHAP (Revised: Waste Operations)		1990	H	EPA	NA	168.2
1,2-Dichloropropane Drinking Water Standard		1991	H	EPA	NA	653.0
Hazardous Waste Land Disposal Ban (1st 3rd)		1988	H	EPA	2	1,190.1
Municipal Solid Waste Landfill Standards, Revised		1991	H	EPA	< 1	41,250.0
Formaldehyde Occupational Exposure Limit[c]		1987	H	OSHA-H	31	86,201.8
Atrazine Alachlor Drinking Water Standard		1991	H	EPA	NA	92,069.7
Hazardous Waste Listing for Wood Preserving Chemicals		1990	H	EPA	< 1	5,700,000.0

Agency Abbreviations:
CPSC - Consumer Product Safety Commission
EPA - Environmental Protection Agency
FAA - Federal Aviation Administration, DOT
FDA - Food and Drug Administration, HHS
OSHA-H - Occupational Safety and Health Administration, Health Standards, DOL
OSHA-S - Occupational Safety and Health Administration, Safety Standards, DOL
MSHA - Mine Safety and Health Administration, DOL
NHTSA - National Traffic Safety Administration, DOT
FRA - Federal Railroad Administration, DOT

Notes:
(a) 70-year lifetime exposure assumed unless otherwise specified.
(b) 50-year lifetime exposure assumed.
(c) 15-year lifetime exposure assumed.
(d) 12-year exposure assumed.

In many of these cases, the underlying statute being implemented is unfriendly toward benefit-cost analysis (e.g. those involving air pollution or occupational health). In other cases (e.g. those involving potentially hazardous wastes), the statute is silent with respect to benefit-cost analysis and the regulatory agency has chosen not to apply it. Finally, there are also cases in which the underlying statute prescribes some degree of benefit/cost balancing (e.g. drinking water, pesticides, toxic substances) but the regulatory agency either failed to perform this required function or performed it poorly.

The morals of this story should be obvious. Where legislation requires benefit/cost analysis and balancing, there is a strong likelihood (but no guarantee) that regulatory agencies will produce sensible regulations that conserve scare resources. However, where legislation is silent or hostile toward such concerns, agencies will tend to produce regulations that lack common sense. These lessons depend, of course, on the existence of a meaningful enforcement mechanism in which a central review authority is capable of holding agencies accountable for the decisions they make.

At the federal level in the United states, we have such a mechanism in Executive Order No. 12291. Unfortunately, only a few of the States have any form of regulatory review and in none of the States does it appear to be very effective.

The most important gap in our regulatory review mechanism is that risk assessments generally are not subject to the same level and intensity of centralized review. This means that political biases embedded in risk assessments may not be discovered and corrected, and our estimates of cost-effectiveness may be overly sanguine. This is the next great challenge for regulatory review in the U.S. – to develop a review mechanism that subjects proposed regulatory actions to the same level of scientific scrutiny that they receive with respect to their economics.

