EXECUTIVE OFFICE OF
THE PRESIDENT

OFFICE OF MANAGEMENT
AND BUDGET

REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT

April 1, 1988 - March 31, 1989

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THE REGULATORY MESSAGE OF THE PRESIDENT

TO THE CONGRESS OF THE UNITED STATES:

When I took office I set in motion a plan to improve and rationalize the regulatory activity of Federal agencies. The program was designed to ensure full analysis of possible regulatory impacts, to bring about greater coordination within the government, and to increase public information about and participation in the process. To enhance presidential oversight, I issued Executive orders directing regulatory agencies to justify their exercise of regulatory discretion, demonstrate the likely benefits and costs of individual regulations, and better inform the public of their plans and activities. To provide leadership for these efforts to improve the regulatory process, I established the Presidential Task Force on Regulatory Relief, chaired by Vice President George Bush. I believe these steps have served the American people well and assured greater constitutional accountability.

Experience over the past 2 decades suggests the need for the President to establish publicly the overall direction for regulatory agencies by announcing the general, govenment-wide principles, both economic and social, to which regulatory agencies should adhere as they implement their statutory responsibilities. Our Administration has established a process in which the Office of Management and Budget issues an annual *Regulatory Program of the United States Government* setting forth the regulatory proposals of my Administration for the coming year. The *Regulatory Program* improves agency regulatory management by requiring agencies to observe the President's regulatory priorities and coordinate with OMB and one another. In addition, these reports provide the Congress and the American people—before the publication of any proposed regulation—with a comprehensive outline of how the Administration intends to exercise the discretion the Congress has provided.

The President must also provide for day-to-day oversight of agency regulatory developments. This oversight process, carried out through the Executive Office of the President, includes monitoring agency activity, coordinating government-wide issues, identifying issues of concern, and, with appropriate interagency discussion, ensuring that any remaining issues are resolved.

This Administration understands that American life is burdened by too much regulation and that true regulatory reform must involve regulatory reduction. Today, more than 100 Federal agencies maintain thousands of regulations that have an enormous impact on how we live and what we do. Regulations tell us what is safe and what we can buy. Government regulates how we make, price, sell, transport, use, and discard the products of everyday American life.

This pervasive government power can be used for good or ill. And as regulation grew over the past 5 decades, government "red tape" became a great burden on our free enterprise system. Over the last 7-1/2 years, we have substantially reduced that burden, cutting red tape and slowing the pace of new regulation.

When I became President in 1981, I directed that Federal agencies, within the scope afforded by law, should reduce the excess burden of government regulation that is borne by evey worker, consumer, business, and State and local government in this Nation. Under the guidance of the Presidential Task Force on Regulatory Relief, Federal agencies have eliminated unnecessary regulatory costs ranging in the tens of billions of dollars. Federal reporting requirements have been eased wherever possible, and we have worked hard to ensure that the paperwork burden imposed on the American people does not get out of control. As we have weeded out and eliminated wasteful, unnecessary, and intrusive regulatory standards, we have also encouraged the development of useful regulations that will increase benefits to society as a whole.

The steady but enormous progress the Vice President and I have made over the past 7-1/2 years to improve the way government regulates has been one of our Administration's proudest achievements. However, much more remains to be done. Managing the Federal regulatory machinery will continue of necessity to be a high priority for Presidents in the years ahead. For this reason, I am certain the new Chief Executive will want to continue this endeavor to serve the public interest by insisting that regulatory activity be productive.

RONALD REAGAN

THE WHITE HOUSE,
September 1988

PART I. OVERVIEW AND SUMMARY

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INTRODUCTION

This is the fourth annual *Regulatory Program of the United States Government*, a product of the Office of Information and Regulatory Affairs. This report is in two parts. The bulk of it is in Part II, entitled "The Regulatory Program by Agency," and contains the regulatory programs for 1988–89 of 26 executive agencies. It is customary to precede this part of the report with a summary and, to some extent, a review of the overall Federal regulatory program. This year, Part I, entitled "Overview and Summary," summarizes the experience of eight years of effort to improve the system of Federal regulation.

The Office of Information and Regulatory Affairs (OIRA) is a part of the Office of Management and Budget (OMB) in the Executive Office of the President. OIRA was formally established in 1981 under the terms of the legislation known as the Paperwork Reduction Act of 1980.[1] OIRA's dual mission—to reduce the burden of paperwork requirements imposed by Federal agencies on the public (in the form of reports, questionnaires, and required documentation of all sorts), and to oversee the regulatory activity of the Federal agencies—has placed it at the focal point of much of what the Government does.

To some extent, institutionalized Presidential regulatory oversight constitutes a challenge to long-established relationships between the legislative branch and individual agencies, and between the Government and special-interest groups; and to the governmental behaviors that developed over the years as a result of them. The Reagan Administration was not the first to raise the challenge. As this report indicates, it has made this endeavor a major administrative effort.

In 1986, in recognition of the role of OIRA, Congress amended the Paperwork Reduction Act of 1980 to require that the Administrator of OIRA, who was previously appointed by the Director of OMB, be appointed by the President and be subject to Senate confirmation. This gives the Congress a substantial say over the selection of the Administrator and a more formal oversight role regarding the work of the Office. At the same time, the combination of congressional creation and Presidential appointment with Senate approval further confirms the role of the Office.

As the President states in his introductory message, it is important that the United States Government systematically and objectively establish governmentwide regulatory policies and priorities. The Federal regulatory structure is massive and complex. Over 100 Federal agencies regulate the public. Many agencies have overlapping responsibilities. Some duplicate the work of others; all have goals that differ from, and that are potentially inconsistent with, each other.

Federal regulations impose costs of over $100 billion annually on the American economy. These costs constitute a hidden tax, a compliance burden that is shifted from the entity regulated to the consumer, who pays higher prices or higher State and local taxes. This hidden tax can also be regressive, burdening poor people and smaller businesses disproportionately.

In addition, setting regulatory standards requires agencies to balance difficult and sensitive issues. Federal regulation, for example, cannot eliminate all safety, health, and environmental risks. As a result, federal regulators have to decide where to begin and where to stop, who should reduce what risks, how much the potential harm should be reduced, who should be held responsible, and how to establish and balance regulatory priorities in order to maximize the benefits to all. The piecemeal regulation of safety and health risks—calling for disparate costs of compliance to reduce equivalent amounts of risks—wastes economic and social resources, which, if applied on a consistent basis, would permit a much greater overall reduction of safety and health risk.

The President has therefore had a long-standing commitment to improving the system of Federal regulation to ensure that it is used rationally and effectively to better the lives of Americans. He directed that his Administration follow a basic set of regulatory principles, stating:

> In promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, all agencies, to the extent permitted by law, shall adhere to the following requirements:
>
> (a) Administrative decisions shall be based on adequate information concerning the need for and consequences of proposed government action;
>
> (b) Regulatory action shall not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society;
>
> (c) Regulatory objectives shall be chosen to maximize the net benefits to society;
>
> (d) Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and
>
> (e) Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.[2]

[1] 44 U.S.C. chapter 35

[2] Section 2 of Executive Order No. 1229, February 17, 1981 (46 FR 13193, February 19, 1981).

By establishing these regulatory principles and designating specific Administration officers as responsible to oversee agency compliance, the President institutionalized Presidential regulatory oversight for the Federal government. This Overview and Summary describes the problems the President faced, his obligation to act, and what he did to improve Federal regulation.

THE PROBLEM

During the last half-century Americans have often turned to the Federal government to provide specific solutions to troublesome economic and social problems. As a consequence, Federal regulatory programs have been created as pragmatic answers to specific problems.

The number of problems which the Federal government was expected to solve grew rapidly, and so did the regulatory answers. In almost all cases, however, the regulations were narrowly targeted at specific problems, and developed without considering the cumulative impact of multiple, successive, sometimes inconsistent Federal regulations.

Thus, each new set of regulatory responses has tended to be a patchwork of isolated rules with little overall integration into the larger system of Federal law and policy, or long-term goals. In part, this has been because the long-term additive costs and structural dislocations have not been readily apparent at the time of promulgation. In part, it is because over time the cumulative effect of some regulatory programs has become excessively burdensome and counterproductive. For some programs the expected benefits never materialized or disappeared as conditions changed; for others the costs and adverse impacts far exceeded expectations. Moreover, as the number of regulations increased, it became apparent that the cumulative impact of many regulations could be far greater than the marginal impact of each individual regulation.

In some cases costs and uncertainties of regulation have deterred private investment in activities that are regulated, leading to reduced innovation and slower productivity growth. This may have compromised the market improvements the regulations had sought to achieve. For example, although food standards have become partially outdated by other regulatory developments, the old system has been perpetuated, inhibiting the use of new technical knowledge to develop innovative, nutritious products. Interstate Commerce Commission regulation of the trucking industry at one time established routes, service, and pricing. This slowed the development of alternate or complementary forms of transportation that might have created more flexible and efficient means of delivery. Outdated safety regulations that have been on the books for 17 years have prevented cheaper, more comfortable, and more protective personal equipment from being used by workers to protect themselves from injury.

The President's regulatory principles are designed to encourage Federal agencies to weed out and eliminate wasteful, unnecessary, intrusive regulatory standards, while encouraging the development of needed regulations that would increase the benefit to society as a whole. The increasing cost of regulations; their failure to keep up with changing social, economic, and technological conditions; their cumulative adverse effects on American society and its economy; and the basic need to fit regulations into the larger legal, social, and economic context led the President to issue his regulatory principles.

THE GROWTH OF THE FEDERAL REGULATORY STRUCTURE

The Federal regulatory structure has grown dramatically in the last 50 years. The bulk of the *Federal Register* consists of notices of proposed and final rulemaking by Federal agencies: Its size is a measure of the amount of government regulation. The *Federal Register* published 2,599 pages in 1936, 5,307 in 1940, and 15,508 in 1945. By 1975, the size of that year's publication had grown to 60,221 pages; by 1980, it had reached 87,012 pages. The *Code of Federal Regulations,* which codifies the official rules of the government, contained 9,745 pages in 1950; 22,877 in 1960; and 102,195 in 1980.[3]

By the early 1970s, Federal rulemaking had become a large part of the work of over 100 Federal agencies. These agencies were controlling major aspects of virtually the entire economy—overseeing the prices set by public utilities, determining the supply of agricultural products, setting the terms of labor contracts and conditions in the workplace, prescribing conditions of import and export, and specifying the nature and extent of pollution control and related environmental impacts.

This growth in government activity caused specific agency regulatory responsibilities to cut across functional areas subject to regulation by other agencies, creating overlap, conflict, and inconsistency. For example, today a wide variety of agencies review, approve, or inspect products for safety before they can be marketed for human or animal consumption. These include the Animal and Plant Health Inspection Service and the Food Safety and Inspection Service in the Department of Agriculture (USDA), the Food and Drug Administration in the Department of Health and Human Services, and the Offices of Pesticide Programs and of Toxic Substances in the Environmental Protection Agency. Similarly, the Offices of Air and Radiation, of Water, and of Solid Waste

and Emergency Response in the Environmental Protection Agency (EPA), the Office of Surface Mining Reclamation and Enforcement in the Department of Interior, the Soil Conservation Service in the Department of Agriculture, and the Nuclear Regulatory Commission all set standards for reducing or cleaning up environmental pollution.

COSTS OF FEDERAL REGULATIONS

Paralleling the growth in the number of Federal agencies and their regulatory activity was the growth in the cost of Federal regulation to American society. In general, there are two kinds of costs imposed by regulatory activity: the direct costs of administering the program, including government personnel, equipment, and supplies; and the indirect costs imposed on society as a result of changes in private activity necessary to comply with the newly imposed rules. The former costs are generally visible; they usually are directly stated in terms of congressionally approved budgets. The latter costs—the societal and economic costs—are much less visible, and often are neither assessed nor stated.

Rough estimates have suggested the burden of Federal regulations on the American economy ranges from 50 to 150 billion dollars a year, and the ultimate cost of the aggregate of Federal regulations is borne by individual consumers. These costs are often hidden. Issuing a regulation may impose relatively low direct costs upon the issuing Federal agency and may often impose little direct burden on the taxpayer, compared to the "hidden tax," a compliance burden that is shifted from the entity regulated (e.g., a business, hospital, college, State or local government) to the consumer who pays higher prices or higher State and local taxes. To the extent that Federal regulations raise costs for commonly used items, such as automobiles, food, toys, or other consumer goods, the "hidden tax" is more regressive than the Federal income tax.

In addition, regulations tend to burden smaller institutions (e.g., highly competitive, small-scale entrepreneurs and loosely organized labor groups) more and to burden larger institutions relatively less. Larger institutions hire experts to participate in the Federal regulatory process. Management of smaller organizations has to devote its own managerial skills and valuable time to regulatory problems rather than working on entrepreneurial or other gainful activities, thus imposing disproportionately higher opportunity costs upon those organizations.

Not only does the cost of Federal regulation have perverse impacts, but also these costs are not subject to the usual controls of the Federal government. Unlike expenditures carried out under Federal spending programs, the dollars spent to comply with Federal regulations do not travel to Washington and back again to the private economy. As a result, regulatory expenditures cannot be scrutinized through the usual disciplines of public finance such as taxation, appropriation, budgeting, and outlay accounting. Instead, those who have to comply—private parties and State and local governments—pay the compliance costs themselves. Indeed, in a period of fiscal stringency, regulatory expenditures are a politically expedient response to demands for various services. The fact that it is often easier for the Federal agency to spend private dollars through regulation than to spend public dollars through government programs suggests the need for special vigilance regarding this form of government spending.

For a variety of reasons the structural incentives to discipline regulatory costs are largely missing. While the benefits of Federal regulation are often directed at some specific subgroup, the costs of Federal regulation are largely hidden or spread out to so many people that the burdens are not, at first, readily apparent. In fact the cost to the consumer of any individual regulatory program may be relatively slight, while the benefits of a regulation for a particular interest group may be relatively high.

Thus those concerned with obtaining regulatory benefits will often have stronger incentives to protect those benefits than those who ultimately pay for these benefits will have to oppose them. Regulatory advocates will have every incentive to maintain vigilant support for the regulatory protection provided—the benefits are typically immediate and tangible, while the ultimate burdens imposed by regulations are often more diffuse. When the cumulative costs and adverse interactive effects of the aggregate of Federal regulatory programs become apparent, consumers who bear the ultimate cost burden may object. But when they do, they tend to object to an amorphous cumulation of adverse regulatory effects, not to the more focused disadvantages of individual identifiable regulatory programs.

DIFFICULTIES IN DEVELOPING REGULATIONS

Early economic regulatory programs sought to ensure the provision of goods and services at fair prices. In some industries, such as the railroads and some forms of communications, the rationale was to prevent a perceived natural monopoly from charging prices higher than necessary to cover the legitimate costs of doing business. In other industries, such as airlines, the intent was to protect an infant industry. One method to accomplish these goals was to give Federal agencies legal authority to determine whether a given firm could enter a particular business, and if so, how much the firm could charge its customers.

By the 1970s, it had become clear that many of these economic regulatory programs did not achieve the goals that had led to their establishment. Significant technological development had eroded what formerly were natural monopolies. Numerous empirical

studies demonstrated that price and entry control had raised, rather than lowered prices; and that such controls restricted, instead of promoted, competition and innovation in the American transportation and telecommunication industries. As a result President Reagan, as well as his predecessors, supported, and Congress approved, the economic deregulation of airlines and the partial economic deregulation of the trucking, railroad, bus, natural gas, and banking industries.

Social regulatory programs control various side effects of economic activity, particularly safety, health, and environmental hazards. Such programs may be needed because the marketplace does not always achieve the optimal degree of safety and environmental protection. Many private decisions made in the marketplace do not take into account all the social costs of pollution and other potential risks to society. Regulation can provide an incentive for the marketplace to take these factors into account.

Over the past 20 years with more sophisticated analytical tools available, Americans have been made more conscious of the unintended, unwanted side effects on safety, health, and the environment of many activities, effects that previously were simply ignored. Laboratory tests demonstrated that commonly used products such as saccharin or the dyes used in food coloring could induce carcinogenic effects in rats or mice. These effects were extrapolated to human populations. Sometimes direct evidence of carcinogenic effects in humans was observed, as with asbestos. But often the risk was theoretical and statistical and involved great uncertainty. Nevertheless, the public became concerned, and pressure built to regulate; to seek to reduce the harm, both real and potential, caused by these unintended side effects of otherwise productive economic activity. Congress began to enact broad regulatory enforcement programs.

These sweeping legislative mandates left the Federal regulatory agencies with difficult choices in administering their safety, health, and environmental regulatory programs. They had to decide where to begin and where to stop; what was to be regulated; how much should the harm be reduced; who should reduce the harm; who, if anyone in any meaningful sense, was responsible; and how to establish and balance regulatory priorities in order to maximize the benefits to all. Agencies were pushed to do this quickly, yet in accord with full administrative due process subject to likely (and actual) challenge in court.

These basic regulatory tensions were made even more difficult by the open-ended and sensitive nature of the regulatory programs involved.

First, changing technology and business behavior cause existing safety and health regulatory programs to be constantly expanding, even without any change in the scope of existing authorizing statutes. The commercial use and dispersion of chemicals, drugs, and food additives is constantly changing. For example, as new chemicals and chemical processes move from a few laboratories in a few central industries into small dispersed shops, plants, and factories, administrative controls grow to keep up with the dispersion of manufacturing activity.

