Business Roundtable℠

Toward Smarter Regulation

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Executive Summary

America is experiencing a dramatic increase in government regulation, with the most significant growth in the environmental, health, and safety areas. While the goals of many of these regulations may be laudable, there is a growing realization that we are wasting resources: Legislatures and agencies simply are not allocating limited resources in a cost-effective manner. We could achieve as good or better protection of human health and the environment at far less cost by regulating smarter.

Regulations are like "hidden taxes" that impose costs that are not readily apparent, yet are enormous. Just as the public must pay for government spending programs through higher taxes, they must also pay a high price for regulations – as customers, employees, and stockholders. The soaring costs of regulation stifle productivity, wages, and economic growth. Regulations also undermine jobs and international competitiveness. The increasing strain on our nation's resources brings into sharp focus the challenge for the '90s and beyond: The nation must not only reduce regulation, but when we choose to regulate, we must regulate smarter.

Regulators cannot regulate smarter unless their leaders allow it and demand it. Strong leadership must change the current incentives that drive agencies to create new regulations with little restraint, but offer virtually no reward for reforming or eliminating existing regulations or obviating the need for new ones.

Business is not alone in calling for regulatory reform; taxpayers, state and local governments, academics, members of Congress, the President and the Vice President have all expressed concern about the rising tide of regulations. To provide a framework for smarter regulation, The Business Roundtable recommends that federal, state, and local governments implement the following twelve tenets of rational regulation:

1. Risk-Based Priorities and Public Education: To provide more cost-effective protection to human health and the environment, regulatory priorities should be based upon realistic considerations of risk. Agencies must educate the public about the level of risks proposed for regulation compared to risks familiar to the public, as well as the cost of reducing that risk. The government should estimate the relative risks posed by different substances, products, or activities and decide whether, and

how, to regulate based on those risks. Resources should be committed where the greatest risks can be reduced at the least cost. The government should ensure that the public understands the magnitude of each risk compared to more familiar risks, as well as the costs of reducing that risk.

2. Risk Assessment and Risk Management: Risk assessment methodologies should be continuously improved, and agencies should establish a clear distinction between assessing risks and deciding how to manage them. The scientific process of risk assessment should be made as objective as possible, and uniform standards should be applied. Any necessary policy or scientific judgments should be disclosed. Cost-effective approaches to managing risks should be promoted.

3. Sound Science: Agency decision making should be grounded on the most advanced scientific knowledge currently available. New regulations should be based on the most advanced and credible scientific knowledge, and existing regulations and methods should be regularly updated to incorporate scientific advances. In making decisions and setting priorities based on risk, agencies should use "best estimates," not worst-case estimates of risk.

4. Benefit-Cost Analysis: Benefit-cost analysis should be utilized by agencies when developing regulations, with preference given the least costly regulatory alternative that accomplishes program objectives. First, agencies should use benefit-cost analysis to determine whether or not a proposal should be considered for adoption. Second, agencies should use cost-effectiveness analysis to select the regulatory option that achieves regulatory objectives in the least costly way.

5. Market Incentives and Performance Standards: Market-oriented solutions and performance standards should be favored over command-and-control regulation. Market-based regulatory approaches reproduce the efficiency of a free market by internalizing the cost of a regulated activity or substance. They allow regulated parties to meet or exceed regulatory goals in the least costly way. Moreover, market incentives and performance standards adapt to changed circumstances more quickly than government command-and-control regulation.

6. Productivity, Wages, and Economic Growth: Methodologies should be implemented and continuously improved to assess the impact of major regulations on productivity, wages, and economic growth, as well as the adverse impact on jobs and international competitiveness in industries that bear the burden of regulation. For our economy to grow, regulatory and economic goals must become complementary, not conflicting. Government must be more sensitive to the impact of regulation on wages, prices, jobs, and international competitiveness.

7. Coordination Among and Within Agencies: Coordination of regulatory activities among and within agencies should be improved to eliminate inconsistencies, duplication, and unnecessary regulatory burdens. To address problems within the jurisdiction of multiple agencies, a strong interagency committee should engage in strategic planning and develop a coordinated response before regulations are proposed. Each agency should also coordinate its programs that address different aspects of the same problem.

8. Openness: The entire regulatory process, including centralized Executive review and management of agency rule-making, should be open to public scrutiny, to promote the quality, integrity, and responsiveness of agency decisions. Secrecy should be removed from the regulatory development and review process. More rules should be developed through regulatory negotiation, which involves open negotiations between regulators and interested parties.

9. Periodic Review: Programs and regulations should be periodically reviewed for purposes of determining whether they should be reformed, discontinued, or consolidated. Periodic review allows for government-wide priority setting through reforming or eliminating regulations, updating scientific methodologies, reorganizing an agency, or reallocating responsibility among agencies. Where appropriate, legislatures can ensure a stricter review process by setting firm deadlines by which they will be compelled to evaluate and vote for continuation of a program, or the program will terminate.

10. Federalism: Regulatory authority should be more rationally allocated among the federal, state, and local governments, and federal regulatory programs should avoid unfunded mandates. Many activities and substances are controlled by a mix of federal and state regulation. Modern commercial realities demand a more cost-effective balance of federal and state regulation. The federal government is primarily responsible for achieving this balance and should carefully consider whether to preempt and regulate a field or leave the field to the states. The federal government should also refrain from directing state and local governments to administer or comply with federal programs without providing the necessary funds.

11. Paperwork Burdens: Paperwork burdens caused by regulatory programs should be expressly assessed and substantially reduced. The massive paperwork burdens imposed on business, the public, and governments themselves must be reduced. The Paperwork Reduction Act and OIRA's paperwork control responsibilities should be strengthened. Moreover, administrative process costs – the inflexibility, unresponsiveness, and delay that characterize many regulatory programs – should be examined and reduced.

12. Regulatory Budget: A framework should be developed to account for expenditures required by regulations and to promote greater fiscal restraint on regulatory programs. There is a pressing need for government to be more sensitive to the cumulative costs of regulations. Under a regulatory budget, agencies would have a powerful incentive to regulate in a more cost-effective manner; each agency could be limited in the amount of regulatory costs imposed on the economy each year.

* * *

A unique opportunity for meaningful regulatory reform presents itself. There is a growing consensus not only on the need for regulatory reform, but also on how to achieve it: Government must assess the seriousness of risks proposed for regulation, compare risks to be regulated to risks familiar to the public, disclose the costs of regulation, regulate only if the benefits outweigh the costs, and select the most cost-effective, market-driven method possible. This is smarter regulation. And smarter regulation is better regulation, for consumers, governments, and business alike. President Clinton's Executive Order on Regulatory Planning and Review espouses many of these principles for improving both regulations and the regulatory process itself.

However, the White House, Congress, agencies, and the states must all commit themselves to smarter regulation. The Business Roundtable recommends that governments at all levels implement these twelve tenets. *Our nation cannot afford to ignore the challenge to regulate smarter.*

I. Introduction

Since the 1970s, our nation has implemented far-reaching regulatory programs to protect human health and the environment. Congress created new agencies – such as the Environmental Protection Agency, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission – with broad responsibilities to reduce risks to public health, safety, and the environment. Older agencies, such as the Food and Drug Administration, have been given expanded regulatory authority. Sweeping legislative mandates have directed agencies to reduce risk to the environment, health, and safety, almost without compromise.

Some government intervention in the economy may be necessary to achieve desirable goals such as a cleaner environment, safer working conditions, and safer products. In many instances, specific regulations have been well-conceived and reasonably implemented. These efforts have produced substantial benefits for the country and its people.

And yet, even with the best of intentions, government simply is not allocating limited resources in a cost-effective manner. Despite a dramatic increase in environmental, health, and safety regulation, experience has taught us that often our regulatory efforts have been more costly and less effective than they could have been. Moreover, the enormous costs of federal and state regulations exert a heavy drag on the economy. They depress wages, stifle productivity and economic growth, drive up prices, and impede innovation. They also burden federal, state, and local governments. In our increasingly global economy, excessive regulation seriously undermines the competitiveness of U.S. businesses. Ultimately, the American public suffers.

The costs of regulation are undeniably high, and the costs of many regulations plainly outweigh their benefits. The annual cost of federal regulation was conservatively estimated at $581 billion for 1993; it is projected to rise to $662 billion by the year 2000.[1] Almost 75% of that cost increase is expected from additional environmental, health, and safety regulation.[2] According to EPA projections, by the year 2000 the United States will spend $160 billion annually on pollution control alone – almost 90 percent more than was spent in 1987.[3] Although economic regulation in areas such as transportation and energy has declined, cost reductions from earlier reforms have been dwarfed by new regulation in the environmental, health, and safety areas.[4]

Beyond the problems caused by the rising costs of government

regulation, the regulatory process itself has become unduly rigid, unresponsive, and inconsistent. These problems have sparked increasing concern about the rationality of the regulatory process and a growing determination to do something about it.

The Need For Priorities and Reform

Consumers, business, and governments all have a stake in regulatory reform. Federal, state, and local governments, like business, are part of the regulated community. The enormous liability of federal facilities and municipalities for Superfund cleanups is but one growing regulatory crisis faced by governments at all levels. To absorb the costs of regulation, businesses may be forced to raise prices, reduce production, eliminate jobs, cut research and development, or even go out of business entirely. Likewise, federal, state, and local governments may raise taxes or reduce services; some local governments may even face the prospect of bankruptcy.

Although the direct costs of regulation typically are imposed on businesses and governments, they ultimately are passed on to the American consumer through higher prices, diminished wages, reduced quality or availability of products and services, as well as through increased taxes. Per household, these costs total about $5,900 per year.[5]

These soaring costs of government regulation come at a challenging time. The national debt now exceeds $4 trillion – $16,600 for every man, woman, and child in America.[6] This expanding deficit makes it painfully obvious that our resources are limited. Many government priorities – including crime prevention, education, and defense – must compete for these limited resources. Any increase in regulation must be weighed against other legitimate priorities, as well as against its adverse impact on wages, productivity, and economic growth.