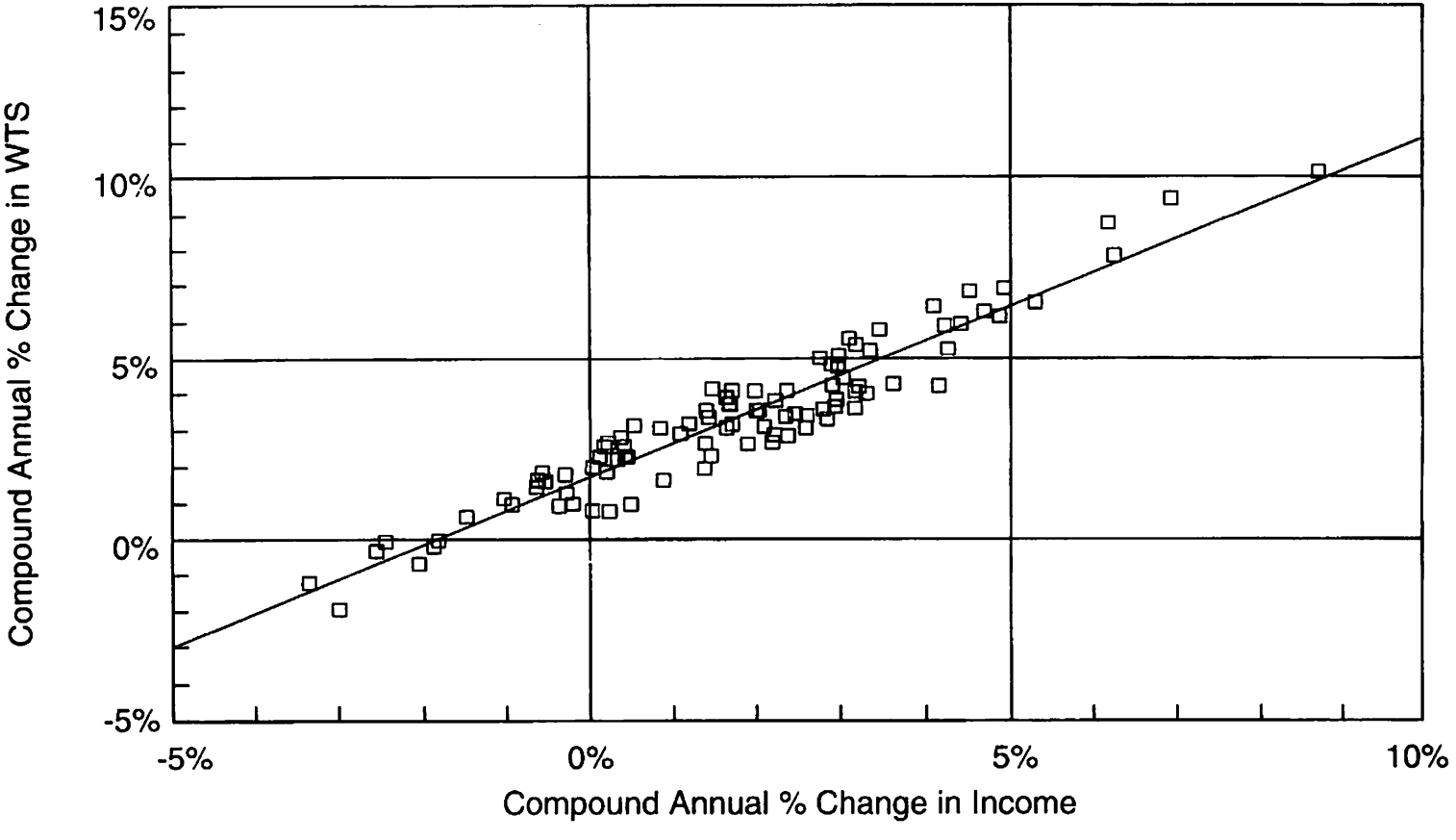
C. Health-Health Analysis

Two of my colleagues at OMB, Drs. Randall Lutter and John Morrall, are currently developing a new analytic approach to deal with regulations which implement statutes that are hostile to benefit-cost analysis. They call it "health-health analysis", and it is based on a simple economic premise. When regulated parties expend resources to comply with regulatory requirements, they must divert these resources from other economically useful purposes. Firms divert these resources from profits (i.e. payments to capital) and wages (i.e. payments to labor), and if markets permit they divert resources from consumers by raising prices. Where State or local governments are the regulated parties, they must divert resources from other public services (i.e. roads, police, schools, social welfare) or they must raise taxes, which is equivalent to diverting resources from taxpayers.

In the U.S. it is commonly said by economists that "there is no free lunch". With rare exception, regulated parties cannot print money.

There is an extensive economics and public health literature which shows that increasing (or decreasing) individuals' incomes indirectly improves (or damages) their health. These studies reveal that reductions in aggregate wage income between $2 million and $6 million result in an expected increase of one in aggregate mortality. Thus, for a regulation intended to reduce the risk of occupational illness, every $2 million to $6 million in regulatory costs that is reflected in reduced wages can be expected to cause an additional indirect expected fatality.

Compound Annual Percent Change in PPP-Adjusted Per Capita Income and WTS



Source: Lutter and Morrall (forthcoming).
Y = 0.016 + 0.923 X
R^2 = 0.91

Figure A

The relationship between income and health is easiest to see in international comparisons. Figure A overleaf plots for over 100 countries the compound annual rate of increase in income observed between 1965 and 1985 against the compound annual rate of increase in these countries' willingness-to-spend to increase longevity, where willingness-to-spend is estimated as the square of longevity multiplied by gross domestic product, divided by an empirically derived constant.

For these 101 countries, there is a striking correlation between the rate of change in income growth and their aggregate willingness-to-spend to increase longevity. On average, a one percent difference in the rate of change in income growth corresponds to a 1.1 percent difference in willingness-to-spend. This is, of course, what economists call a measure of elasticity. It means that as income grows, people spend an increasing share of it on enhancing their health and living longer lives.

We expect to stimulate debate on this issue by summarizing the work of Drs. Lutter and Morrall in our annual publication entitled the *Regulatory Program of the United States.* Despite its common-sense appeal and substantial theoretical and empirical support, the notion that there is a trade-off between wealth and health is quite controversial in Washington these days. Once again, the voices of opposition reflect political and bureaucratic interests which are threatened by the realization that risk reduction is not a free good.

The explanation for this controversy is quite simple. Health-health analysis can be applied directly to each of the regulatory areas mentioned earlier in which there is a statutory prohibition against considering costs (or using benefit-cost analysis as an aid in decision making). In our first application, we asked the Occupational Safety and Health Administration (OSHA) to estimate whether the negative (but indirect) effects on health associated with a particular major regulation might exceed the positive (but direct) health benefits. Since OSHA maintains that the law allows OSHA to look only at health, a *complete* analysis of these effects presumably would improve its capacity to fulfil its statutory charge.

V. Conclusions

The U.S. has extensive experience in using both risk assessment and benefit-cost analysis in regulatory decision making. This experience has been earned despite conflicting legislative mandates, tenacious bureaucratic resistance, and intense political conflict over the direction and purpose of government intervention in an ostensibly market economy that honors consumer sovereignty. Our experience shows that both methods work very well when used properly, but can be quite dangerous in the hands of those for whom the ends justify the means.

For analytic methods to be used correctly in such an environment, there must be quality control procedures to police the various agencies and interest groups who would be tempted to abuse them. Executive Order No. 12291 provides a mechanism to police benefit-cost analysis, but there is no analogous procedural device to ensure the quality and reliability of risk assessment. The development of such a procedural device is the next great challenge.

Neither risk assessment nor benefit-cost analysis can fully protect any decision making regime from decision makers who want to subvert the process. Nor can they overcome those who reject the need for such a process because they seek objectives which cannot be justified based on analysis. Rigorous and sound analysis is an essential ingredient in decision making for any government to remain responsive and accountable to its constituents. For democratic governments, however, accountability is the highest goal of all.