Second, the scope of almost any social regulatory program is basically undefined and arbitrary. The sheer bulk of detail that is potentially subject to regulation for control of unintended, unwanted side effects is unlimited. For example, as more is learned about the chemicals contained in products, production processes, and waste streams, and as production machinery becomes more complex, the number of points where regulatory agencies intervene to reduce potential health and environmental hazards multiplies.

Third, the selection of which unintended, unwanted side effects to regulate (rather than ignore) is sometimes more arbitrary and emotional than rational. One of the most carcinogenic and unhealthy of general human activities is smoking.

> Epidemiologic studies have shown that cigarette smoking is responsible for more than 300,000 deaths each year in the United States. As [Surgeon General C. Everett Koop] stated in the Preface to the 1982 Surgeon General's Report, smoking is the chief avoidable cause of death in our society.[4]

Another of the most serious safety and health hazards is the drinking of alcohol.

> Alcohol contributes to many kinds of accidents and injuries and is involved in more than 50 percent of fatal automobile accidents. Drunk driving is the leading cause of death for persons in the 15–to–24 age group. About one-half of all single-vehicle crashes and two-thirds of nighttime single-vehicle crashes involve alcohol-intoxicated drivers.[5]

But these activities are popular, and consequently attempts to prohibit or severely restrict them in any meaningful way provoke strong opposition. The government will not prohibit a detrimental substance if that substance has a strong enough constituency.[6] If enough people want to, they are free to poison themselves and their friends. Instead, Federal regulators are instructed by the public and Congress to impose much more stringent control requirements on manufacturing activities few people understand, that may have relatively minor health effects, that may harm

[4] *The Health Consequences of Smoking: Nicotine Addiction*, a May 3, 1988 report of the Surgeon General, p. iii.

"The fatality risk of smoking is more than 26 times greater than that of work. . . . [0]f the 565,000 deaths each year from heart disease, 170,000 result from cigarette smoking. Of the 412,000 deaths each year from cancer, 125,000 result from cigarette smoking, with more than 100,000 of these from lung cancer alone." *Economic Report of the President, January 1987*, pp. 184–85.

[5] *Economic Report of the President, January 1987*, p. 187.

a relatively small number of people, or for which there is less popular support.

Fourth, the determination of which safety, health, or environmental side effects to regulate (rather than ignore) and the balancing of costs against risk to human life is in fact so sensitive, yet so difficult, that the public, legislators, and agency regulators may try to avoid admitting that a problem exists. In some cases, any risk to human life is deemed unacceptable; in others, it is an accepted cost of doing business. For example, in advance of any large construction effort, such as building a suspension bridge or a skyscraper, any competent insurance company is able to estimate—on average, for a number of projects—how many workers will die or be severely injured in the course of construction. If this were not the case, the insurance company would not be able to set, in advance, a charge for necessary medical and liability insurance that is low enough to be competitive, yet high enough to earn a profit. While the Occupational Health and Safety Administration has issued a number of safety standards applicable to construction, no one has seriously proposed that construction activities be stopped. Thus the public, legislators, and government officials focus on only certain potentials for loss of life and not on others, preferring to ignore the loss of life in some areas or at least through silence to avoid responsibility for it.

It is the case, then, that Federal, State, and local regulatory systems regulate some safety, health, and environmental hazards to the full potential of American technology, capital investment, and available regulatory enforcement staff. Other equally or more dangerous hazards are not regulated at all, while a number of hazards are regulated at least to some degree. This pattern is more the result of uncoordinated activity than of intentional social choice.

Such a disjointed and imbalanced regulatory structure is inefficient, ineffective, and unfair, both to those benefited and those being regulated. The haphazard regulation of safety and health risks—calling for disparate costs of compliance to reduce equivalent amounts of risks—wastes economic and social resources, which, if applied on a consistent basis, would permit a much greater overall reduction of safety and health risks.

Federal regulation cannot eliminate all safety, health, and environmental risks. As a result, the regulation of each particular safety and health risk has to be kept in balance and proportionate with the regulation of all other such risks. Otherwise there is great inconsistency and thus unfairness.

At its worst, case-by-case regulation of safety, health, and environmental risks can be counterproductive to the goals it seeks. For example, regulation of new drugs seeks to avoid the risks of marketing unsafe and ineffective new drug products. To do so, it inevitably delays the marketing of drugs that ultimately prove safe and effective. When numerous treatment alternatives are readily available, the risk of harm to public health from such delays is acceptable. When, however, a new drug shows promise against a serious and life-threatening condition such as AIDS, for which there is no established alternative, delay in introducing the product may harm, rather than enhance, public health.

Similarly, the environmental effects of new toxic chemical substances cannot be assessed in isolation. An admittedly dangerous chemical may represent a less risky alternative to an existing substance in widespread use. If so, strict regulation of new risks without considering the context of existing risks may prevent overall reductions in environmental risks. Likewise, workplace regulation of one hazard may draw resources from the control of other hazards which pose greater risks.

In addition, as Federal regulatory attention spreads to an ever-increasing set of "problems," the failure to keep costs imposed as low as feasible also means that other goals of society—not just safety, health, and environmental ones—are sacrificed unnecessarily. For example, to require excessive proof before a drug can be marketed can delay introduction of lifesaving drugs and deter investments in pharmaceutical research and development. The longer it takes for regulatory approval by a Federal regulatory agency, the less likely is the development of a new, improved product or a more efficient production process. The more business and private investment is diverted from research, development, and production facilities, the fewer jobs will be created, and the lower will be national income and growth.

Administrative efforts to resolve these issues have led to complicated risk assessment and risk management analyses based on estimates of exposure and actuarial trade-offs, comparisons of relative risk, and the equalization of marginal benefits and costs. While logically and analytically sound, at least in principle, such decisionmaking is neither widely understood nor popular with advocates of particular programs. Even asking the question "Is there a better way?" provokes an outcry from some advocates, tending to limit meaningful assessment of regulatory methods and needs.

THE PERVERSE EFFECT OF INSTITUTIONAL INCENTIVES

The difficulties that are inherent in the development of sensible regulatory strategies are compounded by the vagaries of human nature and the innate dynamics of large Federal agencies.

[6] For example, the risk of cancer from drinking one soft drink per day with saccharin is one-half the cancer risk from drinking one beer a day. Wilson & Crouch, *Risk/Benefit Analysis* (Cambridge, Mass., Ballinger, 1982), pp. 182–3. Yet saccharin, not beer, was what was banned.

First, regulatory agencies have a tendency to look for immediate results. Consequently they start to control undesired side effects by tackling the easiest and most understood problems even if these are not the most serious or hazardous. Because of a natural desire to show results, these problems are tackled by imposing fairly strict deadlines for accomplishing a solution.

Even when a new technique on the horizon promises much better control, institutional incentives do not permit the trade-off of doing a significantly better job tomorrow in exchange for a worse job today. This tendency arises in part because of the inherently short stay of most upper-level managers of agency staffs, who are in general advocates for the particular regulatory goal involved.

Second, this tendency for regulatory agencies to solve the known and manageable (rather than the perhaps more serious problem) is compounded by the tendency of regulatory agencies to be overly optimistic concerning the effectiveness of regulations in controlling private behavior. Regulatory agencies can usually affect only a few selected aspects of the problems they are charged with ameliorating. For example, an agency may decide to tighten a regulation that is not achieving the desired effect. If the problem is one of noncompliance or nonenforcement, however, the effect of making compliance more difficult may only worsen the problem.

Because of the uncontrollable aspects of these problems, and because regulated entities are able to adjust their behavior to accommodate regulatory specifics without necessarily accomplishing the regulatory goals, those regulated may respond in unexpected ways that undermine or even eliminate the expected benefits of a regulation. For example, childproof tops on medicine bottles may be so difficult to open that users may prefer just to leave the top loose, thus undermining the basic purpose of the regulation. Also it is generally more convenient from an enforcement perspective for the government to regulate product or workplace design than it is to regulate human behavior. Accidents or unsafe practices, however, result from both design and behavior factors, and in many cases design standards may have a negligible effect on accident rates. For example, regulations required the installation of automobile seat-belts for years before anyone was required to use them.

Third, regulatory agencies are generally averse to risk, and have a tendency to be overly stringent in setting regulatory standards for products or production activities, even when faced with uncertain or incomplete information. Even if there is high scientific uncertainty, as with saccharin, the cautious approach for the one with regulatory authority is to act, rather than wait, and thus avoid facing the constituent and political criticism of being overly concerned with scientific and technical details, and of being callous or indifferent to human health. If a product, workplace, or behavior is deemed safe, nothing happens, and no one receives any unwanted attention. The agency is liable to receive a disproportionate share of the blame or criticism, however, when an accident or harm does occur.

Fourth, regulatory legislation has tended to favor well-organized special-interest groups at the expense of the general public. Legislative and agency regulatory policies often represent a series of compromises made in response to pressures from organized groups with the largest and most immediate stakes in the results. This advocacy form of representation almost always means that organized special interests petition government for preferential treatment and work hard to achieve special governmental advantages that may ultimately cost the country as a whole. Given existing budget constraints, and the difficulty in raising taxes, advocacy groups have also found it easier to accomplish their intended goals by having regulations direct certain groups to spend the money needed to accomplish the desired goals.

Moreover, an agency succeeds by accomplishing the statutory goals set for it as thoroughly as possible, and has every incentive to do only that. Thus, a bureaucracy will generally try to do its job but only its job. Agency personnel usually develop a strong allegiance to particular goals and often pay little attention to balancing single-purpose objectives against other competing goals. Primary agency constituencies naturally support "their" goals and oppose the goals of "others."

While agency personnel may seek to maintain their sphere of control, they may have insufficient knowledge to prescribe detailed solutions. Even if one assumes that careful study would reveal how best to achieve a regulatory objective at a particular moment in time, there is no reason to suppose that the same procedures would be correct one year, or even one month, later. When, however, the procedures that people and firms have to follow are prescribed by regulation, one can hardly update them any more frequently than that. Due process and administrative procedures require regulatory development to be slow and highly detailed. In situations in which technology and other relevant factors are changing rapidly, the likely outcome is that the procedures prescribed by regulation, even if reasonable to begin with, will quickly become obsolete.

In addition and acting as a block on regulatory improvement, those segments of the affected public that may benefit unfairly from an existing regulation will oppose any change. Many competitive advantages may come from the way a rule is written. For example, a regulation requiring that chemical exposure be reduced in the workplace may disproportionately affect small businesses. Similarly regulations increasing the cost of labor will benefit the more capital-intensive companies at the expense of those whose processes are more labor intensive. By having placed themselves into a good position under

an existing regulation, some companies are in a better competitive position than one where the forces of the marketplace are allowed to operate or where a more sensible, evenhanded regulation is put in place.

Fifth, the dynamics of passing legislation itself may at times impede improvement of the Federal regulatory structure and instead provide incentives to continue the problems that are already evident. For example, a regulatory statute may be written to help an advocacy group by limiting entry to newcomers, or by holding prices and technological development at a fixed level. The economic benefits from such regulatory protection can be worth as much as a tax exemption or a direct grant, but are much less obvious as a political favor. But such specialized favors to one advocacy group may hurt American society and its economy disproportionately more than any benefit that may have been provided.

The fact that the passage of a regulatory statute tends to provide short-term political benefits and imposes costs more slowly makes this approach even more tempting. There is inevitably a lag between the time a statute passes and the time the economic costs and social restrictions are imposed. The "hidden tax" may take a while to become evident or even be identifiable. Given this inherent time lag, a legislator may be tempted to benefit a particular constituent by enacting some form of protective regulatory program, because, when the costs to the general public are finally apparent, he or she may no longer be in office and thus may avoid association with the costs of implementing the statute.

Sixth, there is a tendency for legislators who support a regulatory program to state its goals in absolute terms, such as "I favor clean air and pure drinking water; I am opposed to cancer." Stating regulatory goals in such absolute terms may provide good publicity and a favorable opinion among voters. On the other hand, an agency is seldom able to achieve results in such absolute terms, particularly given the costs of compliance involved. The legislative advocate may then be tempted to come back later and complain that the absolute goal was only partially attained.

This mixture of legislative goals (some hidden, some stated in absolute terms—piecemeal implementation based on which advocacy group received whose attention first and the administrative need to set practical priorities for enforcement—has led to a confusing and discordant regulatory structure.

THE PRESIDENT'S CONSTITUTIONAL DUTY TO OVERSEE AGENCY REGULATIONS

Reflecting the proper role of the President and the President's responsibilities as Chief Executive, the Founding Fathers provided the President with the basic authority to oversee and coordinate the work of the heads of Federal agencies. As described more fully below, the Constitution gives the President the authority to manage the Executive branch; to supervise and guide Presidential appointees in the exercise of their executive functions; and to require their written opinions on matters within the scope of their responsibilities.

EXECUTIVE POWER

The executive Power shall be vested in a President of the United States of America (Article II, Constitution of the United States). The Constitution vests the executive power in the President.[7] While the Founding Fathers understood that there would be Federal agencies responsible for the day-to-day implementation of Federal law, they clearly and consciously chose an independent executive over a collegial body subject to legislative direction.[8]

The Constitution makes the President accountable to the people—the electorate—for the work of the Federal government. The President is the only official given executive authority by the Constitution and the only elected official (besides the Vice President) to be elected by all of the people. The President is therefore the only Federal official accountable to the country as a whole for the administration of the totality of Federal law and of the Nation's regulatory policy.

[7] "The executive power under our Constitution . . . is not shared —it rests exclusively with the President." *Sierra Club* v. *Costle*, 657 F.2d 298, 405 (D.C. Cir. 1981).

[8] See, generally, Strauss, "The Place of Agencies in Government: Separation of Powers and the Fourth Branch," 84 Col. L. Rev. 573 (April 1984); Pierce, "The Role of Constitutional and Political Theory in Administrative Law," 64 Tex. L. Rev. 469 (1985); Strauss and Sunstein, "The Role of the President and OMB in Informal Rulemaking," 38 Ad. L. Rev. 181 (Spring, 1986); DeMuth and Ginsburg, "White House Review of Agency Rulemaking," 99 Harv. L. Rev. 1075 (1986); Cross, "Executive Orders 12,291 and 12,498: A Test Case in Presidential Control of Executive Agencies," 4 Journal of Law & Politics 483 (1988).

On the other hand, as a practical and constitutionally implicit matter, the President does not generally execute Federal regulatory law; heads of Federal regulatory agencies do. Congress, by statute, typically provides legal decisionmaking authority directly to heads of agencies and to the heads of components within agencies. But this convention cannot and does not relieve the President of accountability to the public for the way in which heads of agencies execute the law, and for the way in which the Government implements regulatory policy.

Because the President is politically accountable for what others do, the President is obligated by the very nature of his or her position to supervise them—to make them work together in ways consistent with overall Presidential policies. Specifically and within the discretion and authority provided by existing law, the President is obligated to allocate resources, set priorities, and coordinate the activities of the heads of different regulatory agencies—all in order to assure that the Federal government operates in a coherent and efficient way.

NOMINATION AND APPOINTMENT OF OFFICERS OF THE UNITED STATES

The President . . . shall nominate, and by and with the Advice and Consent of the Senate, shall appoint . . . all other Officers of the United States, ... He . . . shall Commission all the Officers of the United States (Article II, Constitution of the United States).[9] The President appoints at least the head of any regulatory agency. Presidential appointees are generally part of the Executive branch; that is, they work for the President, and generally can be removed by him for any reason, or for no reason at all.

One source of the President's power to manage subordinates arises from the President's ability to remove those appointees in whom he or she lacks political confidence or, less broadly, who disobey his or her valid instructions. If the President wishes particular decisions to be made by a recalcitrant subordinate, the President's recourse is to discharge the relevant official and to appoint a new one who shares his or her inclinations.

Presidential authority over appointees is not absolute. Ultimate legal decisional authority may lie in particular cases in the regulatory agencies. The President may not be legally empowered to make particular decisions statutorily vested in subordinate officials—except to the extent the possibility of a removal may influence such a decision.

Basically, however, agency heads exercise their statutory authority at the President's pleasure, and have done so since the beginning of the Republic. As the size of government has grown, Presidents of both parties have structured working relationships in the Executive branch (by Executive Orders or other instructions), so that they may continue effectively to supervise and guide subordinate officials in the performance of their duties.

FAITHFUL EXECUTION OF THE LAWS

The President . . . shall take Care that the Laws be faithfully executed (Article II, Constitution of the United States). As Chief Executive, the President is constitutionally responsible for the day-to-day implementation of all Federal laws by Federal agencies. This gives the President the responsibility and with it the commensurate authority to oversee the development of regulations by Presidential appointees.

The existence of a single executive, politically accountable to the people faithfully to execute the laws, locates the coordination and dispute resolution function in the Presidency. Given the President's political accountability and constitutional responsibility, the President is uniquely placed to oversee regulatory policy in a way that is responsive to the interests of the public as a whole. Agency officials, in contrast to the President, are only indirectly accountable to the public. They may also be subject to more parochial pressures from individual advocacy interests and agency staff. For these reasons, a supervisory role by the President helps ensure that discretionary decisions by regulatory agencies are responsive to the needs of the general public.