Too many regulations and regulatory programs have suffered from inadequate analysis and discipline. Both the Legislative and Executive Branches must share responsibility – first, to address this problem, and second, to cure it. The Business Roundtable believes that existing and proposed regulatory programs should ensure that:

- Stated goals are in fact attainable.
- Each program or regulation is worth the added cost to the nation (in increased prices and lower wages and productivity, for example).

- Each regulation is the most efficient means to achieve its objective and minimizes adverse economic impacts.

Toward "Smarter" Regulation

The regulatory process must be reformed. Governmental resources at all levels must be allocated more rationally. And business must devote its resources to becoming more innovative and productive. The question is not only how the nation can reduce regulation, but also how we can regulate smarter. This question is crucial in both good and bad economic times.

The concept of smarter regulation is not novel. The increasing regulatory burden has led to a growing demand for reform across a spectrum of American society – from leaders of all business sizes, academics, public interest groups, government officials, and the general public. This demand has already sparked some important steps toward reform; indeed, Vice President Gore's recent National Performance Review report expressed alarm at the cost of regulation and concluded:

> We must clear the thicket of regulation by undertaking a thorough review of the regulations already in place and redesigning regulatory processes to end the proliferation of unnecessary and unproductive rules.[7]

To this end, President Clinton signed Executive Order 12866 on Regulatory Planning and Review on September 30, 1993. This Order carries forward the concern of the last three Administrations by calling for a vigorous regulatory planning and review process and embracing many principles that would improve both the regulatory process and regulations themselves.

However, the hard work necessary to "reinvent" regulation still lies ahead. To further this worthy goal, The Business Roundtable recommends that governments at all levels implement the following twelve tenets of rational regulation:

1. *Risk-Based Priorities and Public Education:* To provide more cost-effective protection to human health and the environment, regulatory priorities should be based upon realistic considerations of risk. Agencies must educate the public about the level of risks proposed for regulation compared to risks familiar to the public, as well as the cost of reducing that risk.

2. *Risk Assessment and Risk Management:* Risk assessment methodologies should be continuously improved, and agencies should establish a clear distinction between assessing risks and deciding how to manage them.

3. *Sound Science:* Agency decision making should be grounded on the most advanced scientific knowledge currently available.

4. *Benefit-Cost Analysis:* Benefit-cost analysis should be utilized by agencies when developing regulations, with preference given the least costly regulatory alternative that accomplishes program objectives.

5. *Market Incentives and Performance Standards:* Market-oriented solutions and performance standards should be favored over command-and-control regulation. They allow regulated parties to meet or exceed regulatory goals in the least costly way.

6. *Productivity, Wages, and Economic Growth:* Methodologies should be implemented and continuously improved to assess the impact of major regulations on wages, productivity, and economic growth, as well as the adverse impact on jobs and international competitiveness in industries that bear the burden of regulation.

7. *Coordination Among and Within Agencies:* Coordination of regulatory activities among and within agencies should be improved to eliminate inconsistencies, duplication, and unnecessary regulatory burdens.

8. *Openness:* The entire regulatory process, including centralized Executive review and management of agency rulemaking, should be open to public scrutiny to promote the quality, integrity, and responsiveness of agency decisions.

9. *Periodic Review:* Programs and regulations should be periodically reviewed for purposes of determining whether they should be reformed, discontinued, or consolidated.

10. *Federalism:* Regulatory authority should be more rationally allocated among the federal, state, and local governments, and federal regulatory programs should avoid unfunded mandates.

11. *Paperwork Burdens:* Paperwork burdens caused by regulatory programs should be expressly assessed and substantially reduced.

12. *Regulatory Budget:* A framework should be developed to account for expenditures required by regulations and to promote greater fiscal restraint on regulatory programs.

Each of these tenets is explored in greater detail below.

II. Twelve Tenets of Rational Regulation

1. Risk-Based Priorities and Public Education: To provide more cost-effective protection to human health and the environment, regulatory priorities should be based upon realistic considerations of risk. Agencies must educate the public about the level of risks proposed for regulation compared to risks familiar to the public, as well as the cost of reducing that risk. The escalating costs of regulation and limited resources available make it imperative to establish priorities in environmental, health, and safety regulation. Despite the vast and expanding investment in programs to protect public health and the environment, there is a growing realization that we are not spending our money in the most cost-effective manner to achieve the greatest possible advances. All too often, regulatory priorities are based on misguided public perceptions of risk instead of valid scientific knowledge and reasoned analysis. Accordingly, there is a pressing need to establish a risk-based approach to environmental, health, and safety regulation and to provide the public with better information for evaluating and comparing risks that are candidates for regulation. The goal is not to put economic values before human values, but to achieve effective risk reduction at a lower cost.

Risk-Based Priorities

The problem of protecting human health and the environment may best be defined as the management of risk. The failure to manage risk effectively and to establish priorities rationally translates ultimately into a failure to protect health, safety, and the environment. Through the use of *comparative risk assessment*, the government can estimate the relative levels of risk posed by different substances, products, and activities and can establish priorities in determining whether, and how, to regulate. The government, with public input, should use comparative risk assessment to compare the magnitude of various risks and set priorities where we can achieve greater protection of human health, safety and the environment in the most cost-effective manner.

- The Environmental Protection Agency has recognized the urgent need for a risk-based regulatory approach employing comparative risk assessment. In its landmark report, *Reducing Risk*, EPA warned: “There are heavy costs involved if society fails to set environmental priorities based on risk. If finite resources are expended on lower-priority problems at the expense of higher-

priority risks, then society will face needlessly high risks. If the priorities are established based on the greatest opportunities to reduce risk, total risk will be reduced in a more efficient way, lessening threats to both public health and local and global ecosystems."[8]

Unfortunately, public fears and political expediency – not scientific analysis – often dictate the priorities set by legislatures and agencies. As a result, government risk-reduction efforts have been unplanned, uncoordinated, and inconsistent. Many risk-reduction programs simply have not been effective:

- Some very costly programs and regulations do not address the more serious risks.
  - ➤ Congress originally estimated that the Superfund program would cost $5 billion when it was enacted in 1980. Independent estimates now project the program will cost between $106 and $302 billion for Superfund and between $372 and $744 billion for related remedial programs[9] (in total, up to 25% of the national debt). Notwithstanding these enormous costs, a group of EPA professionals have ranked risks associated with hazardous waste sites well below other problems receiving far less resources.[10]
- Regulations based on uncertain or unsound scientific information are not revised when more reliable data is produced.
  - ➤ In January 1991, EPA's Office of Drinking Water eliminated the primary standard for silver because it determined that there were no adverse human health effects of silver in drinking water; yet the Office of Solid Waste continues to maintain silver on RCRA's toxicity characteristic list, even though the RCRA silver standard was based on the obsolete drinking water standard.[11]
- Some regulatory actions actually increase risk.
  - ➤ Early in the 1980s, government scientists argued that asbestos exposure could cause thousands of deaths. Congress responded by passing a sweeping law that led cities and states to spend between $15 and $20 billion to remove asbestos from public buildings. But three years ago, EPA officials acknowledged after further research that ripping out the asbestos had been an expensive mistake; it raised the exposure of the public because asbestos fibers had become airborne during

removal.[12] It also delayed the opening of many schools and other buildings.

Executive Order 12866 (Sec. 1(b)(4)) states:

> In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

The White House, the Office of Information and Regulatory Affairs, Congress, each agency, and the states should vigorously promote this policy. The Executive Branch should develop a current inventory of known risks, rank them, and periodically update the inventory every two to four years in light of new information. It should seek extensive public involvement in the process. EPA started towards this goal by creating and implementing two seminal reports, *Unfinished Business* and *Reducing Risks*. These reports were prepared by environmental experts who assessed, compared, and ranked the various environmental risks regulated by EPA

- *Unfinished Business* (1987) found that EPA and Congress in most instances had directed resources to problems based on misguided public fears, instead of objective scientific evidence.
- *Reducing Risks* (1990), produced by an independent committee of the Science Advisory Board, revised the risk rankings set forth in *Unfinished Business* and encouraged EPA to base its programs on the severity of risks and the availability of cost-effective options that would reduce the risks and not violate the Agency's statutory mandates.

The other health and safety agencies – including FDA, OSHA, USDA, and CPSC – would benefit from similar projects. Agencies should address highest priority risks first, rank new risks as they are identified in the future, and routinely communicate this information to the public. A coordinating group should be used to facilitate communication and long-term planning among agency leaders; Executive Order 12866 (Sec. 4(d)) provides such a mechanism by establishing the Regulatory Working Group.

Many other efforts could further the establishment of risk-based priorities. For example, President Clinton might issue guidance to agencies to require the use of risk analysis as a tool for making pollution prevention decisions. This would complement the President's

recent Executive Order 12856, which was designed to make pollution prevention central to government operation and procurement. Moreover, a task force composed of scientific experts from the environmental, health, and safety agencies should create a government-wide manual on the regulation of risk. The manual would provide guidance to regulators on how to manage risks.

In the end, the responsibility lies with Congress and state legislatures to promote a risk-based approach to environmental, health, and safety regulation. The most effective legislation for controlling risk will promote risk assessment while providing the agencies with sufficient flexibility to incorporate state-of-the-art scientific knowledge. In the short term, Congress and state legislatures should require the risk-reduction agencies, such as EPA, to conduct comparative risk assessments to set priorities. An Office of Risk Analysis should be created in EPA and other agencies that need increased expertise in analyzing and ranking risks. As statutes are reauthorized, reformed, and created, Congress and state legislatures should require – not inhibit – the consideration of risk, costs, and benefits in designing regulatory policy. Legislatures should set clear goals for regulatory programs, and these goals should be understandable to the regulated community and the public.