Guiding the Federal government, with all of its various agencies and detailed legal authorities, is a difficult and complex task. Diverse Federal agencies implement many laws. Such multiple responsibilities inevitably raise questions of priority, conflict, and coordination that rarely are resolved in the statutes involved. That the legislature may create a statute and order its implementation does not mean that the legislature will provide funding adequate to carry it out; will fully anticipate the indirect, possibly adverse, effects of "full" enforcement; or will understand the indirect impacts of the statute on all others in force. Particular agencies, with their specif-

[9] An appointment places an individual into a Federal position; the commission defines the scope of authority to carry out that position, and the terms on which that position may be retained. For example, on September 11, 1789, President George Washington commissioned Alexander Hamilton to be his Secretary of the Treasury. In so doing, he wrote:

> I have nominated, and by and with the advice and consent of the Senate, do appoint him Secretary of the Treasury for the said United States, and do authorize and empower him to execute and fulfil and the Duties of that Office according to Law, and to have and hold the said Office, with all the Powers, Privileges, and Emoluments, to the same of the Right appertaining, during the pleasure of the President of the United States for the time being.

On September 26, 1789, President Washington commissioned Thomas Jefferson to be Secretary of State, likewise "during the pleasure of the President of the United States for the time being." Cf. Cross, "Executive Orders 12,291 and 12,498: A Test Case in Presidential Control of Executive Agencies," 4 Journal of Law & Politics 483, 503–04 (1988).

ically focused responsibilities, may be indifferent or even opposed to the need for coordination.[10]

In addition to the obligation to resolve conflicts and set priorities among statutes, the President also needs to coordinate the implementation of all Federal law with the President's political program that the voters elected him or her to carry out, and to mold both to changing circumstances. The day-to-day course of national affairs generates new issues to which the President must make a coherent response and for the resolution of which the public will hold the President politically accountable.

This need to coordinate and oversee agency regulatory and other activities requires the President to build ongoing relationships with all agencies, based on substantial lines of communication and guidance to the appointed officials. Reciprocally these officials need to maintain relations with the President consonant with the President's obligation to see to the faithful execution of the laws.

The President, given his or her capacity for centralization, is able to energize and direct regulatory policy in a way that would be impossible if that policy were to be set exclusively by agency officials. An agency-by-agency approach to regulation does not permit a useful evaluation of tradeoffs between legitimate but nonetheless competing objectives. Leaving balancing functions in the agencies would create multiheaded government, government with neither the capacity to come to a definitive resolution nor the ability to see that any resolution is honored in all agencies to which it may apply.

Over the past ten years and before, it has been the Presidential role to seek information and provide it to Federal regulatory agencies in order to promote coordination and awareness of national regulatory policy issues, to require agency analyses and agency responses on national policy concerns relevant to the agency's regulatory responsibility, and to direct that given perspectives be further considered in implementing regulatory policy. Given the overall problems with the Federal regulatory structure, it has been the President and officials in his Executive Office who have asked such questions as: Are there better and more effective regulatory approaches than the shopworn schemes of the past? Are the full costs of government regulatory programs well understood? Are they reasonable in relation to the benefits they produce? What is the cumulative impact of all regulatory programs on the country's economy?

WRITTEN OPINIONS FROM EXECUTIVE OFFICERS

The President . . . may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices, . . . (Article II, Constitution of the United States). The Founding Fathers specifically obligated the heads of agencies to respond to requests from the President for opinions in writing. These reports may be demanded in private, preliminary to agency action in time for relevant response on the President's part, and in a form that the President is able to specify—for example, an explanation of reasons behind proposed courses of action, a plan for undertaking an intended rulemaking, a benefit-cost analysis, or a regulatory agenda, calendar, or program.

The Presidential managerial oversight required by the Constitution goes back to the first days of the Republic. Since 1789, agency heads have sought and received prior advice from the President and officials in his Executive Office on important executive actions.[11] Such Presidential communication, coordination, and direction are the essence of executive managerial oversight, just as reauthorization and appropriations hearings are the basic oversight tools for a legislature.

[10] Such centralized regulatory oversight efforts are naturally opposed by individual program advocates and those in an agency that agree with such program advocates. Advocates that stand to benefit from allocation of resources to "their" issue would prefer to have policy direction and regulatory planning authority rest exclusively in "their" program agency. Such advocacy groups would then have greater opportunity to shape the outcome of a rulemaking to their liking through years of prerulemaking orchestration of agency staff, congressional staff, and the trade press.

[11] For example, President Thomas Jefferson reported approvingly that President George Washington had routinely reviewed the correspondence prepared by his cabinet officials before it was mailed, a practice that President Jefferson resumed:

> Having been a member of the first administration under Gen. Washington, I can state with exactness what our course then was. Letters of business came addressed sometimes to the President, but most frequently to the heads of departments. If addressed to himself, he referred them to the proper department to be acted on: if to one of the secretaries, the letter, if it required no answer, was communicated to the President, simply for his information. If an answer was requisite, the secretary of the department communicated the letter and his proposed answer to the President. Generally they were simply sent back after perusal, which signified his approbation. Sometimes he returned them with an informal note, suggesting an alteration or a query. If a doubt of any importance arose, he reserved it for conference. By this means, he was always in accurate possession of all facts and proceedings in every part of the Union, and to whatsoever department they related; he formed a central point for the different branches; preserved an unity of object and action among them; exercised that participation in the suggestion of affairs which his office made incumbent on him; and met himself the due responsibility for whatever was done. During Mr. Adams' administration, his long and habitual absences from the seat of government, rendered this kind of communication impracticable, removed him from any share in the transaction of affairs, and parcelled out the government, in fact, among four independent heads, drawing sometimes in opposite directions. That the former is preferable to the latter course, cannot be doubted. It gave, in deed, to the heads of departments the trouble of making up, once a day, a packet of all their communications for the perusal of the President; it commonly also retarded one day their dispatches by mail. But in pressing cases, this injury was prevented by presenting that case singly for immediate attention; and it produced us in return the benefit of his sanction for every act we did. T. Jefferson, *The Complete Jefferson*, 306–07 (S. Padovr ed. 1943).

THE MECHANISMS FOR ASSURING AGENCY ADHERENCE TO THE PRESIDENT'S REGULATORY PRINCIPLES

Given the ongoing and increasingly serious problems with the Federal regulatory structure, and the President's constitutional responsibility to manage and oversee Federal regulatory actions, President Reagan set in motion a regulatory program to ensure greater coordination, more analysis of possible regulatory impacts, more administrative rationality, more public notice of proposed Federal regulation, and increased Executive involvement in the regulatory process.

INSTITUTIONALIZING EXECUTIVE REGULATORY OVERSIGHT

President Reagan was not the first modern Chief Executive to concern himself with the disorder in the regulatory programs of the Federal government. In 1971 President Nixon established in the Executive Office of the President a "Quality of Life" review of certain regulations. As a result, the Office of Management and Budget (OMB) Memorandum implementing this review process required agencies that promulgated rules in the environmental, health, and safety regulatory areas to coordinate their regulatory activities with other Federal agencies.[12] In 1974 President Ford issued an Executive Order to require agencies to prepare, and OMB to review, inflation impact statements for major agency rules.[13]

In 1978 President Carter implemented various actions to strengthen executive regulatory oversight. First, he issued an Executive Order requiring detailed regulatory analyses of proposed agency rules and review by the Executive Office of the President.[14] Second, he created the Regulatory Analysis Review Group, which comprised representatives from the principal Federal economic and regulatory agencies. The purpose of this group was to examine in detail a limited number of regulatory analyses with substantial economic impact. Third, in October 1978 President Carter created the Regulatory Council, a group consisting of the heads of Federal regulatory agencies. The Council's principal function was to develop and publish semiannually the *Calendar of Federal Regulations*, which provided analytical synopses of 120–180 major regulations under development that were likely to have substantial economic or public impact, and assisted the regulators in developing cost-effective and consistent regulations.

Building on this experience, but going substantially beyond it, President Reagan put in place two major Executive Orders to ensure more systematic executive oversight of agency regulatory developments. The first, issued in 1981, instructed the regulatory agencies to demonstrate the likely benefits and costs of a regulation to Executive Office officials before the agencies could issue the regulation. The second, issued in 1985, mandated the annual *Regulatory Program of the United States Government.* This was designed to improve agency regulatory management by providing the President and his political appointees direct opportunity to review major regulatory activities for the coming year, to focus the Administration's regulatory priorities, and to coordinate with each other.[15]

These oversight mechanisms permitted the President to balance and coordinate Federal regulatory policy, providing a perspective that could only come from a single Chief Executive. To implement these two Executive Orders, the President directed officials in his Executive Office to carry out the needed coordination and oversight of the development of agency regulations. These Orders are modelled on the role of the Office of Management and Budget in the development of the fiscal budget. In both areas, a central task is to ensure that potentially conflicting and inconsistent proposals are assessed and ultimately reconciled. In both cases, the President, through officials in his Executive Office, is able to supervise the decisionmaking process. And in both settings, the budgetary model is a device for increasing (and exposing to public view) control by agency heads over agency staff decisionmaking. This Executive regulatory oversight process ensures early involvement of the politically accountable officials in the agencies.

EXECUTIVE ORDER NOS. 12291 AND 12498

Today Executive Order No. 12291 (see Appendix I for full text) is the backbone of Executive regulatory

[12]October 5, 1971 memorandum for the Heads of Departments and agencies entitled "Agency regulations, standards, and guidelines pertaining to environmental quality, consumer protection, and occupational and public health and safety," from OMB Director George P. Shultz.

[13]Executive Order No. 11821, 39 FR 41501 (November 29, 1974), extended by Executive Order No. 11949, 42 FR 1017 (January 5, 1977).

[14]Executive Order No. 12044, 43 FR 12661 (March 24, 1978).

[15] For a more detailed description of the historical background for these Executive Orders, see a chapter in the 1987 *Regulatory Program of the United States Government*, entitled "Executive Regulatory Oversight of Federal Regulation and Regulatory Paperwork" (pp. xxxii to li).

oversight activities. In it President Reagan instructed his appointees to follow his regulatory principles. To assure that they did, he also instructed them to submit all of their proposed regulations to OMB prior to issuing them.

Within OMB this regulatory review authority is carried out by the Office of Information and Regulatory Affairs (OIRA).[16] That Office reviews agency draft rules to ensure that the President's regulatory principles are being carried out. If they are not, that Office returns the rules to the agency for further work by the agency to make them consistent with those principles.

OMB does not have a veto over the rulemaking actions taken by agency heads under the statutory rulemaking authority assigned to them. This keeps the statutory prerogatives of the agency heads intact. OMB reviews the draft agency regulation for consistency with the President's regulatory principles, to identify possible issues of concern, and to review them for the President. If in working with the agencies, OMB and the agency head disagree, OMB or the agency head are always able to take the issue to an appropriate cabinet body, and as appropriate, to the President himself, in order to resolve it.

By 1985 it became obvious that more could and should be done. Despite OMB review of agency draft regulations and despite the mammoth expenditures Federal regulations exacted from some and the benefits they gave to others, Federal regulations were still being managed far less systematically than direct government spending.

The inadequacy in regulatory oversight was caused by the length of time required to develop many of the more important Federal regulations and by the ability of agency program advocates to build a public constituency supporting a draft regulation before agency and Executive office management had a full opportunity to focus on its implications. Agency staffs would often spend considerable time and invest substantial effort in hearings and in developing a factual record and special-interest support for these regulations. Millions of dollars in contract or other studies might be invested. Then, because review under Executive Order No. 12291 occurred at the very end of the regulatory development process, the rule would first be seen by the agency head, and then shortly after by OMB. This pattern of regulatory development made it very difficult to have agencies prepare the kind of analyses that the President and several of his predecessors thought should be brought to bear on those rules to help coordinate and focus agency decisionmaking.

As a result, President Reagan decided he needed to involve agency heads, policy officials, and the public earlier in the rulemaking process. On January 4, 1985, he issued Executive Order No. 12498, "[i]n order to see that the laws are faithfully executed, and that the policies of this Administration are reflected in the regulations issued under those laws."[17] (The full text of this order is included in Appendix II.)[18]

He called on his Administration every year to publish a Regulatory Program. In issuing this Executive order, however, President Reagan did not just direct his Executive Office to publish a book. His Executive order established an annual regulatory planning process. Each major regulatory agency drafts at the beginning of each year a summary of its regulatory policies, and a list of specific regulatory development projects under way. OMB then reviews each agency's draft regulatory program on behalf of the President. OMB reviews each one for consistency with the Administration's regulatory policies and priorities and the draft regulatory programs of other agencies. OMB will also identify further regulatory or deregulatory actions that are necessary to achieve consistency with Administration policy. If OMB and the agency cannot resolve a policy dispute, it is referred to an appropriate forum in the White House and, when necessary, to the President himself. Following this Executive review, the Administration publishes its decisions in the Regulatory Program.

The 1988 Regulatory Program, of which this overview is a part, sets forth for each agency its objectives for the 1988 Program Year (April 1, 1988—March 31, 1989), what issues the agency believes require immediate attention, and what the agency is doing to ensure the cost-effectiveness of the alternatives it proposes. If an agency later asks OMB to review an important rulemaking that was not included, but that should have been, OMB may return it to the agency for further work and for inclusion in the next

[16] OIRA was established in January 1981 as required by Section 3503 of the Paperwork Reduction Act of 1980 (Public Law 96–511). S. Jay Plager, the present Administrator of OIRA, is the fifth to hold that position since its establishment in 1981. He was preceded by James C. Miller III, now Director of OMB and a member of the President's Cabinet; Christopher DeMuth, now President of the American Enterprise Institute in Washington, D.C.; Douglas H. Ginsburg, now Judge of the U.S. Court of Appeals for the District of Columbia; and Wendy Lee Gramm, now Chairman of the Commodity Futures Trading Commission. Under the Paperwork Reduction Act, as amended by the Paperwork Reduction Reauthorization Act of 1986, OIRA is responsible for reviewing, approving, and disapproving collections of information imposed on the public; providing principles, guidelines, and guidance concerning the acquisition, use, and management of Federal information resources (including computers and telecommunications); and coordinating and giving policy direction in Federal statistical activities. OIRA is also assigned responsibilities under the Budget and Accounting Procedures Act of 1950, as amended (statistical policy, 31 U.S.C. 1104(d)), the Brooks Act (Public Law 89–306, as amended), the Privacy Act of 1974 (5 U.S.C. 552a), and Executive Order No. 12046 (Telecommunications Policy, March 17, 1978).

[17] The Regulatory Message of the President, 1985 *Regulatory Program of the United States Government* (p. vii).

[18] The Administration has published Regulatory Programs for 1985, 1986, 1987, and now, 1988.

year's Regulatory Program.

The Regulatory Program, in conjunction with the Executive Order No. 12291 review process, serves a number of purposes. The Regulatory Program provides a formal mechanism by which to involve agency heads, policy officials, and the general public early in the rulemaking process. With these publications, the Administration has presented, for the first time for all to see, a comprehensive Administration program of upcoming regulatory policy. Annual publication permits Congress and the American people to understand more fully the Executive's regulatory choices and its priorities; to understand more fully at an earlier stage, before the publication of any proposed rule, how the Executive intends to exercise the regulatory discretion that Congress has provided it by statute.

In addition, this Executive order enhances the agency head's effective control over his or her staff. By providing agency heads an annual opportunity to focus on the work of their agencies in a planning rather than a reactive mode, stressing broad vision and priority settings and involving them early enough, agency heads can have a greater impact on the regulatory options proposed. Given the required procedures for coordination, agency heads can better determine whether a particular regulatory action is worth starting before committing agency resources to it, and whether the regulatory activity is consistent with Administration policy.

The personal involvement of agency heads in regulatory policymaking also enhances their accountability to the President for the regulatory choices they make. Scarce government resources must be allocated according to some set of priorities. Given his Constitutional responsibilities, the President decided that regulatory priorities should not be determined unilaterally by each agency. Rather these priorities should be selected by the President's Administration as a whole, through a process that takes into account a wide spectrum of agency demands and Presidential policies. As President Reagan stated in issuing Executive Order No. 12498, each agency is to become "accountable for the management of the regulatory process, to ensure that policy options are not narrowed prematurely and that each significant regulatory proposal will be considered in relation to the others."[19]

OMB PROCEDURES FOR IMPLEMENTING EXECUTIVE ORDER NO. 12291

In order to ensure that the public and the Congress are fully informed of the Administration's regulatory policies, OMB/OIRA has adopted procedures to:

> maintain two type[s] of documents in our public files relating to regulatory reviews—all comments received from any member of the public, and all our final recommendation letters to agencies under Executive Order No. 12291. These files will also be accessible to the public in the reading room during normal business hours.[20]

Furthermore, in accordance with disclosure procedures adopted by OIRA on June 13, 1986, OIRA will disclose and publicly release upon request material provided to it by the agencies for Executive Order No. 12291 review, including the draft rules themselves.[21]

In addition, OIRA has agreed with several agencies (the Department of Housing and Urban Development, Labor, Transportation, the Treasury, and the Environmental Protection Agency) to additional disclosure procedures. Under these procedures, whenever the Administrator or Deputy Administrator of OIRA acquires factual information regarding an ongoing rulemaking as a result of a telephone call or a meeting, he or she will communicate that information to the agency's General Counsel and advise the General Counsel of the source of the communication. In addition, on the rare occasions when a meeting is scheduled to discuss a rule with persons who do not work for the Federal government, agency officials will be invited to attend. Furthermore, OIRA will send to the agency copies of all written information pertaining to these rules that it receives from persons outside the Federal government.[22]

[19] "Development of Administration's Regulatory Program," Presidential Memorandum for the Heads of Executive Departments and Agencies, dated January 4, 1985 (see Appendix II).

[20] May 30, 1985, memorandum, entitled, "OIRA Procedures #3," from the Deputy Administrator to OIRA Staff, p. 5. See Memorandum for the Heads of Departments and Agencies Subject to Executive Order Nos. 12291 and 12498, entitled, "Additional procedures concerning OIRA reviews under Executive Order Nos. 12291 and 12498 [Revised]," from Wendy L. Gramm, Administrator, OIRA, dated June 13, 1986, procedure #11 [hereinafter, referred to as "OIRA Disclosure Procedures #11"]. See Appendix III.

[21] See OIRA Disclosure Procedures #1, #2, #3, and #10, in Appendix III. OMB has generally not made similar materials publicly available that are developed by the agencies or OMB in other Executive review processes because they are deliberative documents and predecisional in nature and are not required by the Freedom of Information Act to be released. As a general matter, such disclosure would chill the full and frank interchange of views between the President and his appointees that is critical to the effectiveness of the policy formulation process. OMB's ability to withhold E.O. 12291 review material under the Freedom of Information Act has been upheld. (Memorandum Opinion in *National Tank Truck Carriers* v. *OMB*, C.A. No. 82–93 (D.C.D.C., May 28, 1982)).

OIRA has also—as a matter of policy—restricted its discussions, meetings, and other contacts with persons outside the Executive branch on rules under Executive Order No. 12291 reviews. Only the Administrator and the Deputy Administrator of OIRA may meet or discuss a rule under Executive Order No. 12291 review, unless they specifically authorize some other individual in OIRA to do so.

[22] See OIRA Disclosure Procedures #4 to #7, and #11, in Appendix III.

REGULATORY POLICY GUIDELINES

In addition to creating a process to improve Executive coordination of agency regulatory decisions, Executive Order No. 12291 sets out President Reagan's governing goals for the agency regulatory programs. These Presidential regulatory principles are complemented by regulatory review requirements which, to the extent permitted by law, require agencies to assess the benefits and costs of their regulations and to attempt to achieve the greatest net social benefits in making their decisions. As experience with Executive Order No. 12291 accumulated, the Administration refined these policies and developed a set of ten Regulatory Policy Guidelines to assist agency regulatory analysis in the rulemaking process.[23]

The ten guidelines attempt to address the most frequently encountered issues in Federal regulation and guide the agencies in the administration of regulatory programs. Of necessity their application is subject to the caveat that this type of analysis is not precluded by law. The guidelines make clear that a significant obstacle to making many regulations more rational is the language of the statutes themselves. For example, statutes sometimes require uniform national engineering standards when far superior policies for attaining the goal sought are available, or they require severe restrictions or prohibitions of certain products without considering the total public health consequences.

For analytical purposes, the ten Regulatory Policy Guidelines can be divided into two categories: those that address economic and analytic justification for regulatory proposals, and those that suggest the particular types of strategies or regulation that are most likely to produce fair and responsive government.

POLICY GUIDELINES REQUIRING ECONOMIC AND ANALYTIC JUSTIFICATION

> Regulatory Policy Guideline No. 1:[24] Regulations should be issued only on evidence that their potential benefits exceed their potential costs. Regulatory objectives, and the methods for achieving these objectives, should be chosen to maximize the net benefits to society.

The first guideline restates the basic principles of Executive Order No. 12291. It applies to all kinds of regulation: economic (the regulation of markets and economic relationships); social (health, safety, and environmental regulation); and administrative (the management of Federal funds and resources).[25]

As with Executive Order No. 12291, this guideline is to be used only "to the extent permitted by law." Executive branch policies cannot override explicit statutory directions. Some regulatory statutes direct certain actions regardless of costs, benefits, or both. On the other hand, where there is policy discretion the President has a Constitutional responsibility to provide guidance to the departments and agencies in exercising the discretion they do have.

The point at which a given regulation's benefits exceed its costs can be a matter of uncertainty and controversy.[26] A Regulatory Impact Analysis (RIA) is required by Executive Order No. 12291 for "major" regulations and is to contain a benefit-cost analysis for such proposed regulatory actions.[27] In recent years there have been a number of agency RIAs that contained carefully prepared analyses in support of major regulatory initiatives and demonstrated net benefits that were clearly positive, for example, the RIAs analyzing the Department of Transportation's (DOT's) center high-mounted stop-lamps, the Environmental Protection Agency's (EPA's) lead phasedown, and the Occupational Safety and Health Administration (OSHA's) fall protection regulations.[28]

DOT issued its regulation requiring automobiles to have a center high-mounted stop-lamp in 1983. DOT first conducted extensive analyses estimating the potential benefits and costs. To do so, DOT conducted several experiments in which fleets of automobiles were equipped with various types of stop-lamps in order to measure their relative effectiveness in reducing rear-end collisions. This regulation is one of the most highly visible success stories of the Administration's regulatory reform program. These stop-lamps are seen almost every time one follows an automobile manufactured since 1986.

EPA's lead in gasoline phasedown rule was also accompanied by extensive and high-quality economic analysis that clearly established that the benefits of

[23] These Regulatory Policy Guidelines were set forth in the August 11, 1983, Report of the Presidential Task Force on Regulatory Relief.

[24] These Regulatory Policy Guidelines do not appear in numerical order in this text. They are given the same numerical designations as they were given in the August 11, 1983, Report of the Presidential Task Force on Regulatory Relief.

[25] For a discussion of this taxonomy and list of the regulatory programs each category entails, see the 1985 *Regulatory Program of the United States Government,* pp. xiv–xxiii.

[26] Appendix V provides guidelines on how to estimate benefits and costs and how to organize these data and facts to aid the policymakers in their regulatory decisions.

[27] Generally, a major rule is a regulation that is likely to result in (1) an annual effect on the economy of $100 million or more, (2) a major increase in costs or prices, or (3) significant adverse effects on competition, employment, investment, productivity, or innovation.

[28] The 1987 Regulatory Program also discussed nine regulatory impact analyses performed by five agencies. See "The Role of Regulatory Impact Analysis" in the 1987 *Regulatory Program of the United States Government* (pp. xv to xxii).

lead phasedown exceed the costs.[29] This regulation has been applauded by public health specialists, environmentalists, and consumers.

Finally, OSHA's fall protection standard, issued in 1985 for the construction industry, was supported by benefit-cost analysis using best estimates, proper discounting techniques, and sensitivity analysis that established the economic desirability of the regulation.[30]

> *Regulatory Policy Guideline No. 4:* Regulations that seek to reduce health or safety risks should be based upon scientific risk-assessment procedures, and should address risks that are real and significant rather than hypothetical or remote.

This guideline is, perhaps, the most controversial one of the ten. In fact, some statutes, such as the Delaney Clause of the Food and Drug Act, sharply restrict agencies' ability to consider the magnitude of risks; the Delaney Clause requires that food additives that "induce cancer in man or animal" must be banned without indicating any consideration of remoteness of risk.[31] And until the Supreme Court ruled that before OSHA may issue a rule it must make a determination that a "significant" risk exists and would be substantially reduced by the proposed standard, OSHA declined to estimate the benefits of its proposed health standards, on the grounds that its statutory mandate did not require such considerations.[32]

When agencies do risk assessments or benefit estimates of health and safety regulations, it is frequently the practice to err on the side of caution and overestimate risks by the use of conservative assumptions and risk assessment models.[33] Moreover, since these conservative assumptions are often made by different technicians at different phases of the risk assessment process, the degree of total overestimate or bias is almost never known. Thus the decisionmaker may be left with no way of knowing whether the "risks are real and significant rather than hypothetical and remote." Even though these conservative policies are well-intended, they are likely to be less protective of the public health than policies based on a best estimate of risks. Resources and effort wasted on *de minimis* risks hamper the ability of society to reduce other real and significant risks that would provide even greater safety overall.

In accordance with this second regulatory policy guideline, many of the regulations issued in the last several years have been directed at reducing real and significant risks. Examples include OSHA's 1987 grain-handling regulations aimed at reducing the risk of grain elevator explosions, OSHA regulations that reduce occupational exposure to human carcinogens, such as asbestos and benzene, both issued in 1986, and the 1984 rule issued by the National Highway Traffic Safety Administration (NHTSA) requiring passive restraints and encouraging State seat belt laws.

Despite these successes, statutory prohibitions on risk assessment and some agency policies still lead to wasteful regulatory efforts aimed at speculative and insignificant risks when compared to the greater risks that other substances and activities pose. Control of the latter would provide greater benefits at less cost to society. It is important to improve risk assessment techniques and to assure that, to the extent permitted by law, regulatory decisions take into account real expected risk reductions.

POLICY GUIDELINES AIMED AT PRODUCING FAIR AND RESPONSIVE GOVERNMENT

Better economic analysis may help focus a regulatory program and help decisionmakers make it more efficient and internally consistent. But taken alone, to make the existing web of regulations more refined and coordinated only means that for each subject area the government will be more effective in regulating. By itself, this means that government controls will become more efficient, and compliance will become more effective, more pervasive, and more overwhelming in controlling the man on the street.

In other words, more and better analysis of the possible effects of a given regulation does not solve the problem of cumulative effects making the public subject to many different kinds of regulations, often unexpectedly, from a varying mix of governmental regulators, whether Federal, State, or local. The man on the street may still feel a sense of frustration or alienation at what he views as his lack of participation in formulating these regulations; in not having them flexible to fit his or her particular circumstances or needs, unanticipated at the time the regulations were formulated; and in not allowing him or her enough individual discretion to meet the widely different circumstances that exist across this large and economically diverse country.

As a result, the Administration has also sought through the review process of Executive Order No. 12291 to address the problems of the cumulative impact of regulations; the varying mixture of Federal, State, and local regulators; and the public sense

[29] See EPA, *Costs and Benefits of Reducing Lead in Gasoline: Final Regulatory Impact Analyses* (February 1985).

[30] Preliminary Regulatory Impact and Regulatory Flexibility Assessment of Subpart M—Fall Protection (29 CFR Part 1926.500-.503), OSHA Office of Regulatory Analysis, August 30, 1985.

[31] 21 U.S.C. 376(b)(5) and 21 U.S.C. 348(C)(3)(A).

[32] See the Benzene decision, *Industrial Union Department* v. *American Petroleum Institute,* 448 U.S. 607 (1980).

[33] This problem is discussed below in greater detail. It was also the subject of a chapter in the 1986 *Regulatory Program of the United States Government,* entitled "Improving Coordination and Consistency in Risk Regulation" (pp. xix to xxvi).

of alienation and nonparticipation. Through implementation of this Order, the Administration has sought to provide an understandable rationale for government action and, through Executive Order Nos. 12291 and 12498, to better articulate its long-term regulatory goals.

Those Regulatory Policy Guidelines that seek to have the government act in fairer ways can be subgrouped into three categories. Several guidelines help harness market incentives to further social and economic goals. Others seek to have the Federal government reduce regulatory burdens on State and local governments. Still others seek to have regulatory agencies streamline their regulatory procedures.

Harnessing Market Incentives

Many aspects of a particular regulatory program can benefit from the greater use of incentives based on market performance. Such reliance on market incentives leaves the public freer to undertake its own activities in accord with incentives and constraints similar to its day-to-day activity.

> *Regulatory Policy Guideline No. 2:* Regulation of prices and production in competitive markets should be avoided. Entry into private markets should be regulated only where necessary to protect health or safety or to manage public resources efficiently.

This is the regulatory principle that has guided efforts to "deregulate" rate and entry barriers in such industries as airlines, trucking, buses, communications, and finance. Most of the deregulation that has been accomplished in these industries has been accomplished through legislation and the deregulatory initiatives of appointed commissioners responsible for the so-called independent regulatory agencies.

One area in which Executive branch agencies do issue regulations that set prices and output is the labor market. The Fair Labor Standards Act (FLSA) sets minimum wage rates (the "price" of a worker's services) and maximum working hours, and allows the Federal government to issue regulations to help enforce those conditions. One of the first regulatory actions of the Administration was to stay Labor Department regulations issued at the end of 1980 that would have reduced the number of workers that could be employed as managers or professionals, exempt from the minimum wage and overtime provisions of the FLSA. This action opens up opportunities for managerial training jobs and increases competition in these markets.

In addition, the Department of Labor in the past issued regulations that restricted where or how people could work in order to make it easier to enforce the wage and hour laws. Starting in the forties, the Department placed off-limits seven industries for workers who wanted to work at home: knitted outerwear; handkerchiefs; gloves and mittens; embroideries, buttons and buckles; jewelry manufacturing; and women's apparel. In 1984 this Administration issued a final rule lifting the homework ban in knitted outerwear if employers applied for a certificate. In March of 1988 the Administration issued a proposed rule that would lift the ban in the remaining industries, except women's apparel and hazardous jewelry manufacturing operations, which are being addressed separately.

> *Regulatory Policy Guideline No. 3:* Federal regulations should not prescribe uniform quality standards for private goods or services, except where these products are needlessly unsafe or product variations are wasteful, and voluntary private standards have failed to correct the problem.

The private economy produces wide variations in goods and services in response to differences in the preferences of consumers. Standardizing the safety or other quality features of products may, however, be beneficial where products have subtle but important features that are difficult for consumers to assess, as in the case of technically complex products such as drugs and automobiles, and unbranded products such as many agricultural commodities. In these cases standardization reduces information costs. Standardizing the products of different suppliers may also promote economic coordination, as in the case of frequency calibrations on radios and televisions; and automobile bumper heights.

When standardization is good for consumers for safety or other reasons, it will often be good for producers as well, by expanding the markets of individual sellers, minimizing product liability, or for other reasons. That this is so is demonstrated by the fact that the American economy is "regulated" by thousands of safety and other product standards established privately by trade associations and independent standards-setting bodies. These standards do not need to be enforced by a government agency, because sellers have strong private incentives to follow them. Ignoring these standards could leave sellers open to ruinous tort liabilities or to eroding sales because their products are incompatible with other products or with consumers' expectations.

There are circumstances where private markets, standards-setting procedures, and liability law may fail to provide products and services that are in the best interest of consumers. When the health effects of products become apparent only over long periods of time and when causality from the product of a given producer is difficult to determine, product quality standards may be needed. This does not mean, however, that regulatory agencies should impose product standards whenever any degree of health, safety, or economic risk has been identified, for some degree of risk is a feature of virtually all goods and services. Rather the test should be whether existing levels of product quality are needlessly risky or wasteful from the consumer's point of view and whether private incentives for adopting product standards are for

some reason inadequate.

The Administration has revised uniform quality standards in several areas to the benefit of consumers and producers alike. Examples include: the deregulation at the Federal level of minimum property standards for housing, leaving this matter to be determined by State and local codes; the relaxation of energy standards for buildings and automobiles after energy prices were deregulated so that consumers could determine whether to pay for energy use in capital costs or in operating costs; and the relaxation of automobile bumper standards so that consumers could choose the type of bumper most suited to their own driving style and financial profiles, that is, by choosing between a more easily damaged but less expensive bumper and a less easily damaged but more expensive bumper.

Regulatory Policy Guideline No. 5: Health, safety, and environmental regulations should address ends rather than means.

Regulations that impose precise engineering requirements are generally cost-ineffective, especially when applied on a uniform nationwide basis. The best means of accomplishing a given environmental end varies from firm to firm, region to region, and over time. Imposing engineering uniformity on these natural variations almost always results in more economic cost than necessary to achieve a given environmental benefit, or too little environmental benefit for a given economic cost. Moreover, government-prescribed uniform technology retards productivity growth, dampening market competition and reducing incentives for innovation in both production and pollution-control markets.

For these reasons, regulatory standards should be adopted in terms of results or performance rather than specifying the means employed to achieve the results. With performance-oriented standards, regulated firms are responsible for meeting a prescribed regulatory target, but are free to choose or invent the easiest or most cost-effective methods to reach the target.

In practice, the distinction between performance standards and design standards is a continuum rather than a simple dichotomy. Regulatory policymaking usually involves selecting a point on a spectrum running from pure design standards to pure performance standards. The variety of approaches to protecting workers from airborne health hazards is a typical example. There is a spectrum of choices theoretically available in defining a standard, ranging from a design standard to an exposure standard to a health standard, the ultimate objective.

While moving toward the performance end of the spectrum produces more cost-effective regulations, this tendency is offset by difficulties of enforcing performance standards in certain circumstances. A pure health standard would be impractical, for example, where the disease being protected against manifests itself only after decades of exposure. Uncertain causation between a given design and a given performance objective is not, however, an argument against performance standards, since this uncertainty also applies to any design requirement prescribed by the government. To the degree that performance can be measured or reasonably imputed, a standard based on this level of performance is always superior to more means-oriented regulation.

Examples of standards more at the performance end of the spectrum than the design end include: OSHA's hearing conservation standard issued in 1983 that uses temporary shifts in hearing loss to trigger hearing protectors, FDA's "tamper-resistant packaging" regulation, and OSHA's grain-handling regulations that allows firms several options for reducing the risks of grain dust explosions.