Public Education: Improved Risk Communication

Risk communication is critical to establishing risk-based priorities that are acceptable to the public. The government must educate the public about the level of risks proposed for regulation compared with familiar risks, as well as the costs of regulating them. Agencies often fail to regulate in a cost-effective manner because priorities are based on misguided public fears. All too commonly, agencies fail to inform the public adequately about risks proposed for regulation or misinform the public by making biased or exaggerated risk estimates. This distorts the public's perception of risk, which in turn influences the legislature's agenda and leads to irrational and costly regulatory mandates.

Government has the responsibility to accurately inform the public about the level of risks and to minimize distortion and exaggeration of risks. *Risk communication* is an interactive process in which government, the public, business, media, and the environmental and scientific communities exchange information and opinions about risk

and related concerns. In the past, risk communication has been viewed as a one-way channel from experts to the public, but risk communication should be a two-way street. Effective risk communication should satisfy the public that they are informed about the relevant issues within the limits of available knowledge. It should also generate information on which decision makers base their choices. This framework for effective risk communication should extend to all levels of the regulatory process.

To allow public involvement in the important decisions about whether, and how, to regulate various risks, government must educate the public about the risks to be regulated – in terms nonexperts can understand. This can be achieved through the process of *risk comparison*. Risks proposed for regulation that are unfamiliar to the public should be compared to familiar risks to convey the magnitude of the risk involved.

Risk comparison is critical to permitting the public to engage in the regulatory decision-making process. Moreover, risk comparison techniques are improving. One technique, risk ladders, improves the validity of risk comparisons by providing a range of probabilities for a single class of risk. Risk comparisons are most useful when they involve risks that occur in the same decision context, exhibit similar risk-perception attributes (such as whether they are voluntary or involuntary), and have similar outcomes. Multiple comparisons often will be more helpful than single comparisons. While the nature of different risks often varies in some respects, there should not be inflexible rules for comparing risks. The goal of risk comparison should be to enable the public to make informed choices about the risks they incur and the costs of reducing those risks. Government should inform the public about the relative magnitude of regulated risks, as well as those proposed for regulation, compared to risks commonly encountered and understood by the public. The government must also disclose to the public the potential cost of regulating those risks.

Environmental, health, and safety agencies should develop public risk communication programs. As part of their risk communication programs, agencies should summarize relevant qualitative and quantitative information on the nature of each risk, the nature of the benefits that might be achieved if the risk were reduced, the available alternatives, and uncertainty about risks, costs, and benefits. Agency

risk messages should include an estimate of the magnitude of the risk as well as a characterization of the current or potential efforts to reduce it. This includes the cost and adverse consequences of regulating the risk, who must pay the cost, the effectiveness of various regulatory options, and whether regulation of the risk creates additional risks of its own. Agencies should use risk communication to educate the public so they can be involved in formulating policies and establishing priorities – not to generate support for predetermined conclusions.

Effective risk communication also requires that when agencies assess the size of risks and decide how to manage those risks, decision making should be open to the public. To improve the quality of risk communication with the public, agencies should: distinguish policy or judgmental considerations from scientific considerations when estimating the size of risks and deciding how to manage them; instead of using single-value or worst-case risk estimates, identify a range of credible risk estimates and their corresponding probabilities of occurrence; and disclose and explain any uncertainties in data or scientific knowledge. The important value judgments that must be made in deciding how to manage risks should be disclosed.

Risk communication should be based on a written record that is available to the public: A record facilitates understanding and improvement of the agency's decision. It also prevents surprise when information on a particular risk is disseminated and enhances the consistency and accuracy of that information.

Comparative risk assessment and risk communication provide the means for implementing a more effective and efficient approach to environmental, health, and safety regulation. Comparative risk assessment allows agencies to estimate the size of various risks so that rational priorities can be established and risk can be reduced in the most cost-effective manner. Risk communication enables the public to understand the magnitude of a risk proposed for regulation compared to familiar risks, as well as the costs of reducing that risk. If elected officials and regulators fail to implement this risk-based paradigm, we will lose the opportunity to better protect human health and the environment at less cost and to increase public confidence in the regulatory process itself.

2. Risk Assessment and Risk Management: Risk assessment methodologies should be continuously improved, and agencies should establish a clear distinction between assessing risks and deciding how to manage them. Recent scientific and technical advances have made it possible to improve the core of the regulatory process, risk assessment and risk management.

Risk assessment is the technical process for estimating the level of risk posed by a product or process – that is, the probability that a given harm will occur. Risk assessment, as applied to a substance, proceeds in four major steps: (1) hazard identification, determining what kinds of adverse health effects a substance, product, or activity can cause; (2) dose-response assessment, predicting the degree of adverse effects at a given exposure level; (3) exposure assessment, estimating the amount of exposure; and (4) risk characterization, combining the foregoing into a numerical range of predicted deaths or injuries.[13]

Once risk assessment estimates the risk, *risk management* – the policy-oriented or political determination of what to do about the risk – should be employed. Unfortunately, agencies often merge the primarily scientific process of risk assessment with the primarily political process of risk management. This undermines both the validity and quality of agency decision making.

Separate Risk Assessment and Risk Management

Risk assessment and risk management should be separated as much as possible – both by agencies when conducting risk analyses and by legislatures when designing statutes.

The risk assessment should constitute an agency's best effort to employ the most advanced scientific and technical methods to predict accurately the size of the risk. Because risk assessments often require assumptions to fill information gaps, however, the intrusion of subjectivity into science cannot be totally eliminated. This subjectivity has two components: scientific (or professional) judgment and policy judgment. Nevertheless, most intrusions of scientific and policy judgments can be identified, and these value judgments made in the risk assessment process should be clearly and fully disclosed to the public.[14]

Once the agency makes the most accurate and objective estimate of the relevant risks in the risk assessment process, it can then make an open decision on how best to address that risk in the risk management phase.

Improve Risk Assessment and Risk Management Methodologies

A number of steps can be taken to improve the risk assessment and risk management processes. First, risk assessment methodologies and guidelines should be reviewed and updated to reflect the state of the art. In the short-term, agencies should review their risk assessment guidelines and methodologies and make improvements where appropriate.

- The Clean Air Act Amendments of 1990 created a Risk Assessment and Management Commission and directed the National Academy of Sciences to prepare a report on EPA's risk assessment methodology. This helped motivate EPA to reconsider and update its risk assessment guidelines.

The White House and Congress should strengthen the expertise of the Office of Science and Technology Policy in risk analysis. OSTP could be assigned the responsibility to develop detailed guidance for agencies on how best to use science in the evolving risk assessment process and to develop government-wide risk assessment guidelines. Uniform risk assessment guidelines could also be developed by an interagency committee or by experts outside of government. Those guidelines would:

- bolster the credibility of agency risk assessments;
- prevent duplication and foster joint risk assessment efforts among agencies regulating the same substance;
- define the types of data and interpretations relevant to agency testing procedures and help the regulated community to understand agency decisions; and
- promote uniform risk assessment procedures among the states.

Greater efforts are also needed to develop a more complete and current database of relevant scientific data to be used in the risk assessment process. The lack of scientific data and the uncertainty about various risks significantly hinder measuring and comparing risks accurately. The growing volume and reliability of scientific data, however, have greatly improved the risk assessment field. The data decrease the need to rely on inference and informed judgments to bridge gaps in scientific knowledge.

The government should establish a mechanism that would allow new

scientific information to be easily and quickly incorporated into the risk assessment process. This mechanism should allow for information to be provided by the agencies, academia, business, and the general public. Agencies also should establish procedures to reevaluate risk assessments and risk management decisions in light of scientific advances.

In addition to improving risk assessment methodologies, agencies should favor cost-effective approaches in the risk management phase as a matter of policy. Once the risk assessment process identifies the level of risk posed by a substance, product or process, policymakers should consider the full range of options for reducing or eliminating the risk. The principle for choosing among options should be reducing risk in the most cost-effective manner. Regulatory options should be analyzed in light of the full spectrum of costs and benefits (including risks of alternatives and the economic consequences of the regulation).

Risk assessment and risk management are promising tools for helping regulators achieve the ultimate goal of our environmental, health, and safety programs – greater reduction of risk to health and the ecology with our limited resources.

3. Sound Science: Agency decision making should be grounded on the most advanced scientific knowledge currently available. The difficulty of allocating limited resources for maximizing risk reduction is compounded by the common failure of agencies to base their analyses on the most advanced scientific principles. Without sound science, risks cannot be accurately assessed and effectively compared.

Science and technology are constantly evolving and improving; often they outpace the life cycle of regulations. Indeed, some regulations may become obsolete before they are adopted. This makes it all the more imperative that agencies use the most advanced and precise scientific methods to calculate risk estimates that form the basis for agency decisions. Moreover, agencies should regularly update their regulations and programs to incorporate advances in scientific knowledge.

To establish priorities and make regulatory decisions, agencies often must compare the size of various risks by using risk assessments. Unfortunately, agencies often lack complete data, leading to scientific

uncertainty. To compensate for scientific uncertainty, agencies must rely on default assumptions, which are sometimes codified in inference guidelines. To increase the reliability and credibility of their risk assessments, agencies should strive to structure their default assumptions and inference guidelines so that they will accurately reflect real risks. In characterizing risks, agencies should consider the probability that estimated risk values approximate the true size of the risks.

When faced with gaps in scientific data, agencies all too often have used a series of worst-case default assumptions and upper-bound probability estimates throughout the risk assessment process. The cumulative effect of these highly conservative assumptions may be to produce greatly exaggerated estimates of risk.

Agencies often base their decision on single-point estimates of risk, which assign a single value for a risk estimate. Typically, agencies incorporate policy judgments into single-point risk estimates by basing them upon highly conservative or worst-case estimates. Single-point estimates, however, do not reveal the degree to which risk estimates are both uncertain and highly conservative. Unrealistic risk estimates, however, undermine the credibility of agencies' scientific methods, can cause undue public alarm, prevent cost-effective regulations, and limit the public's ability to understand and respond to regulatory decisions.