A step beyond performance standards is structuring regulations to provide individuals with information on health benefits and risks, so they can make their own judgments—this shifts discretion concerning exposure to the risk back to the individuals involved. For example, in June of 1987 the Food and Drug Administration issued a final regulation that permits individuals with serious or life-threatening illness access to experimental drugs. Prior to issuance of this rule, only individuals participating in clinical trials, with few exceptions, had access to these drugs. Now as soon as very early test results demonstrate safety and there is at least some indication of effectiveness, drug manufacturers are able to apply for "treatment use" of experimental drugs, and consumers on advice of their doctors can make the decision for themselves.

In the same vein in August 1987 the Food and Drug Administration published a proposal to modify its policy on health claims on food labels. In the past, health claims have been prohibited on labels. FDA's proposal would permit health claims on food labels if they are truthful, non-misleading, and adequately supported by scientific evidence. Making this information available to consumers will allow consumers access to educational information and will permit consumers to make better informed judgments about the products they purchase and consume.

Regulatory Policy Guideline No. 8: Where regulations create private rights or obligations, unrestricted exchange of these rights or obligations should be encouraged.

Regulatory policies frequently create rights or obligations with substantial value in private markets.[34] A license to use a certain portion of the broad-

[34] For a fuller description of the Administration's program to promote the trading of rights and obligations created by regulatory actions see the chapter in the 1986 *Regulatory Program of the United States Government,* entitled, "Efficient Allocation of Regulatory Rights and Resources" (pp. xxvi to xxxi).

cast frequency spectrum, a permit to land at a certain airport, and a permit to explore for oil on a certain tract of the outer continental shelf are valuable rights secured through regulation. In the same way, requirements to limit pollution from certain kinds of products or production facilities are costly obligations imposed through regulation.

Perfect regulation would allocate such rights and obligations precisely to those firms and individuals who could use or meet them to produce the greatest benefits to society as a whole. But regulation is never perfect and rarely as good as private markets in allocating rights and obligations.

Frequently private exchange of regulatory rights and obligations occurs so naturally that it does not require a formal policy of encouragement at all. Drug companies have the unquestioned right to sell licenses to produce and market drugs approved for marketing by the FDA. When a manufacturing plant is purchased, so is the obligation to continue meeting OSHA health and safety standards (which reduces the plant's price by the cost of meeting these standards).

In other cases marketing rights have been uncertain without the blessing of the regulatory agency itself. In the early years of the FCC, there was doubt whether broadcasting licenses could change hands privately when stations were sold; the issue has long since been resolved in favor of free exchange with minimal FCC review. The marketability of airport landing "slots" was a contentious issue in the airline industry after the 1981 air traffic controllers' strike limited control capacity at several major airports. Free trading of slots was permitted for the first time in 1982, easing shortages in both large cities and small communities by allocating these scarce rights to their most highly valued uses.

One of the Administration's most promising innovations has been the encouragement of emissions trading. Emissions trading encompasses several methods of improving the cost-effectiveness of stationary-source air regulation. Common to these methods is use of the "bubble" concept, by which total emissions from one or more facilities are considered to emerge from a giant bubble surrounding the facility, allowing companies to control more than required at stacks where costs are low in exchange for less control where costs are high. Under the bubble, compliance can often be accomplished more efficiently than by use of uniform stack-by-stack controls. This is because inexpensive extra controls at one stack can be used to meet more expensive control obligations at another.

Bubbles also have potential to encourage innovative emission control approaches, reach small or dispersed sources that would be difficult to control directly, and secure more reliable, less-polluting production changes that the Environmental Protection Agency (EPA) cannot mandate. Individual bubbles can elicit information needed for better air-quality planning, speed compliance, and strengthen enforcement. They can also provide financial reasons for companies to seek innovative control strategies which surpass requirements at some of their sources, instead of planning merely to meet those requirements through traditional means.

EPA's 1986 Final Emissions Trading Policy replaced an original Bubble Policy issued in 1979 and an Interim Emissions Trading Policy published in 1982. It reflects over seven years' experience with bubbles, and many differing views within and outside the Agency. It provides the framework for review and approval of environmentally sound bubbles and related actions by EPA or States under the Clean Air Act. By clearly defining approval requirements, the Policy will allow States and industry to implement bubbles with greater confidence and predictability. Similar incentive-based approaches are now being implemented or explored by the EPA in several other areas of air, water, and waste pollution control.

Reducing Burdens on State and Local Governments

A second category in which several of the guidelines can be grouped involves reducing regulatory burdens on State and local governments. Federal grants to State and local governments always come with strings intended to ensure that Federal funds are not misspent. In recent years these strings have often grown into a tight web of restrictions that have hampered local efficiency and accountability, increased program costs, and hurt the individuals the programs were intended to serve. Following President Reagan's deep commitment to restoring a proper balance to our Federal system, the Administration has focused particular attention on freeing States and localities from burdensome and unnecessary Federal regulations.

> *Regulatory Policy Guideline No. 9:* Federal regulations should not preempt State laws or regulations, except to guarantee rights of national citizenship or to avoid significant burdens on interstate commerce.

This guideline supports the President's policy of restoring the principle of "Federalism" to American government. The economic efficiency basis for Federalism rests on the general superiority of decentralized decisionmaking for a complex economic system. These advantages apply with particular force to regulatory decisions.

First, local regulations are more apt to be responsive to local circumstances. The costs and benefits of regulatory policies often vary substantially from place to place, depending on local preferences, geography, climate, population density and demography, economic conditions, and much else. National regulations that seek "average" solutions will typically be overly broad or lenient in some places and too narrow or strict in others.

Second, local regulations afford citizens a greater degree of choice among divergent public policies. One

State can promote temperance, another gambling; one State can encourage tourism, while another welcomes heavy industry.

Third, local regulations allow for diversity and experimentation. The actual effects of regulatory policies are frequently a matter of uncertainty and controversy, and often the best way to assess actual effects is to compare the experience of different States. While local regulations permit the States to learn from one another's successes and failures, national regulations suppress this information.

These considerations suggest that the Federal government should defer to State and local governments, except where rights of national citizenship (such as legal equality among the races) or significant burdens on interstate commerce are involved. The control of surface mining and local air pollution problems, for example, are more appropriate to the States than to the Federal government; the Interior Department and EPA have been "defederalizing" these aspects of their regulatory programs. On the other hand, regulating the safety characteristics of motor vehicles in general is appropriate to the Federal government, since the products being regulated are usually marketed on a nationwide basis, the benefits of multiple approaches to the safe design of motor vehicles are probably small, and a number of widely differing State standards could impose large costs on interstate commerce without being justified by local needs or considerations.

It is not a sufficient case for Federal regulation that the object of regulation is part of interstate commerce. All interstate businesses comply with an array of differing State corporation and securities laws, workers compensation programs, local zoning ordinances, and so forth. As the widespread adoption of the Uniform Commercial Code and other uniform state laws illustrates, States often have strong incentives to standardize their laws when doing so will significantly promote interstate commerce.

Whether something *could* be regulated by the Federal government under the Constitution is a different matter than whether the Federal government *should* step in. The policy question is whether the burdens on interstate commerce arising from divergent State and local regulations are so great that they outweigh the advantages of diversity and local political choice. At the same time, Federal regulation may be justified, even when the object of regulation is exclusively local, if the benefits of regulation are primarily local but the costs fall disproportionately on citizens of other States. In such cases States have incentives to be too restrictive; common examples are State restrictions on nuclear waste disposal facilities, and truck sizes on interstate highways that connect out-of-state markets.

One major success in this area has been the Department of Housing and Urban Development's (HUD's) shift in 1985 from requiring that all federally insured single and multifamily dwellings meet federally prescribed minimum property standards to reliance on existing State or local building codes. In the past builders had to meet the more stringent of the local or Federal codes, codes that sometimes were in conflict. Considerable cost savings and homes built more in line with local conditions and preferences should result.

In another major step the Administration has returned to the States primary authority to allocate water resources. In reversing a 1979 legal opinion on so-called "nonreserved" Federal water rights, this Administration reaffirmed that, unless otherwise directed by Congress, the individual States shall govern how Department of the Interior agencies acquire new water sources. This new policy protects the States' historic rights to determine water allocation.

> *Regulatory Policy Guideline No. 10:* Regulations establishing terms or conditions of Federal grants, contracts, or financial assistance should be limited to the minimum necessary to achieving the purposes for which the funds were authorized and appropriated.

Agencies that administer Federal transfer payments face a temptation to add conditions in pursuit of statutory and nonstatutory goals that are not germane to the purpose for which the funds were authorized and appropriated. Sometimes these conditions find their way into law, such as the air quality attainment conditions on Federal transportation funds. This kind of linkage between two programs is generally a poor way to manage either of them. Irrelevant conditions on transportation grants can only diminish their usefulness. It makes no environmental sense to make the enforcement of air-quality goals more or less strict depending on a State's need for transportation funds.

Too often Federal transfer payments are restricted with so many strings or such detailed reporting and recordkeeping requirements that the usefulness of the payment to the recipient or to the Federal taxpayer nearly vanishes. Obviously some controls are needed to prevent abuse and to ensure that funds appropriated to achieve a specific purpose are channeled efficiently toward that end. But beyond these basic requirements, the transfer of Federal funds should be accompanied by the delegation of maximum discretion in their use. This is particularly the case when the recipient is a State government. Federal grants to States should continue to be shifted more toward block grants, revenue sharing, and transfers of revenue sources.

The Administration has been quite successful in reducing both the red tape and the restrictions placed on funds granted to States and localities in almost every area. Categorical grant programs have been shifted to block grant programs in the Departments of Health and Human Services (HHS), Housing and Urban Development (HUD), and Education (DEd).

The Department of Labor has also reduced the inflationary wage restrictions placed on the use of Fed-

eral funds (including funds provided to States and localities) for construction and services. The Davis-Bacon Act and Service Contract Act were passed to assure that the Federal government paid prevailing wages. Overtime restrictions were built in that tended to push wages above what the private sector was paying for similar work. The regulatory changes enacted to date attempt to restore "prevailing" wage to its original meaning of "market wage."

The Executive branch has also worked closely with States to establish more flexible, less burdensome Federal assistance mechanisms. Earlier in this Administration, for example, a joint State and Federal task force worked out a set of cash management policies and practices to govern the exchange of funds between the State and Federal governments. This agreement was formalized in a July 1983 Memorandum of Understanding. In 1984, four States piloted a new reciprocal interest funding technique that was found to be a viable alternative to existing techniques. Moreover, this alternative had sufficient flexibility to fit easily into the States' existing systems. Regulatory language to implement the interest-remitted option is now in place and allows States to select from a variety of cash management techniques.

Streamlining Regulatory Procedures

The third category under which the regulatory policy guidelines can be grouped addresses ways in which Federal regulatory agencies can streamline this regulatory process. Environmental and public protection statutes frequently require members of the public to obtain government permits or approvals before undertaking certain activities. When the approval process becomes lengthy, uncertain, and bureaucratic, the result can be costly delays in the introduction of beneficial new products or the commencement of important development projects. This Administration has placed heavy emphasis on making Federal permitting programs more prompt, predictable, and efficient.

> *Regulatory Policy Guideline No. 6:* Licensing and permitting decisions and review of new products should be made swiftly and should be based on standards that are clearly defined in advance.

Regulatory programs requiring review or approval of new products and new production facilities have expanded manyfold in recent years. New drugs, new medical devices, and new food additives require approval of the Food and Drug Administration. New pesticides and new chemicals must be reviewed by the Environmental Protection Agency. New powerplants and transmission lines, factories, pipelines, ports, and other major construction projects may need Federal approval for air and water discharges, rights-of-way, or effects on navigable waters, in addition to a long list of State and local approvals. Virtually any economic activity on the vast Federal landholding (including the outer continental shelf as well as most of the land in the Western States) requires the approval of the managing Federal agency. A facility that crosses several jurisdictions, such as an interstate oil pipeline, requires multiple government permits.

On top of the system of Federal permits is an additional layer of "cross-cutting" requirements. According to the nature of the project, the issuance of even a narrow Federal permit may trigger additional requirements for environmental impact assessment, archeological and historic preservation review, endangered species protection, coastal zone management planning, and other requirements.

While these permitting systems have doubtless reduced the chance that a needlessly unsafe product will be introduced or an excessively obnoxious facility be built, it has also increased the likelihood of the opposite error: that a worthwhile product or facility will not be approved. One reason is simply inevitable errors of judgment. But the problem runs much deeper than this, for regulatory agencies face systematic incentives to err on the side of caution and delay. An agency charged with assuring that all new products are safe is likely to be excessively cautious in granting approval. It will get none of the credit for good products but a large share of the blame for bad ones, and there is bound to be substantial uncertainty about which is which before a given product is actually marketed.

To the regulator the hazards of an erroneous approval seem far more immediate than the hazards of depriving the public of a new drug or chemical or factory that could be better than the old. And representatives of the old products and facilities that would have to compete with the new ones will supply the regulator with reasons aplenty why the new ones would probably not be any better after all. So there is a natural bias to disapprove or, more often, to delay a decision pending receipt of more information.

The challenge is to speed up the various permitting processes without materially increasing the risk of erroneous judgments. The Administration has had some success in this. One major success in this area is the approval process for new drugs. The Food and Drug Administration has instituted reforms and procedures to speed up the investigation and application process for new drugs, especially where they might be useful in the treatment of patients in serious or lifethreatening situations. The Environmental Protection Agency adopted several exemptions from its "premanufacture review" requirements for new chemicals, eliminating or reducing requirements for types of chemicals that pose no environmental risk, and streamlined its permitting requirements under its air and water quality programs. The Army Corps of Engineers streamlined its process for issuing permits for discharge of sludge and fill material into U.S. waters, cutting the average processing time in half.

Regulatory Policy Guideline No. 7: Qualifications for receiving government licenses should be the minimum necessary. Where there are more qualified applicants than available licenses, the licenses should be allocated by auction or random lottery rather than by administrative procedures.

Many regulatory programs, often operated by independent commissions, license entry into particular markets. Licensing may also be used to promote health or safety or simply to manage the use of scarce resources controlled by the government. In the case of licensing to promote health and safety the qualifications of individual applicants are important to the regulatory program, but in the case of simply allocating scarce resources they are not. Approving new drugs for safety and new pesticides for environmental effects requires careful case-by-case review to determine the qualifications of applicants. On the other hand, because licensing Federal land for grazing does not require government appraisal of the personal characteristics of individual ranchers, case-by-case review is not needed. Sometimes both kinds of licensing take place in the same agency. The Federal Aviation Administration must assure that commercial airlines and airline pilots meet demanding safety qualifications. But when the FAA allocates scarce airspace around congested airports, it need not decide which airlines use the available slots safely, because airlines have already been certified as to safety. Therefore, the market should be allowed to allocate the slots according to economic efficiency.

Where licensing is undertaken simply to allocate government-controlled resources, there is no need at all for quality standards, case-by-case reviews, or administrative proceedings. Direct use of the price system, through auctioning licenses or charging fees, is all that is necessary to allocate the resources to those who can use them most productively. Where auctions or fees are prohibited by statute, random lotteries at least avoid the costs and potential abuses of allocating rights by administrative procedures. When combined with the private marketing of rights, lotteries also ensure that the resources in question are put to their most valuable economic use.

Regulatory agencies on occasion have confused licensing to allocate resources with licensing to protect consumers or the environment. A virtue of auctions, fees, and lotteries over administrative allocation is that they force a clear distinction between the two purposes, and prevent inappropriate expansion of the government's regulatory powers through vague and subjective licensing standards. For example, the original legislative purpose of radio and television licensing was to promote efficient use of the electromagnetic frequency spectrum. The Federal Communications Commission's licensing procedures were long used, however, to scrutinize in detail the quality of individual applicants and the past performance of renewals. This is not only unnecessary to efficient spectrum management but has raised serious problems under the nation's primary deregulation policy, the First Amendment. With the emergence of new communications technologies competitive with broadcasting, the FCC has cut back substantially on the administrative procedures required to obtain or renew various broadcast licenses.

In the transportation area, both the Interstate Commerce Commission and the Civil Aeronautics Board granted route approvals between city-pairs on a "need" basis, which often worked to the detriment of new firms seeking entrance and to the benefit of firms with existing approvals. The reforms of the ICC and airline deregulation have allowed competition to blossom between numerous city-pairs in both the trucking and airline industries, dramatically expanding service and lowering costs for consumers overall.

SUMMARY

The President's regulatory principles and the guidelines supporting them represent the infusion not only of economics into the rulemaking process but also of better government management; of proper allocation of regulatory activity between the Federal, State, and local governments, and the free market itself; and of ultimate fairness to those benefitted and regulated. The initial inquiry under the President's regulatory principles is always whether Federal intervention is needed: why the problem a regulation would address is not adequately addressed by private markets, or State or local authorities; and whether the regulation would actually improve upon the functions of the market and existing State and local programs.

But in all cases, the "bottom line" of the regulatory principles stated in Executive Order No. 12291 is whether a proposed regulation will benefit society as a whole. To accomplish this goal, agencies need to have considered all the available evidence of the rule's likely consequences—whether these consequences are issues of economic impact; fair management; or of appropriate allocation of authority and responsibility to the Federal, State, or local governments, and particularly to individuals operating in an open marketplace and a free society.

MAKING FEDERALISM WORK

Since the beginning of this Administration, Federalism has been a key theme in Federal policymaking. As President Reagan observed in January 1988:

> When our Administration came to office, we took it as one of our chief aims to reawaken the Federalist impulse and approach the Constitution with a new fidelity—in short, to restore power to the States. By now you should know how, since 1981, we've worked to widen the scope for independent State decisionmaking. I'm proud to say that our Federalism focus is continuing.[35]

Although this "Federalist impulse" has been evident for the last seven years and has been discussed in previous Regulatory Programs, at no time has it been stronger than during the past year. This chapter describes the efforts undertaken by this Administration since the last Regulatory Program to make Federalism work. These actions include:

1. adhering to Federalism principles in Executive branch;
2. implementing State and local recommendations for more efficient government; and
3. establishing new mechanisms for ensuring that the Federal government regulates State and local concerns only when there is specific authority and genuine need for Federal intervention.

FEDERALISM IN FEDERAL RULEMAKING

The Federal government issues thousands of regulations every year, touching on almost every aspect of American life. Just as they affect individuals and businesses, many of these rules directly affect the ways that State and local governments govern. This Administration has long recognized, however, the constitutional and administrative boundaries on Federal action, the time-proven effectiveness of State and local administration of Federal programs, and the importance of building into Federal rulemaking maximum administrative flexibility for State and local governments.

The Executive branch has undertaken over the past year and plans to initiate this year several particularly significant Federal regulatory activities affecting States and localities. Many of these rulemakings might be considered "deregulatory" from a Federal perspective. But whether they provide administrative flexibility, promote efficiency, decentralize the decisonmaking process, or simply incorporate the views of State and local governments in Federal rulemaking, each embodies a respect for the authorities and capabilities of the non-Federal levels of government.

Providing Administrative Flexibility

States and localities are partners with the national government in providing services to the American people. And as such partners, States and localities must be provided with the flexibility they need in order to serve best their citizens. Consistent with that philosophy, the Department of Health and Human Services (HHS) has taken major regulatory actions over the past year to enhance the ability of State and local governments to control federally funded assistance programs. Two examples of such action involve increased State flexibility in paying for prescription drugs under the Medicaid program, and reducing complexity and delay in acquiring computers and computer-related equipment in the Aid to Families with Dependent Children (AFDC) program.

HHS issued regulations in July 1987 that transferred to the States more discretion and flexibility in the actual design and administration of a payment system for prescription drugs under the Medicaid program. Under these new rules the Federal role is limited to oversight and accountability only to the extent necessary to establish upper limits on State expenditures for prescription drugs that may be eligible for Federal matching. Prior to these rules the Federal government set national payment limits for drugs on a prescription-by-prescription basis for state Medicaid agencies. The rules are cost-effective, with anticipated savings of as much as $100 millon a year in Federal funding and $60 million a year to the States.

In September 1987 HHS issued proposed rules designed to improve the system of review and approval of general plans and specific requests for the purchase of computers and computer-related equipment for the AFDC program. Under the existing rules States were required to submit advance planning documents for Federal review prior to engaging in automatic data processing (ADP) acquisition. They were also required to submit requests for proposals (RFPs), contracts, and contract amendments for Federal review and approval even after the advance planning documents had been approved.

States complained that this process placed the Federal government in the position of too closely monitoring State actions, and it imposed paperwork requirements that resulted in unnecessary and unwarranted delays in computer acquisition. In the end, States asserted, the AFDC program was suffering because of such delays. Although some level of Federal scrutiny is appropriate in this area due to past State systems failures, HHS agreed that the existing system is too cumbersome. The proposed

[35] Remarks to the National Conference of State Legislators at a White House Briefing on the Administration's Domestic Agenda, January 29, 1988.

rules issued in 1987 were designed to require more "up front" planning by the States but reduce many of the existing prior approval requirements. When finally promulgated, the new rule should more properly balance State accountability and State flexibility.

The Department of Housing and Urban Development (HUD) also has several policy initiatives designed to provide maximum feasible local control in the implementation of Federal assistance programs. HUD's Office of Public and Indian Housing, for example, has undertaken a decontrol initiative to give public housing agencies (PHAs) and Indian Housing Authorities (IHAs) maximum authority and responsibility for the management of their local programs. Decontrol is a continuing regulatory relief effort that HUD intends to expand to additional areas for PHAs and IHAs with good performance records.

HUD's pending rules on Lease-Grievance Procedures similarly provide for more local flexibility for PHAs, and will place increased reliance on State-administered landlord-tenant laws. In addition a number of new programs or program amendments in the Housing and Community Development Act of 1987 (Public Law 100-242) will afford opportunities to the Department to further the principles of Federalism. For example, the revised funding methods in the Comprehensive Improvement Assistance Program (CIAP) (Section 119 of the Act) require the Department to develop an equitable formula for allocating CIAP funds according to HUD's assessment of modernization needs. In addition, implementation of the new law will increase local choice of improvement projects and will lead to greater local control.

In the same vein the Department of Energy (DOE) initiated several regulatory actions in 1987 to enhance the ability of State and local governments to administer federally funded assistance programs. For example, DOE has proposed easing some of the restrictions on expenditures under the State Energy Conservation Program. The major impact of this regulatory change would be to allow States greater discretion in spending oil overcharge monies on capital equipment. Furthermore, because of changes to the Residential Conservation Service required by the Conservation Service Reform Act of 1986, DOE initiated a rulemaking allowing States to assume the lead role in the processing of applications for utility waivers from the provisions of existing State plans.

The Department of Agriculture (USDA) has also attempted to provide more administrative flexibility in its program rules for State agencies. For the past few years, for example, the Farmers Home Administration (FmHA) has intensified its efforts to utilize and involve the private sector as a source of agricultural credit. FmHA developed a program called "Operation Assist" to emphasize the Administration's efforts to shift from direct government lending to private sources of lending with a government guarantee. FmHA field personnel assist eligible borrowers to obtain private credit through local lending institutions by introducing the applicant to the lender and providing the necessary paperwork to enable the lender to determine if the institution would consider the applicant for a FmHA guaranteed loan.

The Administration's efforts to shift from insured to guaranteed lending has significantly increased the private sector's involvement as a source of agricultural credit at fair and competitive rates.

Promoting Efficiency Through Governmentwide Common Rulemaking

States have long complained about inconsistent Federal requirements for grants and other assistance programs. They point to Federal departments and agencies with significantly different and sometimes inconsistent administrative requirements for similar grants and programs. They perceive these inconsistencies as one of the biggest obstacles to efficient administration of Federally assisted grants and programs.

Recognizing this problem, in 1987 the President directed all Federal grant-making agencies to propose simultaneously and subsequently adopt verbatim a single, governmentwide grants management common rule. This common rule replaced agency implementation of Office of Management and Budget (OMB) circular No. A-102, "Uniform Administrative Requirements for Grants and Cooperative Agreements with State and Local Governments." Although the circular was considered at the time of its adoption in 1971 a breakthrough in the simplification of grants management, the President noted that "after 16 years, some of the provisions are out of date, there are gaps where the standards do not cover important areas, and agencies have interpreted the circular in numerous different ways in their regulations."

Consequently, the President requested agencies to propose a common rule within 90 days and issue a final rule within one year. On March 11, 1988, the agencies completed their assignment by issuing the final rule, which becomes effective for grants awarded on or after October 1, 1988. The common rule eliminated redundant and inconsistent administrative requirements among and within the 24 Federal grant-making agencies. It rescinded all inconsistent grants administration provisions in program regulations, and its provisions supersede (unless otherwise mandated by statute or approved by OMB) all similar provisions of noncodified program manuals, handbooks, and other materials.

The single, governmentwide grants management common rule also contains numerous policy changes to further Federalism, regulatory relief, and business-like management of grants. Two particularly significant Federalism changes affect States.

First, States no longer must follow uniform Federal standards or requirements for financial management systems, equipment, or procurement. Instead States

will expend and account for grant funds according to their own State laws and procedures. Second, in state-administered programs (other than the open-ended entitlement programs), States no longer have to apply uniform Federal administrative standards to subgrantees. Instead States are free to condition and manage funds which flow down to subgrantees according to their own State laws and procedures.

Recently several States and State organizations, including the National Governors' Association (NGA) and the National Association of State Budget Officers (NASBO), have proposed revision and simplification of Circular No. A-87, "Cost Principles for State and Local Governments." This Circular, first issued in the late 1960s, provides uniform rules applicable to about $115 billion in grants and contracts to State and local governments. It defines allowable costs for Federal assistance programs and sets forth the procedures to recover them. OMB is currently working with these organizations to explore proposed changes.

Although OMB hopes to provide more flexibility for State procedures through these revisions, it must also preserve accountability for Federal funds. The Office of the Inspector General (OIG) at the Department of Health and Human Services recently conducted a comprehensive review of the implementation of the Circular by State and local governments. The auditors examined the methods used by State and local governments in allocating administrative cost to Federal programs, as well as methods used to determine the allowability of cost. The OIG audit identified significant problems with some State operations that must also be addressed during the review of the Circular. OMB looks forward to working with State representatives to address these problems. OMB plans to issue the draft revisions to Circular No. A-87 for comment in the summer of 1988.

Cutting Federal Red Tape

Sometimes the best way the Federal government can help States is simply to pare down onerous administrative requirements. Just as with any business person or individual, Federal paperwork or other administrative requirements are burdensome and costly to State and local administrators.

The Department of Transportation's Federal Highway Administration (FHWA) has been particularly sensitive to the problem of excessive Federal red tape and has taken steps to alleviate it. Over the past several years FHWA has issued amendments to various environmental impact regulations prescribing policies and procedures for preparing environmental documents pursuant to the National Environmental Policy Act (NEPA), and evaluations of project proposals that would use land from public parks, recreation areas, refuges, and historic sites pursuant to Section 4(f)of the Department of Transportation Act of 1966. These policies and procedures were first issued in 1971 and have been revised several times.

The last revisions, issued on August 28, 1987, relieved significant administrative burdens on States in a number of ways, including: (1) streamlining the project-development process and providing increased decision-making authority to agency field offices; (2) eliminating duplication in FHWA's public involvement regulations; (3) contributing to the establishment of a one-stop environmental impact process in which public involvement is fully integrated with other project development and environmental procedures; (4) clarifying the conditions under which a supplemental environmental impact statement is required; (5) eliminating the need for FHWA and state highway agencies to prepare environmental assessments and findings of no significant impacts for over 300 projects per year nationwide. In the future, these types of projects will be processed as categorical exclusions. The revised rule will avoid the need to prepare reports for these projects, estimated to cost $40,000 each, and will save at least six months in processing time.

Decentralizing the Decisionmaking Process

Government works best when decisionmaking responsibilities are placed at the lowest possible level. Important decisions affecting people should be made by those closest to the problem. Moreover, responsiveness to local preferences and conditions is best assured by providing local institutions with authority and responsibility for action. Over the past year Executive departments and agencies have initiated or completed several rulemakings intended to decentralize decisionmaking in Federal programs.

Recent regulations issued by the Department of the Interior implementing provisions of the 1977 Surface Mining Control and Reclamation Act (SMCRA) provide a good example of this decentralization effort. The Act has a vigorous Federalism focus and clearly intends that the States have primary responsibility for assuring that the objectives of the Act are met in a manner that is responsive to local conditions. SMCRA encourages States to develop regulatory programs for surface coal mining and reclamation operations and coal exploration operations so that they can assume regulatory responsiblity from the Federal government. Once states have developed such programs and demonstrated that they can adequately implement those programs, they may assume regulatory responsibility (primacy) over both initial and permanent surface coal mining and reclamation operations as well as coal exploration operations.

One of Interior's current rulemaking efforts underscores the Administration's commitment to primacy: the proposed Evaluation of State Responses to Ten-Day Notice Rule, issued on September 9, 1987 (52 FR 34050). SMCRA provides that OSMRE will not inspect a mine site in a State awarded primacy where it

has information that a possible violation of the regulatory program exists, absent an imminent danger to persons or property, or imminent harm to the environment, without giving the State ten days' notice of its intention to inspect. The State must also be allowed to take appropriate action to correct the possible violation or to show good cause for not correcting it. The Ten-Day Notice Rule will define "appropriate action" and "good cause" for the first time. Definition of those terms will enhance primacy and support Federalism by outlining the conditions under which a State's response to a ten-day notice is acceptable, thereby obviating the need for Federal inspection of the operation. Under the rule OSMRE will accept any State response to a ten-day notice that is not arbitrary, capricious, or an abuse of discretion under the State program. The rule also gives examples of good cause. In addition the rule establishes an appeals procedure for States wishing to challenge an OSMRE decision to authorize a Federal inspection.

In a similar decentralization effort the Department of the Interior's National Park Service has taken steps to shift a greater number of decision-making responsibilities and capabilities for historic preservation to the State Historic Preservation Offices. Each State Historic Preservation Office (SHPO) functions as the agent of the National Park Service in administering the historic preservation programs within the State. The National Historic Preservation Act, as amended, provides SHPOs with overall direction and policy for the State Historic Preservation Programs, and the operating program instructions contained in the Historic Preservation Fund Program Manual provides guidance for program management.

By implementing the State Program Review Process, the National Park Service has begun to shift its responsibilities for overview and monitoring of the State historic preservation programs in the direction of management by exception with the SHPOs rather than on a project-by-project basis. Using the on-site programmatic audit as the major mechanism for monitoring and reviewing State compliance with Federal requirements, the Service has greatly reduced the necessity for individual project-by-project review work. This will eventually reduce the number and frequency of requests that States will have to submit for review and approval. It will also enable the Service to concentrate on programwide needs, such as consistency of program operations among and between States, and on providing hands-on technical assistance in program development and execution.

Benefiting from State Views in the Development of Federal Rules

Federalism depends on promoting an active and open dialogue between the Federal government and its State and local partners. To that end in 1985 the Environmental Protection Agency (EPA) established the State/EPA Committee, composed of 17 State members. The Committee, which meets quarterly, provides EPA with consultation and advice on EPA operational issues.

In addition EPA has found that regulatory negotation offers a valuable forum for consulting with State and local officials. Between three and six State and local representatives have participated in each of EPA's seven negotiations to date. Like the other participants in a regulatory negotiation, State and local interests are a party to the consensus on which EPA bases its proposed rule. Their participation in a negotiation is especially important, because EPA relies on State and local agencies to implement many regulatory programs. Three recent negotiations illustrate how the negotiation process can allow EPA and other parties to draw constructively upon State and local experience and design rules that are more responsive to State and local concerns.

In the Asbestos-in-School negotiations, for example, the negotiating committee included representatives of local school districts, State educational agencies, and State health agencies. The parties agreed that EPA's proposed rule allowed flexibility for local authorities to determine what response actions were necessary where asbestos was found. Based on the negotiating committee's recommendations, EPA has allowed, as described in its proposed rule, issued April 30, 1987 (52 Federal Register 15833), "discretion within a range of acceptable response action alternatives, given the condition of the material, local circumstances, technological feasibility of response actions, economic considerations, and other relevant factors."

In the negotiations on proposed Emission Standards for Woodburning Stoves, the process allowed EPA and the other parties on the negotiating committee to consult directly with representatives of two States with experience in regulating woodstove emissions, as well as two other States that were considering standards for woodstoves. The Oregon and Colorado representatives provided data and a perspective that the full committee was able to draw on during the negotiations.

Similarly in developing rules restricting underground injection of hazardous wastes, the negotiating committee benefited from the participation of officials from three State agencies. Together these three agencies represented a range of views on underground injection. The participants agreed that the State officials' contributions led to a proposed rule that was more compatible with State programs and practices than the conventional rulemaking process might have produced.

Examples of a consultative process between States and the Federal government can also be found in rulemaking by the Federal Emergency Management Agency (FEMA). As part of its 1987 Regulatory Program FEMA developed criteria for earthquake haz-

ards reduction assistance to State and local governments. These criteria were developed in close coordination with State and local representatives.

In July 1986 FEMA sent a policy paper describing the substance of and intent behind major provisions of a possible proposed rule to its regional offices. FEMA instructed these offices to circulate the paper to the states for comment. The agency considered the State comments over the next year as it drafted the regulation.

FEMA published the proposed rule on July 6, 1987. As a result of comments on the proposal, most of which came from States, FEMA made significant changes in the final rule, published September 8, 1987. The most significant of these changes was to delay State cost sharing requirements until fiscal year 1989 to accommodate State legislative and budget cycles and constraints. As a result of additional comments and discussions with State officials FEMA made other changes to the final rule as well as to the formula developed by the agency to apportion earthquake program funds among eligible States. In addition FEMA intends to make adjustments to the "formula factors" for the FY 1989 allocations, and plans to consult with the affected States during this effort.

LISTENING TO THE STATES: RECOMMENDATIONS FROM THE NATIONAL GOVERNORS' ASSOCIATION

Much of the Administration's recent success in making Federalism work is due to the interest and efforts of State and local governments. The most clear example of this was the National Governors' Association's (NGA's) Federal Assistance Review Project. On February 21, 1988, Office of Management and Budget (OMB) Director James C. Miller III presented the NGA with a final report on the Administration's implementation of 47 NGA recommendations for alleviating federally imposed administrative burdens.

This project began 16 months earlier when in October 1986 Governor John Sununu of New Hampshire, then Chairman of the NGA's Federal Assistance Review Project, wrote to the President with recommendations for improving the administration of Federal assistance programs. These recommendations, collected from 26 States and national organizations, affected 19 Executive branch departments and agencies.

Pursuant to a subsequent meeting between Governor Sununu and the President, the White House Office of Intergovernmental Affairs and OMB, in cooperation with the affected departments and agencies, undertook an extensive review of all the NGA recommendations. During this review OMB and agency officials frequently contacted NGA staff and State officials for additional information or to discuss possible solutions to the issues raised.