Common agency practices contribute to biased risk estimates:

- Agencies often use highly conservative or worst-case assumptions for exposure estimates when more accurate data are available.[15]
  - ➤ OSHA bases occupational cancer risks on the assumption that a hypothetical worker is exposed at the permissible exposure limit 8 hours per day, 5 days per week, and 50 weeks a year, for 45 years.[16]
  - ➤ EPA sometimes assumes that an individual is exposed to emissions at a distance of 200 meters from the factory, 24 hours a day, every day, for 70 years.[17]
- Regulators often assume that there is a linear relation between the dose of a substance and its response or effect when there is no scientific rationale for the assumption.[18]
- Researchers sometimes base their research on reactions of animals that are most sensitive to the substance under review, instead of

> using animals that would best replicate a human reaction to the substance.[19]

When regulators lack information for a value or parameter needed for a risk estimate, they should use uncertainty analysis techniques. Uncertainty analysis techniques identify a range of possible values and their probability of occurrence. To promote public accountability, agencies should explain assumptions, inferences, and value judgments made in the risk assessment and characterize their impact on the estimated value of the risk.

Although risk assessments should provide a range of risk values to indicate data limitations and scientific uncertainty, the "best estimate" of risk – the most credible estimate possible from available scientific information – should be provided for policymakers and the general public in the risk management phase.

The use of sound science is only one tool for improving regulation, and it does not relieve political leaders and regulators of the responsibility for making the inevitably difficult decisions required. But it will help prevent misallocating vast resources to reduce inconsequential risks, will promote open decision making, and will increase public confidence in the regulatory process. Ultimately, the public will benefit.

Executive Order 12866 (Sec. 1(b)(7)) emphasizes the importance of sound science:

> Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

The White House should work with agencies to promote this goal and should hold them accountable for adhering to it throughout the regulatory review process, and state agencies should apply this same principle.

Moreover, agency scientific and technical expertise can be improved at the federal and state level. As EPA has proved, agencies can effectively use outside experts to analyze internal scientific capabilities and to recommend structural improvements. Federal agencies such as OSHA and state environmental agencies should emulate EPA and FDA and create scientific advisory panels to participate actively their strategic planning and internal reform processes.

Science should be institutionally represented in agency decisions that depend on scientific evidence. Scientists can validate analytical methods and procedures, even if the ultimate regulatory decision will be based partially on science and partially on policy. Periodic outside review procedures bolster the scientific credibility of agency decision making.

Emphasis on the scientific soundness of the regulatory process will make that process more credible and transparent. It should reduce the tension among the White House, Congress, the agencies, and the states and should increase public confidence in regulatory policy.

4. Benefit-Cost Analysis: Benefit-cost analysis should be utilized by agencies when developing regulations, with preference given the least costly regulatory alternative that accomplishes program objectives. Every regulatory program consumes financial resources – of the government that is regulating, of the regulated community that must comply with the regulations, and, ultimately, of the consumers of the product or activity that is regulated. Since resources are limited, the government should maximize the benefits and minimize the costs of regulation, so that resources are not squandered. To further this goal, agencies should make better use of benefit-cost analysis, in which the benefits are weighed against the costs of a regulatory proposal *before* decisions are made and regulations are implemented.

Benefit-cost analysis generally proceeds in the following four steps: (1) identifying relevant impacts, (2) calculating monetary values for impacts, (3) discounting for time and risk, and (4) choosing among policies. First, all relevant impacts of a proposed action must be identified and classified as either costs or benefits. Second, impacts must be valued. When there is no organized market to value an impact, innovative techniques are required. Third, values should be discounted for time and risk. Costs and benefits accruing in different time periods should be discounted to their present values. When costs and benefits involve uncertainties, analysts should attempt to assign probabilities to various contingencies so that expected net benefits can be calculated. Finally, when efficiency is the primary goal, the combination of policies that maximizes net benefits should be preferred.

Even when values other than efficiency are important, or major impacts cannot readily be estimated in monetary terms, benefit-cost

analysis is still useful since its first step – identifying and categorizing impacts as benefits or costs – can provide a starting point for better decision making.

In the first instance, federal and state agencies should use benefit-cost analysis to decide whether or not a proposal should be a candidate for adoption – whether its benefits exceed its costs. Second, agencies should use cost-effectiveness analysis to select the regulatory option that achieves regulatory objectives in the least costly way. This analysis should be applied both to substantive regulations and to the administrative process established to implement them, including procedures for issuing permits and reviewing compliance. Benefit-cost analysis should be promoted by the Legislative and Executive Branches at the federal and state levels.

The White House and governors can and should play a central role in promoting the use of sophisticated benefit-cost analysis. Without tight constraints imposed by centralized Executive review under a benefit-cost standard, each agency has an incentive to pursue whatever goal has been set for it by the legislature without regard for other, equally important programs outside of its jurisdiction. This leads to inconsistent, duplicative, and burdensome regulatory requirements, as well as the misallocation of government resources.

To counter this tendency, the White House, through OIRA, as well as governors, can emphasize the importance of benefit-cost analysis and encourage all agencies to set priorities based upon this analysis. The potential gains to be realized by strong centralized review of proposed regulations under a benefit-cost standard, coupled with joint planning by an interagency group, are clear: better policy coordination; enhanced political accountability; and, ultimately, more balanced regulatory decisions.

Executive Order 12866 (Sec. 1(b)(6), (5)) directs agencies to use benefit-cost and cost-effectiveness analysis:

> Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

* * *

> When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective.

Agencies thus are required to conduct a full benefit-cost analysis of significant regulatory actions as part of the decision-making process. Sec. 6(a)(3)(C). The White House and governors should hold agencies accountable for vigorously implementing this basic principle.

Federal and state agencies themselves should promote improved benefit-cost analysis by developing and using standardized guidelines for analyzing the costs and benefits of their regulations. Agencies that already have such guidelines – such as EPA – should periodically review and improve their guidelines in cooperation with other agencies and with the White House or the governor.

Further, when agencies estimate costs, they should attempt to estimate the *full* costs of regulations, not just *compliance* costs. Regulators should carefully consider the potential impact of each regulatory option. Agencies also should consider as a cost the potential benefits foregone by regulation of an activity or substance. If some costs and benefits are nonquantifiable, they should at least be identified.

- Various regulatory options can have different impacts on behavior; behavior induced by some options can actually increase risk.
  - ➤ The National Highway Traffic Safety Administration was confronted with data suggesting that a refusal to relax its fuel efficiency standards for automobiles could increase fatalities from auto accidents. All other things being equal, a large car is safer than a smaller car. However, NHTSA failed to consider whether its "corporate average fuel economy" standards, which promoted smaller cars, could increase automobile fatalities. Accordingly, the D.C. Circuit remanded a CAFE rulemaking decision to NHTSA for further consideration of the potential safety costs of its fuel-efficiency regulations.[20]
- Regulatory costs include foregone benefits.
  - ➤ If a pesticide is banned, food may cost more because less could be produced.[21]

Finally, Congress and state legislatures should promote, not inhibit, benefit-cost analysis. In many instances, agencies are constrained by

restrictive legislative requirements or oversight.

- The Clean Air Act prohibits EPA from considering costs of any kind, much less using benefit-cost analysis, in setting air quality criteria.[22]
- The Supreme Court has interpreted the Occupational Safety and Health Act to prohibit OSHA from basing certain regulations on a formal benefit-cost test.[23]

Accordingly, there is a pressing need for fundamental legislative reform to incorporate benefit-cost principles in statutes. Congress and state legislatures should design legislation to avoid an "at-any-cost" approach to achieving regulatory goals.

- Since EPA, OSHA, and CPSC were established in the early 1970s, many of the larger, more obvious risks have been reduced. As agencies continue to try to reduce smaller, more intractable risks, the cost and complexity of regulations are sharply rising.[24]
- Sometimes programs have standards so stringent that they impose unreasonably high costs without achieving significant additional safety benefits.
  - ➤ In environmental cleanups, for example, it can be extremely expensive to achieve cleanup levels beyond a certain point. At one Superfund site that was mostly cleaned up, an added $9.3 million was spent to meet the program's stringent cleanup standards. The benefits were miniscule: the extra expenditure theoretically meant that the children could safely eat dirt for 245 days per year instead of 70 days annually. But there were no children in the area because it was a swamp. And children were not likely to be there in the future because future development was improbable. Finally, half the volatile organic chemicals probably would have evaporated by the year 2000.[25]

Congress and state legislatures should encourage agencies to balance costs and benefits when designing regulatory programs. Otherwise, federal and state agency efforts to improve regulation may be frustrated by inflexible legislative mandates.

- The Toxic Substances Control Act is a well-designed risk-reduction law based on sound benefit-cost principles. Section 6 of TSCA authorizes EPA to impose a range of controls on a chemical substance or mixture if it poses an "unreasonable risk of injury

> to health or the environment." In applying the concept of "unreasonable risk," EPA must balance the health or environmental risk of a chemical against the economic or social disadvantages of eliminating or restricting the availability of the chemical.

Estimating benefits and costs can be difficult, especially in areas where many benefits are by their nature difficult to quantify. Nonetheless, because limited resources necessitate difficult trade-offs, agencies must make best estimates for benefits and costs – stating clearly and publicly the bases for those estimates – and regulate only where the benefits justify the costs. Once a regulatory goal is established, agencies should select the least costly option for meeting that goal.

5. Market Incentives and Performance Standards: Market-oriented solutions and performance standards should be favored over command-and-control regulation. When properly calibrated and used, market-based approaches and performance standards cost less and accomplish more than government commands and controls. The past three Administrations have advocated that regulators use market mechanisms as much as feasible. Most recently, Executive Order 12866 (Sec. 1(b)(3), (8)) states:

> Each agency shall identify and assess available alternatives to regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices may be made by the public.
>
> * * *
>
> Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

Market Incentives

Market-based regulatory schemes attempt to reproduce the efficiency of a free market by internalizing the costs of the regulated activity or substance, such as pollution, into private production or investment decisions. Market incentives allow regulated parties to achieve compliance in the least costly way, reward innovators who meet or exceed regulatory goals, and adapt to changed circumstances more quickly than government commands and controls.

Typically, regulations apply to a wide variety of activities and firms. Because compliance costs can differ dramatically among activities and firms, uniform standards often impose widely varying incremental costs for achieving a specific benefit. Economic incentives minimize regulatory costs; they allow firms unable to achieve compliance efficiently to buy permits or allowances from low-compliance-cost firms, while encouraging firms that can meet regulatory goals to do so most efficiently. In short, market incentives divert fewer public and private resources and reduce adverse economic consequences to obtain the same – or greater – benefits.

- The acid rain trading allowance program for sulfur dioxide emissions exemplifies the market-incentive approach to regulation. This program provides substantially reduced regulatory costs by providing an economic incentive for least-cost emissions sources to reduce their emissions first. The Clean Air Act Amendments of 1990 set a limit on yearly sulfur dioxide emissions that power plants must meet by the year 2010 (with lesser caps at intermediate deadlines). EPA will allocate annual allowances for emissions sources to meet their individual emissions limits, which are based on reducing their historical average emissions. The allowances can be banked for future use or sold to other emission sources that have higher compliance costs. EPA has estimated that the program could reduce compliance costs by nearly $1 billion per year – about one-fourth of the total cost of achieving its goal without emissions trading.[26]

Economic incentives also induce innovators not only to develop less costly means of meeting a regulatory standard, but also to find ways to exceed the minimum standard and to reap rewards for doing so through cost savings or revenues from credits sold to firms who do not meet the minimum requirements. In contrast, command-and-control regulations provide no incentive for regulated parties to exceed a regulatory goal;[27] they may actually punish firms that do so.

Finally, market incentives are flexible; they allow firms to adapt as their relative compliance costs change over time. Command-and-control regulations usually cannot adapt to changed circumstances without the burdensome costs and delays of new regulatory action. Accordingly, market incentive approaches should be favored over command-and-control regulation.

Performance Standards

To set a regulatory standard, agencies can choose between basing the standard on design or performance. Design standards specify how a product should be built, what technology should be used, or precisely how to reach a regulatory goal. Performance standards, on the other hand, establish the ultimate regulatory goal. They free regulated parties to achieve that goal in the best way they can find. Performance standards generally are superior to design standards: They allow the regulated community to meet or exceed the regulatory goal in the most cost-effective manner.

Design standards may be more attractive to the government because they sometimes are easier and cheaper for agencies to enforce than performance standards. For example, inspectors can verify compliance simply by determining whether a manufacturer is using mandated equipment. But typically, the "savings" from imposing design standards are illusory. Any administrative savings usually are far outweighed by the large costs imposed on the regulated community by design standards. These costs are passed on to the public through higher prices and diminished wages, productivity, and economic growth.

Design standards freeze technology and impede innovation that can produce better results at less cost. An innovative firm that invents a more cost-effective way to meet or exceed a regulatory goal must overcome the heavy burden of changing the agency's standard before it can implement its better method. Accordingly, performance standards should be used when performance can be measured or reasonably estimated. It simply makes no sense to impose the enormous costs and inefficiencies associated with design standards to reduce enforcement costs by a relatively small margin.

In contrast to design standards, performance standards promote innovation to increase safety and reduce costs. Because agencies must consider the comparative performance of different machines or products to write the regulatory standard in the first place, it can be as easy for the agency to base its standard on performance goals, such as fewer injuries or cleaner air.

In some instances, "performance" and "design" standards tend to converge. A standard should not be characterized as a performance standard if there is only one feasible way to meet it; such a standard

is a design standard. Although agencies sometimes transpose performance and design standards, there is a fundamental tension between allowing innovation to improve safety and reduce costs and setting a rigid, easily identifiable standard merely to make the agency's enforcement job easier.

- Under the Resource Conservation and Recovery Act, firms must treat hazardous wastes under "best available technology" standards. Instead of setting a clear standard based on health and environmental risks, the BAT standard changes with each advance in waste treatment. This design standard imposes enormous costs without regard to the actual threat to human health or the environment.[28]

In light of the vital importance of encouraging continual improvements in safety at less cost, performance standards should be preferred over design standards.

Both statutes and regulations should favor market mechanisms and performance standards over commands and controls. Instead of trying to mandate what technologies business should use or how to meet a standard, legislatures and agencies should set standards and then allow the market to develop the most efficient ways to attain them. Mandating *ends*, not *means*, usually offers the most effective form of regulation.

6. Productivity, Wages, and Economic Growth: Methodologies should be implemented and continuously improved to assess the impact of major regulations on productivity, wages, and economic growth, as well as the adverse impact on jobs and international competitiveness in industries that bear the burden of regulation. American businesses of all types, large and small, face increasing competition from foreign competitors in a global economy. Today's global competition is heightened by significant world-wide industrial overcapacity – a factor many believe will be the defining characteristic for the 1990s.

- In key industries – steel, coal, chemicals, textiles, pulp and paper, automobiles, shipbuilding, aircraft, computers, home appliances, and defense – global overcapacity is resulting in a major restructuring.
- Those firms that cannot compete on price and quality will be

driven out of business, which means that jobs will be lost, wages weakened, and tax bases eroded.

- Efficiency and productivity will determine who are the winners and losers; government policies can either advance or retard these objectives.

In response to these economic pressures, successful American corporations are significantly altering the way they conduct their business to become leaner, more flexible, and faster. In this new economic world, the slow-moving, pyramidal corporate structure of the past is facing extinction.

For our economy to grow, regulatory and economic goals must become complementary, not conflicting. Government must make greater efforts to promote productivity, economic growth, and innovation within the regulatory framework and must become more sensitive to the impact of regulation on wages, prices, jobs, and international competitiveness.

Executive Order 12866 (Sec. 6(a)(3)(C)(ii)) requires that benefit-cost analyses of significant regulatory actions include an assessment of their impact on employment, competitiveness, and productivity. The nation would benefit from greater consideration of the industry-wide and economy-wide impacts of regulation.

- A 1993 report by the National Commission for Employment Policy recommended the development of economic models to assess the effects of regulations on jobs and wages.[29]
- In Section 811 of the Clean Air Act Amendments of 1990, Congress directed the President to report on the economic impact of air pollution controls on the international competitiveness of U.S. manufacturers. The American Automobile Manufacturers Association has compiled a report documenting that their competitors operating in countries with more flexible and less prescriptive rules enjoy a significant cost/production advantage over U.S. automobile manufacturers that face onerous requirements on their manufacturing facilities. The new permit rules under Title V of the Clean Air Act can unnecessarily restrict production and operational flexibility without commensurate environmental benefit; this flexibility is critical to the ability of U.S. manufacturers to respond to dynamic market conditions and international competitive pressures.[30]

- A study recently conducted for the U.S. Census Bureau found a strong correlation between regulation and reduced productivity. The study found that significantly regulated plants have substantially lower productivity and slower productivity growth rates than less regulated plants. The magnitude of the impacts were found to be larger than expected: A $1 increase in pollution abatement costs reduced productivity by about $3 - $4.[31]

More information is becoming available on the negative effects of regulation on wages, productivity, and economic growth, as well as the differential economic impact on jobs and international competitiveness in many industries. Because these issues are vitally important to the American people, they should be directly considered when legislatures and agencies make regulatory decisions. The Legislative and Executive Branches at the federal and state levels should promote the use and improvement of state-of-the-art analytical tools to assess the economic impacts of regulations.

7. Coordination Among and Within Agencies: Coordination of regulatory activities among and within agencies should be improved to eliminate inconsistencies, duplication, and unnecessary regulatory burdens. Regulatory agencies have a variety of mandates that overlap – among agencies, including federal and state agencies, and even between different programs of a single agency. Consequently, there is a need for greater coordination of regulatory activities among and within agencies.

Interagency Coordination

To reduce duplication and inconsistency, a strong coordinating committee is needed to identify and address interagency problems. Executive Order 12866 (Sec. 4(d)) provides for the establishment of an interagency committee – the Regulatory Working Group – that can perform this function at the federal level.

Through the Regulatory Working Group or a similar interagency committee, agencies should engage in strategic planning to address problems before regulations are proposed. Where significant environmental, health, or safety problems demand action from multiple agencies, the interagency committee should coordinate common risk-reduction approaches for the agencies involved. The committee should rank the relative risks posed by particular problems in an effort to maximize risk-reduction in a cost-effective way. The relative risk

rankings could be updated periodically. An interagency committee could also promote the exchange of information among agencies and make each agency more sensitive to existing regulations from other agencies. The committee also could identify common research needs and allocate responsibility for fulfilling those needs among agencies. Finally, to address overlap and inconsistency originating in statutory requirements, the interagency committee could develop a forward-looking, comprehensive legislative program.

The strategic planning process should be open, incorporating views from the general public, including business, academia, and public interest groups. This strategic planning process could be used to educate Congress and involve the public in the decision making. Agencies could exchange information, data, and feedback, which would facilitate improvements in regulations and laws. These tenets of rational regulation should guide this process.

Intraagency Coordination

In addition to interagency coordination, there is a need for greater coordination of programs within each agency as well. Individual program offices within an agency often are assigned responsibility for implementing a specific law or part of a law. This narrow approach, and the growing complexity of statutes and regulations, has fragmented many programs, even within the same agency. Different programs often attempt to control different aspects of the same problem. Without coordination of programs, inconsistencies, unproductive duplication, and outright conflicts may result.

- EPA's Office of Solid Waste and Emergency Response at one time designated trace levels of carbon tetrachloride and chloroform found in chlorofluorocarbons as hazardous waste, thus discouraging refrigerator recyclers by threatening them with Superfund liability. Meanwhile, EPA's Office of Air and Radiation was urging that refrigerators be recycled to preserve the ozone layer. At the same time, the FDA allowed CFCs to be used in asthma inhalers.[32]

Agency efforts to coordinate regulatory programs should focus on reducing risks in the most cost-effective way. When properly designed and implemented, regulatory programs that address multiple environmental media, such as air, water, and land, have great potential to reduce both risk and costs. Unfortunately, the emphasis on highly prescriptive media-specific regulation in current environmental laws

often creates obstacles to cost-effective regulation.