On June 29, 1987, President Reagan, Vice President Bush, and OMB Director Miller met with Governor Sununu and Governor George Sinner of North Dakota. The President presented the Governors with an interim report describing progress in the Administration's review of the NGA's recommendations. During the meeting the President reiterated his Administration's commitment to reducing Federal regulatory and paperwork burdens. He expressed his hope that all Governors would continue to point out instances when the Federal government's actions interfere with the States' abilities to govern effectively and efficiently.

Implementation of the various recommendations typically required one of three types of action: administrative, regulatory, or statutory. For example, administrative action was taken to implement a paperwork reduction suggestion made by the State of Oregon. The State pointed out that certain progress reports, other monitoring reports, and the yearly application for Federal funds under the Justice Department's Office of Juvenile Justice programs all required reporting of the same information. Oregon recommended that the Justice Department require the submission of only the annual monitoring report and eliminate the same information in the annual progress report. The Department adopted this recommendation, and the revised reporting requirements are now in effect.

Actions requiring notice and comment rulemaking are more complex and take longer to complete because of the time needed to draft a notice of proposed rulemaking, analyze public comment, and draft a final rule that takes into consideration all comments received. Consequently, implementation of some of the NGA recommendations requiring regulatory action has only recently been completed, while other regulatory proposals have been published for comment but are not yet final.

In response to concerns from Nebraska and other States, the Departments of Agriculture and Health and Human Services are revising regulations governing the processing of eligibility determinations for Aid to Families with Dependent Children (AFDC) and Food Stamps. Because of differences between the two programs, States have to process the same eligibility information twice. A proposed rule to permit States to process some eligibility information only once was issued in September 1987. A final rule will be issued before October 1988.

Still other NGA recommendations required statutory change for implementation. The State of Missouri, for example, was concerned that teenage girls in foster care who became mothers were being excluded from receiving benefits under the AFDC and Medicaid programs. The problem was that foster care payments were being considered as income in AFDC and Medicaid eligibility determinations. Two statutory changes have ameliorated this problem. First,

the Tax Reform Act of 1986 specified that foster care payments under Title IV-E of the Social Security Act were not to be counted as income of the family. Second, Section 9133 of the Omnibus Reconciliation Act of 1987 provided that in cases where teenage girls receiving Title IV-E foster care have children of their own, the foster care payment shall include a sum necessary for the care of both mother and the child. As a result of this latest statutory change, both parent and child are eligible to receive benefits under Medicaid.

Another recommendation requiring a statutory revision came from both North Dakota and the National Association of State Aviation Officials. Because of Federal budgetary constraints and improvements in State administrative capabilities, they suggested that States be permitted to administer Federal airport development grants. The Administration proposed legislation providing 22 percent of airport improvement funds to States through a block grant. Although Congress did not adopt this specific provision, it agreed to an experiment based on the concept of the Administration's proposal. The legislation enacted provided for a pilot program for up to three States to assume administrative responsibility for all airport grant funding other than for funding designated for use at primary airports. On December 30, 1987, the President signed into law this legislation, known as the "Airport and Airway Improvement Act Amendments."

In some instances the Administration used a combination of statutory and regulatory changes to implement State recommendations. The State of Washington, for example, endorsed a statutory change to permit State Medicaid, AFDC, and Food Stamp programs to develop more flexible procedures in eligibility determinations in lieu of the requirement to verify all sources of income for applicants. The Omnibus Reconciliation Act of 1986 provided such relief, and an interim rule published by the Department of Agriculture on February 2, 1988 (53 Federal Register 2817), is designed to give States total discretion in developing their targeting procedures, so long as they can demonstrate that they are cost-beneficial.

As another example the Association of State and Territorial Health Officials (ASTHO) recommended abolishing a requirement that States hold annual public hearings on their plans for the Department of Agriculture's Women, Infants, and Children (WIC) program. The recommendation was based on a widely shared view that the hearings served little purpose since few people attended them. Both a statutory change to eliminate the requirement, and a regulatory change (published in June 1987) requiring States to solicit public input but permitting them to establish a solicitation process of their choice, were used to implement ASTHO's recommendation.

Implementation of these and other NGA recommendations is one step in restoring the balance between the States and the Federal government, and an important one. The success of this project has depended, in large part, on the commitment of and close cooperation by the Governors, State officials, and Federal departments and agencies. Only through a process of open and frank communication between the Federal government and States and localities can Federal assistance programs be made more effective for the citizens they are intended to serve. The Administration believes this effort has significantly strengthened the communication process and hopes that it will lead to continued progress in improving governmental services at all levels in the years to come.

FEDERALISM IN THE FUTURE

Institutionalizing Federalism: Executive Order No. 12612

To ensure that Federalism principles are an enduring component of federal policymaking, President Reagan issued Executive order No. 12612 on October 26, 1987. This order, entitled simply "Federalism," sets forth fundamental principles and policymaking criteria by which Executive departments and agencies shall be guided in formulating and implementing policies that have Federalism implications.

The Federalism principles enunciated in Executive Order No. 12612 were developed earlier in the Administration by the Domestic Policy Council's Working Group on Federalism. The President formally transmitted these principles to the Cabinet on May 19, 1986. The principles were also published in the *Regulatory Program of the United States Government, April 1, 1985-March 31, 1986.* These principles help define the relationship between the Federal government and the States and localities. Under these principles, that relationship is based on a recognition of the limits of national government, the sovereign powers of the States and the people, and the competency and diversity of the States and local communities.

In addition to these fundamental principles the Order contains several criteria that agencies are to use when developing policies that affect the States and localities. Notable among these criteria are the following:

- Federal action limiting the policymaking discretion of the States should be taken only where constitutional authority is clear and certain and the national activity is necessitated by a problem of national scope.
- With respect to national policies administered by the States, the national government should grant the States the maximum administrative discretion possible.
- When undertaking to formulate and implement policies that have Federalism implications, Executive departments and agencies shall:

— Encourage States to develop their own policies to achieve program objectives and to work with approprate officials in other States;
— Refrain, to the maximum extent possible, from establishing uniform national standards for programs and, when possible, defer to the States to establish standards; and
— When national standards are required, consult with appropriate officials and organizations representing States in developing those standards.

Of particular concern to States and Administration officials has been the tendency of Federal government in the past to ignore or disregard State law in the accomplishment of a Federal objective. To address this concern the order mandates that, to the extent permitted by law, departments and agencies construe a Federal statute to preempt State law only when there is an express preemption provision, or when there is "some other firm and palpable evidence" that Congress intended preemption of state law, or when exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute.

To ensure that the principles and criteria and other requirements contained in this order are followed, E.O. No. 12612 requires Executive departments and agencies to designate an official responsible for their strict implementation. These officials are to determine which proposed policies of the agency have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The assessment is to identify any provision of the policy that is inconsistent with the order's principles and policymaking criteria and to estimate the costs or burdens that the policy will impose on the States.

While E.O. 12612 is intended to be self-implementing, the Order also requires the Office of Management and Budget (OMB) to oversee its administration. In implementing its regulatory review authority under Executive Order Nos. 12291 and 12498 and its legislative review authority under OMB Circular No. A-19, OMB, to the extent permitted by law and consistent with those authorities, "shall take action to ensure that the policies of the Executive departments and agencies are consistent with the principles, criteria, and requirements" of the order.

The National Governors' Association Project, Phase II

Another strong indication that the Administration's Federalism perspective will continue into the future is the ongoing effort of the National Governors' Association to identify ways to make Federal and State programs more efficient. As described above, on February 21, 1988, the Administration presented the Governors with a final report on implementation of almost 50 NGA recommendations for alleviating Federal administrative burdens. The next day Governor John Sununu, Chairman of the NGA, presented the President with over 160 new State proposals for Federal regulatory reform.

These new proposals, which affect 25 departments and agencies, cover a wide range of issues and programs. They include proposals for making Federal programs more helpful to their constituents, eliminating duplicative and conflicting regulations, permitting more reliance on State laws and procedures for the management of Federal programs, speeding up the Federal response to program management issues, updating Federal programs to meet new State needs, and alleviating Federal micromanagement of State and local affairs. The Administration has these proposals under review; several of them are already being adopted.

Some of the NGA proposals reflect a frustration with close Federal oversight of State-administered programs. Environmental Protection Agency (EPA), for example, has the authority to delegate the National Pollutant Discharge Elimination System (NPDES) Permit Program to the States. A major problem with this delegation, according to the State of Minnesota, is that EPA regional offices review major NPDES permits point by point, with the State not being allowed to issue the permit until all EPA concerns are satisfied. Minnesota recommended that EPA overview be limited to an overall evaluation of the success of the Permit Program in protecting water quality, within established guidelines, rather than actual review of all major NPDES permits. EPA is currently considering "differential delegation" of permit programs, such as NPDES, based on a State's performance. Under such an approach EPA would delegate additional administrative authority to those States with a proven record of effectively implementing program requirements. An EPA staff work group was scheduled to present proposals to the State/EPA Committee on July 19–20, 1988.

In another example the State of New Hampshire identified what it believed were unnecessary paperwork requirements and reporting procedures associated with Department of Transportation subcontracting requirements. Specifically New Hampshire recommended the elimination of requirements that States not permit subcontract work to be performed until they have reviewed the agreement and authorized the arrangement in writing. DOT has agreed with this recommendation and is notifying all Regional Administrators of this change in policy. In addition DOT is revising its Federal-Aid Highway Program Manual to reflect this change.

Some NGA proposals call for closer coordination and cooperation among the State and Federal partners. The State of Alabama, for example, identified several Federal statutory and regulatory barriers to providing cost-efficient public transportation services. Alabama recommended that since most of the Federal support for

transportation services comes from the Department of Transportation and the Department of Health and Human Services (HHS), these two Federal agencies should closely work with State and local recipients of these funds to eliminate these barriers. The Joint DOT/HHS Council on Transportation Coordination met in June 1988 to review draft responses to many of the barriers identified by the States. The Council has developed a set of recommendations and clarfying information that will help State and local governments overcome these barriers. This information will be provided to States and localities in the near future.

Still other proposals concern agency policies and regulatory interpretations. The State of Nevada was concerned that residents living in trailer parks are not considered in determining eligibility for loans under the Department of Agriculture's (USDA's) Farmers Home Administration (FmHA) loan program, because trailer parks are considered to be commercial properties. USDA has responded that under existing regulations, all rural residents should be considered in determining loan eligibility, regardless of whether they live in a trailer park. FmHA has reviewed this interpretation with its Utah State Office, which serves Nevada.

The State of New Jersey proposed greater flexibility in compliance with regulations requiring States to maintain and use an income and eligibility verification system (IEVS) to verify program eligibility in the AFDC and Food Stamp programs. These regulations require States to request and verify wage information from a State source on a quarterly basis and from the Social Security Administration on an annual basis. These data bases, according to New Jersey, overlap to a large extent. The State proposes that States have the option, rather than be required, to request wage, self-employment, and pension information from SSA. Recent regulations issued by the Department of Agriculture and rules soon to be issued by the Department of Health and Human Services permit States to exclude SSA wage data if followed up previously from the State source.

These are only a few of the National Governors' Association's regulatory relief proposals that the Administration has decided to implement. A complete report will be issued to the NGA in early August.

SUMMARY

Federalism is a long-standing, enduring philosophy dating back to the beginning of our Republic. Our system of government was founded on the notion that the power to govern this Nation belongs to the states unless designated to the central government—yet one more check on an overly powerful national government. But Federalism has become much more than a defense against tyranny. As this chapter has attempted to illustrate, Federalism is now considered a commonsense, effective way to govern. By using the special abilities and expertise of the States, the Nation can better assure that services are provided fairly and efficiently to its citizens.

While this Administration did not invent the Federalism concept, President Reagan has instilled it with a new and vigorous spirit. By promoting Federalism principles in Executive branch rulemaking, establishing a meaningful dialogue between the national government and the States, and promulgating an Executive order intended to steer Federal policymaking away from unwarranted intrusion into State and local affairs, this Administration has significantly enhanced the role of Federalism in American government. The challenge to future administrations is to build upon this foundation.

THE ROLE OF ECONOMIC ANALYSIS IN THE DEVELOPMENT OF RESPONSIBLE REGULATION

Government regulation permeates everyday life, affecting among other things the labels on our foods, the design of our cars, the fabric of our clothes, and the air we breathe. Federal regulation continues to be one of the major ways that our government achieves basic societal goals, rivaled in influence on our daily lives only by tax and expenditure polices.

Regulations can make important contributions to the Nation's welfare. For example, the National Highway Traffic Safety Administration estimates that its Center High-Mounted Stop-Lamp regulation will annually prevent 40,000 injuries and over $400 million in property damage by reducing the number and severity of rear-end collisions. But these benefits are not free; the regulation is estimated to cost $70 million per year ($7 for each car). The resources used to meet these regulatory requirements are not available to meet other important requirements for the Nation's welfare, such as making cars with lower exhaust emissions. Consequently Federal regulatory actions will improve the Nation's welfare only if the societal benefits of the actions exceed the societal costs; i.e., if the net benefits are positive.

Over the last two decades, we have learned valuable lessons about the development and use of regulations. First, because our society is complex, regulating it is no easy task. Reaching an acceptable administrative resolution of complex regulatory issues requires extensive data collection, thorough analysis, and difficult legal, economic, and political decisions. Developing and enforcing a major regulation can absorb a large share of a regulatory agency's resources. And in the case of controversial rules there can be a protracted period of litigation, court

review, and often remand to the agency for further work.

Second, Federal regulatory initiatives have often failed to achieve their objectives and, in some instances, have had unintended effects that have undermined the regulatory program. Effective regulation must anticipate the ingenuity of the regulated community and the ingrained reluctance of people to change behavior.

Finally, Federal regulation imposes substantial costs on the American economy by redirecting resources from other uses, both private and public, to meet regulatory requirements. Current estimates suggest that Federal regulatory costs may be as high as $150 billion per year; the Environmental Protection Agency (EPA) alone may be responsible for regulatory costs of $70 to $80 billion per year. And the cost of the Federal regulatory structure continues to increase as new regulations are added.

[36] The cost of major EPA and Department of Labor regulations issued in 1987, in billions of 1987 dollars, is as follows:

	Annual Cost	Present Value of Cost Over 30 Years
Environmental Protection Agency		
Pesticides and Toxic Substances		
Asbestos in Schools	$0.33	$3.14
Water		
Organic Effluent Limitation	0.53	4.90
Solid Waste and Emergency Response		
California List	0.09	0.89
Right to Know	0.32	2.99
Air and Radiation		
PM10	0.17	1.66
Industrial Boilers	0.47	0.44
Department of Labor		
Occupational Safety and Health		
Hazard Communication	0.19	1.83
Grain Handling	0.04 to 0.07	0.39 to 0.65
Benzene	0.02	0.23
Formaldehyde	0.06	0.61
Total	2.22 to 2.25	17.08 to 17.34

Note: A more detailed explanation of how these cost estimates were derived is available upon request. The PM 10 estimate is incremental to the existing PM NSPS program.

Over the last year, for example, two major Federal agencies — the Department of Labor and EPA — have issued major rules imposing additional regulatory costs of $2.2 billion per year.[36]

Because of the importance of understanding the effects of major regulations, President Reagan issued Executive Order No. 12291. This Order requires Federal agencies to analyze "the need for and consequences of proposed government action in order to design regulatory measures that, to the extent permitted by law, maximize net benefits to society." Among other things, Executive Order No. 12291 requires Executive branch agencies to prepare a regulatory impact analysis (RIA) for each major rule. The basic objective of the RIA requirement is to ensure that regulatory policymakers have the best information available on the likely benefits and costs of regulatory alternatives so they can make better decisions and to provide the public, Congress, and the courts with a better understanding of the basis for agency decisionmaking.

There are two fundamental questions that must be answered if an RIA is to be useful in helping to guide a rulemaking decision: (1) is there a genuine need for Federal regulatory action and (2) if so, under what conditions can the benefits of the action be expected to exceed its costs? To answer the first question, the agency must determine whether Federal regulation can accomplish the objective more efficiently than the market or some alternative to Federal regulation. If the answer to the first question is "no", there is no need to answer the second question unless statutory requirements mandate Federal regulation. To answer the second question, the agency must identify several alternative regulatory actions and evaluate the benefits and costs of each action while accounting for the uncertainty of those benefits and costs.

ASCERTAINING THE NEED FOR FEDERAL REGULATORY ACTION

The Theory of Markets

According to economic theory, competitive markets generally perform well in supplying the economic goods and services people want. Thus there is a strong presumption that government intervention into markets should only be undertaken when markets are not working, that is, where there is a so-called "market failure." Market failures can be divided analytically into three categories: externality,[37] public good (including problems arising

[37] An externality occurs when one party's actions impose uncompensated costs or benefits on third parties not part of the market transaction. For instance, environmental problems, such as air emissions from a manufacturing plant, may impose soiling costs or health problems on neighbors.

from inadequate information),[38] and natural monopoly.[39] In order to establish the need for a Federal regulatory initiative, then, the RIA should first determine whether the proposed regulatory action addresses a genuine problem.