- An ambitious joint pollution prevention study recently conducted by EPA and Amoco Corporation illustrates the cost of inflexible, media-specific regulation. The study found that if Amoco's Yorktown, Virginia refinery had been free to pursue a flexible, performance-oriented approach to pollution prevention, 90% of the emissions reductions required under applicable regulations could have been achieved for 20-25% of the cost of meeting the specific regulatory requirements. In particular, if a performance-oriented approach to emissions reduction had been followed, releases at the refinery could have been reduced at an average cost of $510 per ton, as opposed to the $2,400 per ton average cost of achieving reductions under EPA's prescriptive command and control regulations.[33]

The Executive Branch has the responsibility to ensure that its programs are coordinated and consistent. Fulfilling that responsibility should become a higher priority.

8. Openness: The entire regulatory process, including centralized Executive review and management of agency rulemaking, should be open to public scrutiny to promote the quality, integrity, and responsiveness of agency decisions. Openness is indispensable to the entire regulatory process, including regulatory planning and development, as well as centralized Executive review of agency rulemaking. Openness brings obvious benefits:

- The input of an informed public and the regulated community improves the quality of agency decisions.
- Openness will help ensure that the values and concerns of the public are addressed by regulators.
- A better informed public will have greater confidence in the regulatory process and the validity of decision making.
- With a better understanding of the regulatory requirements, the regulated community can more faithfully comply with them.
- Fewer legal challenges to final regulations are likely to ensue.

Removing Secrecy

The regulatory process should be open to maximum public involvement at the earliest stages. Executive Order 12866 (Sec. 6(b)(4)) recognizes the need for openness. This policy should be nurtured and

expanded. For example, OIRA should disclose written communications from those outside of the government before a rule is published. The White House should also require agencies to publish their Regulatory Plans when they are submitted to OIRA for review. Regulatory analysis documents that detail the costs and benefits of regulations also should be available to Congress and the public, even if they include information or considerations that the agency may not actually use to create a rule. More generally, the public should have access to the identities and positions of participants in the regulatory process.

Regulatory Negotiation

Agencies also could make better use of negotiated rulemaking, or "reg neg." To draft a rule, an agency can bring together representatives of interested parties for face-to-face negotiations, with the goal of achieving consensus on the proposed language. The primary goal of "reg neg" is to produce better rules, but it also avoids protracted litigation and reduces enforcement costs.

President Clinton recognized the benefits of regulatory negotiation in a Directive that accompanied Executive Order 12866. The Directive requires each agency to identify at least one rulemaking to be developed through negotiated rulemaking.[34] Although not always feasible, agencies should consider using "reg neg" more often, on a wider basis, and earlier in the regulatory planning process. Typically, the short-term costs of regulatory negotiation are fully justified by its many benefits.

In sum, openness can improve the quality and integrity of agency decisions and increase public confidence in the regulatory process.

9. Periodic Review: Programs and regulations should be periodically reviewed for purposes of determining whether they should be reformed, discontinued, or consolidated.

As circumstances and technology change, regulations can become outmoded, duplicative, or unnecessary. As an indispensable part of good regulatory management, Congress, the White House, agencies, and states should periodically review existing regulatory programs to determine whether they should be reformed, discontinued, or consolidated.

Legislatures ordinarily operate under the assumption that programs should continue unless there is an overwhelming reason to curtail

them. By conducting periodic review, legislatures can ensure that government resources are allocated to best address the needs of the public. Periodic review should allow for government-wide coordination and priority setting through reforming or eliminating regulations, updating scientific methodologies, reorganizing an agency, or reallocating responsibility among agencies.

In appropriate instances, Congress and states legislatures can ensure a stricter review process by incorporating sunset provisions in regulatory programs. Sunset is a powerful tool for managing the proliferation of government programs: Within set deadlines, the legislature is compelled to evaluate and vote for the continuation of a program, or it will terminate. This forces a review of priorities. Programs that are not rational or justifiable – perhaps because they have simply outlived their usefulness – can more readily be eliminated or incorporated into other programs. Routine periodic review of duplicative or overlapping programs provides an opportunity for Congress to consolidate them, even if it decides the programs should be continued. If similar programs are reviewed at the same time, Congress can more readily compare their effectiveness and streamline and rationalize them.

Regulatory programs would also benefit from periodic review by the Executive Branch. Executive Order 12866 (Sec. 5(a)) requires each federal agency to develop a program for periodically reviewing its existing significant regulations to determine whether they should be modified or eliminated to make the agency's regulatory program more effective, less burdensome, and more consistent with the President's priorities and principles set forth in the Executive Order. However, the White House does not now have in place a formal process for timely oversight and execution of these important reviews; it should develop and implement such a process without delay. The President also should issue a Directive, like the Negotiated Rulemaking Directive, to require each agency to identify and review at least three significant regulations.

Finally, agencies – individually or through an interagency coordinating group – should themselves initiate periodic review of their programs to eliminate outdated, duplicative, and irrational regulations. Where legislative authority is required to terminate or modify unproductive, outdated programs, the Executive Branch should aggressively pursue legislative action.

10. Federalism: Regulatory authority should be more rationally allocated among the federal, state, and local governments, and federal regulatory programs should avoid unfunded mandates. The expansion of government regulation has raised concerns about the rational allocation of regulatory authority and costs among federal, state, and local governments.

Allocation of Regulatory Authority

The growth of government regulation in recent decades has taken place at both the federal and state levels. In some cases, such as pollution control and waste disposal, new and expanded federal programs have supplanted state and local regulation. In other cases, states have added new and costly regulations of their own – both in areas that were traditionally matters of state policy (such as automobile insurance) and in areas that were traditionally matters of national policy (product labeling). The growth of state regulation has been encouraged by Supreme Court decisions that take a more lenient approach toward state policies affecting and burdening interstate commerce.

The mix of centralized national regulation in some areas and an array of state regulations in other areas has not always been a good one for American consumers and businesses. The traditional virtues of federalism – decentralization and responsiveness to varying local circumstances – remain important today. At the same time, however, markets, production technology, and business organization have become increasingly national and international in scope. State regulation that made sense at a time of primarily local markets can produce highly costly and wasteful conflicts and duplication where national businesses are affected. This is often the case today. For businesses whose products are sold nationwide and abroad, inconsistent and duplicative state regulation increases prices and chills productivity, wages, economic growth, and innovation.

Modern commercial realities demand a more cost-effective balance of federal and state regulation; achieving this balance is primarily the responsibility of the federal government. In general, three factors should be considered in determining whether the federal government should preempt and regulate a field itself or leave the field to the states:

- Is the problem primarily a national one, with little variation in the

nature of the problem among states and regions?
- Will state regulation lead to needless duplication of effort, costly conflicts among differing state rules applicable to national markets and national business firms, or opportunities for individual states to pursue local policies at the expense of citizens of other states?
- Does the policy in question present important controversies and uncertainties, so that state policy experimentation may produce new information to resolve the uncertainties?

These guidelines will not resolve every controversy over regulatory jurisdiction, but they do suggest several areas where large improvements could be made. For example, to the extent that regulation of the labeling of foods, beverages, and other products that are distributed nationally is appropriate, these regulations should be national rather than local: The costs of differing labels in different states is very large, while the benefits are small or nonexistent.

On the other hand, many pollution problems are primarily local or vary in severity from locality to locality; federal regulation to address these problems may still be justified (where a single item of commerce is involved, such as automobiles, or where necessary to overcome "NIMBY" – Not In My Backyard – problems), but should be resorted to with care. Transportation regulation presents states with numerous opportunities for imposing price and service controls that are paid for by citizens of other states, and the trend toward greater preemption in this area is appropriate and should be continued.

When Congress appropriately determines to preempt state regulation, it should not adopt a one-way approach that preempts only weaker, but permits more stringent, state regulation. This approach loses the benefits of preemption without gaining offsetting benefits from state experimentation.

Unfunded Mandates

The federal government also regulates state and local governments directly in the course of administering federal expenditures and federal programs. As the federal budget deficit has soared, Congress has increasingly used unfunded mandates. *Unfunded mandates* require state and local governments to administer or comply with federal programs, but do not include funding for the costs of administration or compliance. These unfunded mandates burden state and local governments in the same way that regulations burden business.

Unfunded mandates force state and local governments to raise taxes, cut services, or potentially to face bankruptcy. Likewise, regulations require businesses to raise prices, eliminate jobs or product lines, cut research and development, or even go out of business entirely.

Congress has imposed numerous obligations on the states to fund programs designed to achieve federal objectives. While this pattern has been familiar for some time, it has become even more significant in the 1990s. Unfunded programs do not appear in the federal budget deficit, yet they impose very real costs at the state and local levels. These programs threaten to overwhelm state and local governments who fear that raising taxes for businesses and consumers will stifle economic growth and jobs and hence erode the tax base.

- The City of Columbus, Ohio has had to comply with 67 new environmental mandates since 1988. Columbus is expected to spend $1.3 billion to $1.6 billion on environmental compliance from 1991 to 2001. In 1991, the average Columbus household paid $160 for environmental protection; by 2001 this cost is projected to rise to $856 per household, or more than the per-household cost of fire or police protection.[35]

The federal government should not burden state and local governments with unfunded mandates, especially where the benefits of a program do not fully accrue at the state or local level. Clearly, duplicative and inconsistent regulation must be prevented. Nonetheless, programs should be sufficiently flexible to facilitate innovation at the state and local level. In some instances, the federal government could define a program's objective (comparable to performance standards), but allow state and local governments to achieve those outcomes by the means they think best. When practical, agency leaders should grant waivers to allow state and local governments to experiment with innovative programs that may more efficiently achieve regulatory goals.

Executive Order 12866 (Sec. 1(b)(9)) recognizes the need to reduce unfunded mandates and to provide greater flexibility to state, local, and tribal governments:

> Whenever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental

> interests. Each agency shall assess the effects of federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

This policy is supplemented by Executive Order 12875, which calls for reducing unfunded mandates; increasing waivers from federal requirements for state, local, and tribal governments; streamlining the process for applying for waivers; and providing greater consultation with those governments on federal matters that uniquely affect their interests. These concepts should be vigorously implemented and should be applied to regulated businesses as well.

11. Paperwork Burdens: Paperwork burdens caused by regulatory programs should be expressly assessed and substantially reduced. In our vast regulatory system, paperwork burdens impose huge costs. Federal paperwork burdens alone have been conservatively estimated to consume over 6.4 billion person-hours per year in the private sector – at a cost of at least $128 billion – merely to collect, report, and maintain information.[36] This does not include the massive person-hours federal employees spend on processing and evaluating the information.[36] Furthermore, paperwork burdens are a symptom of unreasonable administrative process requirements – complex, bureaucratic, and adversarial procedures for obtaining permits, reviewing compliance, and the like. These administrative processes impose massive and unnecessary costs by causing delay, frustrating innovation, and impeding process and facility changes that U.S. business must make to meet world competition.

Congress recognized the need to reduce the paperwork burden by passing the Paperwork Reduction Act of 1980, but this statute has not been effectively implemented.

- The Paperwork Reduction Act of 1980 was designed to minimize the federal paperwork burden for individuals, small businesses, state and local governments, and other persons; to minimize the cost of information collection to the federal government; and to maximize the usefulness of the information to the federal govern-

ment. The Act established OIRA and delegated it responsibility for coordinating government information policies, including reviewing and controlling agency collections of information.

Despite the many benefits promised by the 1980 Act, it requires much stronger implementation, and further initiatives to reduce paperwork are imperative. Stringent goals for reducing paperwork requirements are needed at all levels of government. The anticipated paperwork requirements of future legislation should be thoroughly assessed prior to enactment, and these assessments should be disclosed to the public. Alternative information technologies that can reduce the paperwork burden should be adopted.

The Administration should strengthen OIRA's paperwork control responsibilities. Moreover, the Administration and Congress should strengthen and amend the Paperwork Reduction Act. Sound legislative proposals include a government-wide goal of at least a 5% annual reduction in paperwork. In the absence of a legislative mandate, the Executive Branch should nonetheless commit itself to this goal and should annually report its progress in achieving it.

The new legislation should also address the problem of "third party" disclosures of information. The Paperwork Reduction Act was intended to limit the ability of federal agencies to impose paperwork requirements on the public. However, in *Dole v. United Steelworkers of America*, the Supreme Court held that the protections of the Act do not apply where an agency requires that information be provided to a third party (and not the government).[38] An agency can circumvent OIRA's paperwork review simply by not requiring that the information be submitted to the federal government. In that event, OIRA cannot review the agency's information requirement and has no authority to stop it. To remedy this problem, Congress should legislatively overrule *Dole* when it amends the Paperwork Reduction Act.

Excessive paperwork burdens often are caused by unreasonable administrative process requirements. These administrative process costs – the inflexibility, unresponsiveness, and delay that characterize many regulatory programs – are an increasing threat to the competitiveness of U.S. businesses in global markets.

Many major EPA programs, for example, are based on a multi-layered administrative process for permitting, compliance review, and

the like. Facilities otherwise ready, willing, and able to comply with the environmental controls can be rendered noncompetitive by the rigidity and delay of the administrative process. Many of the industries that hold the greatest promise for jobs and economic growth in the nation's manufacturing sector must be able to respond quickly to technological change at a pace dictated by international competition, not the regulatory process. Among these vital industries are electronics, advanced materials, aerospace, custom and specialty chemicals, pharmaceuticals, and automobile manufacturing. In these highly competitive industries, time is precious. They cannot wait for regulatory processes that take years when their products go through entire life cycles in less time. Despite the massive costs imposed by these complex administrative processes, the agencies do not have procedures for considering the costs and benefits of these administrative processes themselves or their potential for being streamlined.

Congress and the agencies should continually examine administrative processes. They should look beyond the direct costs of regulatory controls and take into account the incremental costs and benefits of each layer in the administrative process.

More generally, the adversarial, legalistic nature of the regulatory system must be reassessed. All too often, conflict – not consensus and compromise – characterizes decision making, enforcement, and the relationship among government, business, interest groups, and the public. And increasingly, legislatures and agencies are criminalizing regulatory violations that traditionally were addressed by civil and administrative remedies. In the environmental area, for example, errors in reporting, sampling, record keeping, and the like now are potentially subject to criminal sanctions. At the same time, the growing complexity of environmental regulation increases the likelihood that these errors will occur.

The antagonistic nature of the American regulatory system imposes enormous and unnecessary costs; these include exacerbating litigation and other transaction costs, prolonging delay, and chilling innovation. These costs, like paperwork and administrative process costs, ultimately are borne by customers, employees and stockholders of the regulated community.

The government should strive to achieve absolute paperwork reductions, streamline administrative processes, and reduce the adversarial

nature of our regulatory system. Only where their benefits clearly exceed their costs should mandatory paperwork or complex and adversarial administrative process requirements be imposed.

12. Regulatory Budget: A framework should be developed to account for expenditures required by regulations and to promote greater fiscal restraint on regulatory programs.
The costs of regulation affect us all. They are, in effect, "hidden taxes." American workers see their tax burden on their Form 1040 and state tax reporting forms, but they are told nothing about their regulatory burden. To compound the problem, the decisions to create and impose regulations, especially at the agency level, are remote from public view. Although the public may see that increased government spending will require that they or their children eventually pay the price in higher taxes, they plainly do not realize that collectively they also must pay for regulations – as customers, employees, and stockholders.

Regulatory programs create an illusion that business absorbs their costs. In contrast to taxing and spending programs, regulatory programs impose costs that do not appear in government budget figures, and therefore seem "free." In the end, however, the public pays the price just the same – through higher prices, fewer products, and diminished wages, productivity, and economic growth.

Despite the enormous cumulative burden of regulations, there is no process for setting priorities and forcing trade-offs among different programs or goals. Government spending programs face some discipline through the budgetary process because current spending limits create an incentive to establish rational priorities and to spend money in a more cost-effective way. However, there is no formal budgeting process for the statutory and regulatory programs that direct non-federal resources to achieve public purposes. Regulations are created as their need is perceived, without budgetary constraints or forced trade-offs with other important regulations. Government must become more sensitive to the cumulative costs of regulations.

An accounting system for regulatory costs could measure the cumulative effect of regulations and promote a more efficient regulatory system. Under a regulatory budget, agencies would have a powerful incentive to regulate in a more cost-effective manner; each agency could be limited in the amount of regulatory costs imposed on the

economy each year. If the budget limit had been reached, an agency wishing to add a new regulation would be required to repeal or modify an existing regulation to offset the cost increase from the new regulation. If the agency were unable to offset the cost of the new regulation from other regulations for which it is responsible, the government would have to produce an offsetting reduction from another agency.

In light of the similarities between fiscal and regulatory expenditures, the fiscal budgetary process has been proposed as a model for a similar budgetary process to discipline regulatory expenditures. There have been bipartisan efforts in the Executive Branch and Congress to develop an accounting framework to monitor expenditures directly required by regulation. This work should be encouraged.

The goal of regulatory accounting is worthwhile. Nonetheless, it should be recognized that measuring the private expenditures required by federal regulation raises its own set of problems. The regulated community should not be unduly burdened with extensive and costly record-keeping requirements to validate projected budget estimates. It is also difficult to distinguish expenditures due to regulation from those that would have occurred regardless of regulation. And special challenges arise in estimating the indirect costs of regulation, including lost opportunities for consumers to purchase goods due to higher prices, less desirable products, or complete bans of products or substances. Regulatory accounting must consider these indirect costs, but they can only be estimated with complicated statistical models. Moreover, combining estimates of indirect costs with direct cost estimates could be difficult. Yet, because bans primarily cause indirect costs, measuring only direct costs could encourage agencies to institute bans rather than regulatory controls.

These challenges make regulatory accounting more complex than fiscal accounting, but there are good reasons to persevere in the development of a regulatory budget:

- Although regulatory budgets would require forecasts of private spending on regulations, the forecasts need not be exact to constrain spending (like spending forecasts for fiscal budgets).
- The measurement problem concerning the proper baseline for direct regulatory costs diminishes if an incremental budget approach is used.
- The potential for agencies to use bans to avoid regulatory budget

constraints is outweighed by their tendency to impose costs on the public absent a regulatory budget; rules for estimating indirect costs can be developed.[39]

While a regulatory budget has not yet been perfected, it holds promise for measuring and disciplining the cumulative burden of regulations and allocating resources more effectively. The starting point for a regulatory budget is to develop an accounting system that would use information available from both the fiscal budgetary process and the information-collection budget established by the Paperwork Reduction Act. The important work to develop a regulatory budget should continue.

III. Conclusion

Government regulation can and must be improved. Although some regulations have been beneficial, there is great need – and much room – for a smarter, more cost-effective approach to regulation. To ask how much regulation we should have or how we should best regulate in specific situations is not to put dollars before people. To the contrary: it is to make dollars work more effectively for people.

Regulations exact a heavy toll on wages, productivity, economic growth, prices, and innovation. They burden federal, state, and local governments. We do not see the factories never built, the products never made, the services never provided, or the entrepreneurial ideas drowned in the sea of regulatory process. But, in the end, all of these costs of regulation are borne by the public – as employees, consumers, stockholders, and taxpayers.

Regulatory reform must be a national priority. Because our nation has limited resources and many competing expectations, the soaring costs of regulation make it imperative to reform regulation and to reduce its burdens on the economy. There is growing consensus not only on the need for regulatory reform, but also on how to achieve it: Government must assess the seriousness of risks proposed for regulation, compare these risks to risks familiar to the public, disclose the costs of regulation, regulate only if the benefits outweigh the costs, and select the most cost-effective, market-driven method possible. This is smarter regulation. And smarter regulation is better regulation, for consumers, governments, and businesses alike.

The White House, Congress, agencies, and the states must all commit themselves to smarter regulation. The Business Roundtable recommends that governments at all levels vigorously implement these twelve tenets of rational regulation. Many promising ideas have been proposed to "reinvent" regulations and the regulatory system; President Clinton's Executive Order on Regulatory Planning and Review takes an important first step. However, the hard work necessary to achieve meaningful reform remains to be done.

It will take strong leadership to reform the culture of regulation that permeates government at all levels. Government leaders must remove incentives for regulators to impose burdensome new regulations and red tape, and reward innovators who reform or eliminate irrational regulations or who obviate the need for new ones. Government employees, like private-sector employees, must put the "customer"

first and be more accountable for achieving results, not for developing or following Byzantine rules.

If we fail to regulate smarter, and if we fail to change the culture of regulation, then the American public – not just governments and businesses – will suffer. Regulating smarter is a challenge our nation cannot afford to ignore.

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Summary of Recommendations

1. Risk-Based Priorities and Public Education:

Risk-Based Priorities

- The government should use comparative risk assessment to compare the magnitude of various risks and set priorities for achieving greater protection of human health, safety and the environment in the most cost-effective manner.
- Using comparative risk assessment, the Executive Branch should develop a current inventory of known risks, rank them, and periodically update the inventory every two to four years in light of new information.
- Federal and state health and safety agencies should utilize experts to assess, compare, and rank the risks regulated by each agency.
- An interagency coordinating group should be used to facilitate communication and long-term planning among agency leaders.
- The President should issue guidance to encourage the use of risk analysis as a tool for making pollution prevention decisions.
- In the short term, Congress and state legislatures should require the risk-reduction agencies, such as EPA, to conduct comparative risk assessments to set priorities.
- In the long term, as environmental, health, and safety statutes are reauthorized, reformed, and created, Congress and state legislatures should require – not inhibit – the consideration of risk, costs, and benefits in designing regulatory policy.
- Legislation for controlling risk should promote risk assessment while providing agencies with sufficient flexibility to incorporate state-of-the-art scientific knowledge.
- An Office of Risk Analysis should be created in EPA and other agencies that need increased expertise in analyzing and ranking risks.
- A task force composed of scientific experts from the environmental, health, and safety agencies should create a government-wide manual on the regulation of risks. The manual would instruct regulators on how to manage risks.
- Legislatures should set clear goals for regulatory programs, and these goals should be understandable to the regulated community and the public.

Public Education: Improved Risk Communication

- Agencies should improve the risk communication process, which

includes educating the public on the nature of risks potentially subject to regulation; the costs and benefits of regulation; available alternatives; and uncertainty about risks, benefits, and costs.

- The government should educate the public about the level of risks proposed for regulation; risks unfamiliar to the public should be compared to familiar risks.
- Environmental, health, and safety agencies should create public risk communication programs to inform and respond to the public on relevant risks and the costs of managing those risks.
- Risk communication should be based on a written record that is available to the public.

2. Risk Assessment and Risk Management:

- The risk assessment and risk management phases of the regulatory process should be separated as much as possible – both by agencies in conducting risk analyses and by legislatures in designing statutes.
- Risk assessment methodologies and guidelines should be improved; they should be routinely reviewed and updated to reflect the state of the art.
- Professional and policy judgments made in the risk assessment process should be identified and disclosed to the public.
- The White House should issue an Executive Order on risk assessment and risk management policy.
- Congress and the White House should strengthen the expertise of the Office of Science and Technology Policy in risk analysis.
- Uniform risk assessment guidelines for the agencies should be developed by OSTP, an interagency committee, or by experts outside of government.
- Agencies should review their risk assessment guidelines and methodologies and make improvements where appropriate.
- A more complete and current government database of relevant scientific data should be developed for use in the risk assessment process.
- The government should establish a mechanism that would allow new scientific information to be easily and quickly incorporated into the risk assessment process.
- Procedures should be established to reevaluate risk assessments and risk management decisions in light of scientific advances.
- Agencies should favor cost-effective regulatory options in the risk management phase.

3. Sound Science:

- Agencies should use the most advanced and precise scientific methods when making decisions.
- Agencies should regularly update their regulations and programs to incorporate advances in scientific knowledge.
- Agencies that depend on scientific information and judgments but lack scientific advisory boards, such as OSHA, should emulate EPA and FDA and create scientific advisory boards to participate actively in their decision making.
- Periodic outside review procedures should be used to bolster the scientific credibility of agency decision making.
- To increase the reliability and credibility of their risk assessments, agencies should strive to make their default assumptions and inference guidelines accurately reflect real risks.
- When regulators lack information for a value or parameter needed for a risk estimate, they should use uncertainty analysis techniques to identify a range of possible values and their probability of occurrence.
- To promote public accountability, agencies should explain assumptions, inferences, and value judgments made in each risk assessment and should characterize their impact on the estimated value of the risk.
- Although risk assessments should provide a range of risk values to indicate data limitations and scientific uncertainty, the "best estimate" of risk should be provided for policymakers and the general public in the risk management phase.

4. Benefit-Cost Analysis:

- Federal and state agencies should use benefit-cost analysis to decide whether or not to adopt a regulation and should regulate only where the benefits justify the costs.
- Once a regulatory goal is established, agencies should use cost-effectiveness analysis to select the least costly option for meeting that goal.
- Congress and state legislatures should incorporate benefit-cost principles in statutes and avoid an "at-any-cost" approach to achieving regulatory goals.
- The White House and governors should hold agencies accountable for conducting a full benefit-cost analysis of significant regulatory actions.

- Agencies should apply benefit-cost and cost-effectiveness analysis not only to substantive regulations, but also to administrative process, including procedures for issuing permits and reviewing compliance.
- Agencies themselves should develop and use standardized guidelines for analyzing the costs and benefits of their regulations.
- Agencies that already have benefit-cost guidelines, such as EPA, should periodically review and improve their guidelines in cooperation with other agencies and the White House or the governor.
- When agencies estimate costs, they should attempt to estimate the *full* costs of regulations, not just *compliance* costs.
- Agencies also should consider the potential benefits of the activity or substance to be regulated.
- If some costs or benefits are nonquantifiable, they should at least be identified by the regulator.

5. Market Incentives and Performance Standards:
- Both statutes and regulations should favor market mechanisms over command-and-control regulation.
- Performance standards should be favored over design standards in federal and state regulations.

6. Productivity, Wages, and Economic Growth:
- Agencies should directly consider the impact of regulatory options on productivity, wages, economic growth, innovation, jobs, and the international competitiveness of American businesses.
- The Legislative and the Executive Branches at the federal and state levels should promote the improvement of state-of-the-art analytical tools to assess the industry-wide and economy-wide impact of regulations.

7. Coordination Among and Within Agencies:
- To address problems concerning multiple agencies, a strong interagency committee should engage in strategic planning and develop a coordinated response before regulations are proposed.
- Each agency should coordinate individual programs that address different aspect of the same problem.
- Cross-cutting, cost-effective regulatory approaches, such as multi-media environmental regulations, should be favored over piecemeal approaches.

8. Openness:

Removing Secrecy

- The regulatory process should be open to maximum public involvement at all stages.
- OIRA should disclose written communications from those outside of government before a rule is published.
- The White House should require agencies to publish their Regulatory Plans when they are submitted to OIRA for review.
- Regulatory analysis documents that detail the costs and benefits of regulations should be available to Congress and the public, even if they include information or considerations that the agency may not actually use to create a rule.
- The public should have access to the identities and positions of participants in the regulatory process.

Regulatory Negotiation

- Agencies should make better use of negotiated rulemaking.

9. Periodic Review:

- Programs and regulations should be periodically reviewed for purposes of determining whether they should be reformed, discontinued, or consolidated.
- The President should issue a Directive requiring each agency to identify and review at least three significant regulations.
- The White House should establish a formal process for reviewing existing regulations and programs.
- Legislatures should incorporate sunset provisions into regulatory programs to ensure a stricter review process, compelled by termination of the program absent a vote for continuation.

10. Federalism:

- When creating regulatory programs in a field implicating both federal and state interests, Congress should carefully consider whether to preempt and regulate the field itself or leave it to the states; the goal should be to achieve a more cost-effective balance of state and federal regulation.
- The federal government should refrain from burdening state and local governments with unfunded mandates – programs without funding – especially where the benefits do not accrue at the state or local level.
- When practical, agencies should grant waivers to allow state and

local governments to experiment with innovative programs that may more efficiently achieve regulatory goals.

11. Paperwork Burdens:

- Paperwork burdens imposed by all regulatory programs should be assessed and reduced.
- Administrative process costs – the inflexibility, unresponsiveness, and delay that characterize many regulatory programs – should be assessed and reduced.
- The adversarial, legalistic nature of the regulatory process should be reduced where possible.
- The Paperwork Reduction Act should be strengthened; clear and stringent goals for reducing paperwork burdens should be established by Congress and the White House.
- When it amends the Paperwork Reduction Act, Congress should legislatively overrule *Dole v. United Steelworkers of America* to address the problem of "third party" disclosures of information.
- The anticipated paperwork requirements of future legislation should be thoroughly assessed prior to enactment, and these assessments should be disclosed to the public.
- Alternative information technologies should be employed to reduce the paperwork burden.

12. Regulatory Budget:

- A framework should be developed to account for expenditures required by regulations and to promote greater fiscal restraint on regulatory programs.
- Congress should impose a cap on the costs imposed on the economy by regulations each year. If the regulatory budget limit is reached, the government should be required to repeal or modify existing regulations to offset the cost increase from any new regulation.

1717 Rhode Island Avenue, NW
Suite 800
Washington, DC 20036-3023

Telephone 202.872.1260
Facsimile 202.466.3509
Website brt.org