In theory the need to establish a market failure is fundamental, because there will be no net benefits to society (in fact there must be a net social loss) resulting from a regulatory action unless there is a market failure. Of course not all market failures can be remedied effectively through government regulation. In these instances the market solution, though imperfect, may be better than the regulatory alternative. An analysis of the underlying problems with the operation of markets should help determine the need for rulemaking.

In those instances in which legislation requires regulatory action without such analysis, RIAs should focus on the least burdensome means of achieving the statute's goals.

Alternatives to Federal Regulation

If the agency identifies a need for governmental intervention, it must then decide whether Federal regulatory action is the best way to resolve the problem. There may be no need for Federal regulatory action if other approaches are more likely to resolve the problem. Such alternatives include: the judical system (for example, liability cases to discipline health and safety protection), antitrust enforcement, workers' compensation systems, and regulation at the State or local level.

In general, because demands among localities for different governmental services differ, and because competition among governmental units for taxpayers and citizens encourages efficient regulation, the agency should look to the lowest level of government (Federal, State, or local) capable of correcting the problem. In some cases the nature of the market failure itself may suggest the most appropriate governmental level of regulation. For example, pollution that spills across State lines is probably best controlled by Federal regulation, whereas localized pollution is probably more efficiently handled by local government regulation. In other instances, only a quantitative benefit/cost analysis can resolve the question, and the agency should include in its RIA an analysis of whether State or local government could more effectively achieve the regulatory goals. '.

BENEFIT/COST ANALYSIS

If the agency determines that Federal regulatory action is necessary, then it must also prepare a benefit/cost analysis of the selected regulatory option and other suitable alternatives.[40] There are certain elements that play a crucial role in developing an effective benefit/cost analysis for policymaking purposes.

Selection and Evaluation of Regulatory Options

Ordinarily the RIA should identify several regulatory options. One option, the status quo, normally serves as the base from which increments in benefits and costs are calculated for the other alternatives.[41] Other options the RIA should consider include varying degrees of stringency or varying dates of compliance. A failure to identify appropriate options substantially weakens the use of the RIA for decisionmaking, because it biases the analysis by effectively precluding consideration of alternatives that may be superior to the regulatory option selected by the agency.

In cases where an agency focuses on a specific "design" standard (a standard that mandates a specific technology), it should also evaluate a comparable regulatory option that achieves that same "performance" level without prescribing the method of compliance.[42] As the 1985 Regulatory Program pointed out, ". . . a regulation should focus on the goals to be achieved rather than on the specific technology or means used to achieve these goals. Setting performance standards in regulations is more efficient than specifying technological solutions (i.e., design standards) because they provide industry with the incentive to be innovative in finding the most cost-effective solutions . . . ."[43]

[38] One type of "public good"—the provision of adequate information for buyers and sellers to make informed decisions in the marketplace—may also be a source of market failure. There are costs, though, as well as benefits in collecting and providing information. As a result a market failure occurs only in cases where the benefits substantially exceed the cost of providing additional information to the market. Where market failure due to inadequate information is the rationale for government action, a regulatory action to improve the availability of information, thereby allowing individuals to make informed decisions in their own best interest, will ordinarily be the preferred alternative. Food and Drug Administration ingredient labeling requirements and EPA's hazard labeling for pesticides exemplify this type of regulation.

[39] Natural monopoly exists where a market can be served at lowest costs only if production is limited to a single producer, as in the case of local telephone, gas, and electricity services. In this case regulation of the monopoly may be desirable because an unregulated monopolist will usually charge a higher price and produce and sell a smaller quantity than the price and quantity that would emerge in a competitive industry.

[40] Occasionally the agency may be prohibited by statute from relying on benefit/cost analysis in its decision to regulate. Even in this case, however, the Executive Order requires a benefit/cost analysis in order to inform the Congress, the courts, and the public of the rule's effects.

[41] If the status quo is an existing regulation, then the RIA should consider "no regulation" as an alternative.

[42] This point follows directly from Guideline #5 in the August 11, 1983 report of the Presidential Task Force on Regulatory Relief, "Reagan Administration Regulatory Achievements" and reaffirmed by E.O. No. 12498. It is also discussed above.

[43] Regulatory Program of the United States Government: April 1, 1985—March 31, 1986, p. xv.

Benefit Estimates

The RIA should describe the beneficial effects of the proposed regulatory change and of its principal alternatives. In each case the agency should explain the way in which the proposed action is expected to yield the anticipated benefits. To the extent feasible, all potential benefits should be monetized—quantified in monetary terms (using constant dollars).[44] Any expected incremental benefits that cannot be monetized should be explained.

In developing benefits estimates the agency should: (1) clearly outline a causal link between the regulatory action and the expected benefits and (2) support its major assumptions and use sensitivity analysis (i.e., show a range of estimates) where appropriate. The identification of a causal link between the regulatory action and identified benefits is a key element of an RIA. The linkage between a regulatory action and the expected benefits of regulation frequently involves a complex sequence of steps. As a result there may be considerable uncertainty about the magnitude (and even the direction) of the effect of a regulatory action in some cases—particularly when the agency considers all the likely indirect effects as well.

Principles for Valuing Benefits

Ordinarily, goods and services should be valued at their market prices. In some instances, however, the market price of a good or service may not reflect its true value to society. If a regulatory action affects such a good or service, its monetary value for purposes of benefit/cost analysis should be derived using an estimate of its true value to society—often called its "shadow price." An example of a market price not reflecting a good's true value to society would be a commodity in a price support program where extra production is purchased by the government for storage.

Valuation of Benefits Not Traded in the Market

In some important instances a benefit does not correspond to a good or service traded in the marketplace. Important examples include reductions in health and safety risks, savings in time, and environmental amenities such as scenic vistas. To estimate the monetary value of a benefit that is not traded directly in the marketplace, the willingness-to-pay valuation approach is useful, because the amount that people are willing to pay for a good or service is often the best measure of its value to them. Willingness-to-pay estimates are derived from statstical analysis of labor or consumer markets or by using sophisticated consumer survey techniques.

Reductions in health and safety risks constitute one of the most important categories of nonmarket benefits. Both explicit and implicit methods can be used to incorporate these risk reductions into the framework of benefit/cost analysis. Among currently available methodologies, a widely accepted way to monetize explicitly reductions in fatality risks is to use the most likely estimate for the reduction in fatality risks times the willingness-to-pay estimate or the value of a unit risk reduction.[45]

An implicit valuation approach could be developed using calculations of the cost per unit of reduction in fatality risk (cost per "statistical life saved"), with costs defined as costs minus other monetized benefits.[46] Alternatives could then be arrayed in order of their total reduction in expected fatalities with the incremental cost per statistical life saved calculated between each adjacent pair of (the mutually exclusive) alternatives.

Cost Estimates

The RIA should also include a schedule of monetized costs that shows the nature of the cost and when it would occur. The numbers in this table should be expressed in constant, undiscounted dollars. Costs include private-sector compliance costs, government administrative and enforcement costs, and costs of reallocating workers displaced as a result of the regulation. Costs that are not monetary outlays—for example, discomfort or inconvenience costs—must be included and should be assigned a monetary value wherever possible.

The important economic concept of opportunity costs is as relevant to benefit-cost analysis of regulations as it is to other types of economic analysis. The opportunity cost of an alternative is the value of the

[44] The RIA should include a schedule of monetized benefits that would show the type of benefit and when it would accrue; the numbers in this table should be expressed in constant, undiscounted dollars. Moreover, the RIA should identify and explain in detail the data or studies on which benefit estimates are based. Where benefit estimates are derived from a statistical study, the RIA should provide sufficient information, so that an independent observer can determine the representativeness of the sample and whether the results were used properly in developing aggregate estimates.

[45] The willingness-to-pay approach to valuing fatality risk reductions has recently been endorsed by a report prepared for the Administrative Conference of the United States. See Clayton P. Gillette and Thomas D. Hopkins, "Federal Agency Valuations of Human Life" (July 1988). While there is extensive literature yielding estimates on the value of small reductions in fatality risk, the available literature on willingness-to-pay estimates for small reductions in the risk of nonfatal illness or injury is far more limited. As a result, the analysis should reflect the best judgment on whether a willingness-to-pay study or a direct-cost valuation (e.g., medical costs and the value of lost production) provides a better estimate of the value of reducing the risk of nonfatal illness or injury.

[46] Gillette and Hopkins, *op. cit.*, also recommend to the Administrative Conference that: "Regulations that are adopted on the justification that they will save lives should state an explicit valuation utilized, or should disclose the value per statistical life implicit in that determination" (p. 62).

benefits foregone as a consequence of choosing that alternative. For example, the opportunity cost of banning a product (e.g., a drug, food additive, or hazardous chemical) is the loss of benefits to consumers of not being able to buy that product.

All costs calculated should be incremental, that is, they should represent changes in costs that would occur if the regulatory alternative is chosen compared to costs incurred under a less stringent alternative. Future costs that would be incurred even if the regulation is not promulgated, as well as costs that have already been incurred (sunk costs), are not part of incremental (or marginal) costs.

The RIA should explain any expected incremental costs that cannot be monetized. An important type of cost that often cannot be monetized is a slowing in the rate of innovation or of adoption of new technology. For example, regulations requiring a costly and time-consuming approval process for new products or new facilities may have such costs, as may regulations setting much more stringent standards for new facilities than for existing ones.

Treatment of Risk and Uncertainty

Where benefit or cost estimates are heavily dependent on underlying assumptions, the RIA should make these assumptons explicit so that information on all elements of the analysis is fully apparent to users of the analysis (e.g., reviewing policymakers, Congress, and the public). Because the particular estimation approach adopted may involve a complicated model, it is important for the agency to make hidden assumptions explicit and present sensitivity analyses (i.e., show the effects of alternate assumptions on costs and benefits) based on plausible alternative assumptions.

Wherever benefit or cost estimates are uncertain, an agency should present "most likely" estimates (in statistical terms, unbiased estimates or expected values). Where possible, an agency should also present information about the likelihood that the true value is different from the estimate or at least present plausible lower and upper bound estimates. Often benefit/cost analyses rely on a number of different studies that yield a range of estimates. In these cases the midpoint of the range of extreme values provided by the studies does not represent the most likely estimate, because the most extreme estimates may be the least reliable. Such an approach ignores the results of the other studies. The correct approach would use all available information and derive a most likely estimate as a weighted average of the estimates of the individual studies, with the weight of each estimate based on the reliability of the study that produced it.

[47] National Research Council, *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington, DC 1983: p. 7.

For many regulations the estimates of benefits are often less certain than the cost estimate. This is particularly the case where the benefits of regulation take the form of a reduction in health and safety risks. Costs can often be calculated by estimating the expenses of purchasing and installing new equipment or of adopting different work practices. On the other hand, benefits may be estimated on the basis of an hypothesized reduction in cancer cases, injuries, or crop damage.

Unfortunately this uncertainty on the health or benefit side is sometimes dealt with in a way that is inconsistent with the way it is generally dealt with on the cost side. Some agencies have adopted the practice of "erring on the side of safety" or adding "margins of safety" at each step in the risk assessment process. This means that the policy official usually does not know *how* conservative the benefit or risk reduction estimates are; just that they are conservative.

These practices, both informal and formal, are counterproductive to the provision of a safer and healthier society because it is impossible (given the bias in the risk estimates) to direct the limited resources available to produce the greatest reduction in risks. This danger is well recognized by policy analysts and scientists, especially those outside the regulatory agencies. For example, the National Academy of Science issued a report in 1983 recommending that:

> regulatory agencies take steps to establish and maintain a clear conceptual distinction between assessment of risks and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic, and technical considerations that influence the design and choice of regulatory strategies.[47]

If both the costs of regulations and the risk reductions they bring about are estimated using the expected value approach a realistic opportunity exists for obtaining the most risk reduction for society from a given level of expenditures.

DISCOUNTING

Discounting takes account of the fact that resources (goods or services) in a given year are worth more than identical resources in a later year, since resources can be invested today so as to return more resources later. Because of this productvity of investment, the timing of benefits and costs must be taken into account. For example, a dollar invested today at 10 percent per year will return $2.59 in ten years. Thus the opportunity cost of a dollar foregone today is $2.59 in ten years. By the same argument, a regulatory benefit occurring today and worth $1.00 is equivalent to a benefit of $2.59 ten years from now. The appropriate way to account for such differences

in the timing of benefits and costs is by discounting.

If costs and benefits occur in different years, the RIA should evaluate the benefit and cost streams (in constant dollars) over a comparable timeframe. Generally the RIA would make the adjustment by discounting the benefit and cost streams to their present values, but there are alternative approaches that are equally valid, such as annualizing the benefit and cost streams over the appropriate timeframe.

CRITIQUE OF RIAS

Last year's Regulatory Program examined some of the key elements of the RIA (as discussed above) in the context of nine RIAs covering a broad spectrum of regulatory actions. As a part of that review, the conclusion was reached that most of the RIAs represented a substantial improvement—particularly in terms of developing benefit estimates—over the economic analyses prepared under the procedures established in earlier years.

At the same time, however, some important shortcomings were identified. Some of these RIAs, OSHA's Asbestos standard RIA, for example, evaluated only a single regulatory option—the selected option.

In addition the treatment of uncertainty in some cases largely failed to convey the full scope of the uncertainty in the analysis. Some agencies, for example, had used "worst case" or "upper bound" estimates instead of most likely estimates in calculating the likely benefits of a regulation. In OSHA's RIA for ethylene oxide (Eto), the health risks are based on "worst-case" estimates of exposure in terms of both the concentration level and the duration of exposure. As a result, the combined effect of these "worst-case" assumptions yields an estimate of exposure risk five to ten times greater than the most likely estimate.

Most of the RIAs used some form of discounting as a way of addressing the problem of adjusting benefit and cost streams so that they could be considered in a comparable time frame. However, in some cases, RIAs only discounted the cost streams, without discounting the benefits. This is the case, for example, in OSHA's RIA for Eto. This differential treatment—discounting costs, but not benefits—can also be a significant source of bias in a benefit/cost analysis. In the Eto RIA, the cost per cancer avoided is increased by a factor of five if neither costs nor benefits are discounted and by more than a factor of ten if a consistent approach is adopted in discounting both benefits and costs.

Finally, once the benefits and costs have been estimated and placed on an equal footing by discounting future benefits and costs to the present and using the same basic methodology to produce "expected value" or most likely estimates, benefits and costs must be presented in some systematic format helpful to decision makers.[48]

In practice, however, many RIAs fail to develop an estimate of net benefits, either because statutes prohibit regulatory decisions based on benefit-cost evaluation or because the data needed for such calculations are simply unavailable. In these cases, RIAs

Table I

RISK-COST TRADEOFFS FOR SELECTED REGULATIONS

Regulation	Agency	Year issued	Cost per statistical life saved ($ millions)
Unvented space heaters	CPSC	1980	$ 0.07
Servicing wheel rims	OSHA	1984	0.25
Fuel system integrity	NHTSA	1975	0.29
Fall protection	OSHA	1985	1.40
Uranium mill tailings (active)	EPA	1983	53.00
Ethylene oxide	OSHA	1984	60.00
Asbestos	OSHA	1986	89.00
DES ban in cattlefeed	FDA	1979	132.00

Sources: *Regulatory Program of the United States Government,* April 1, 1986—March 31, 1987, p. xxi; Morrall, J. F., "A Review of the Record," *Regulation,* November–December 1986.

Note: In 1984 dollars, discounted at 10 percent. Each nonfatal accident requiring hospitalization is treated as equivalent to one-fiftieth of a fatality. This relationship was selected as representative of the willingness-to-pay values for fatality risks relative to injury risks found by research studies. Cancer is counted as a fatality. Cancer latency periods were assumed to be 15 years for lung cancer associated with uranium mill tailings, 30 years for mesothelioma and lung cancer associated with asbestos exposure, and ten years for the leukemia and breast cancer associated with ethylene oxide and DES, respectively.

Discounting benefits and costs at 4 percent instead of 10 percent does not affect the conclusion that there are extremely wide variations in cost per statistical life saved between these regulations, nor does it affect the cost-effectiveness rankings. Discounted at 4 percent, banning DES in cattlefeed still costs 1,500 times more per statistical life than regulating unvented space heaters.

should adopt cost-effectiveness analysis as a way of presenting this information in a systematic way. Unlike benefit-cost analysis, cost-effectiveness analysis does not require the monetization of benefits (although it does require the quantification of benefits).

Last year's Regulatory Program illustrated the usefulness of this type of analysis by presenting a table (reproduced here as Table I) of risk-cost tradeoffs for selected regulations from different agencies.

Once the cost-effectiveness estimates of the alternative regulatory options have been arrayed in a table, the relative merits of the alternatives considered are readily apparent. Table I shows that one million dollars spent per year in complying with OSHA's regulation on servicing wheel rims was estimated to save four "statistical lives" per year compared to two thirds of a "statistical life" every ten years for its Ethylene Oxide rule. Clearly if OSHA could mandate that only one million dollars per year of additional private resources could be spent on health and safety improvement, it would do well to consider issuing the wheel rim rule first.

The fact that Table I reveals a wide divergence in cost-effectiveness of risk-reducing regulations does not necessarily mean that regulatory oversight has failed. Not all the information necessary for fair and efficient decisions is displayed in Table I. For example, not all regulatory options are listed (only a selected sample), different parties pay the costs of and benefit from the different regulations, and other values that matter to society such as individual freedoms and basic rights are not included. Nevertheless, the wide divergence in cost-effectiveness displayed in Table I as well as other studies like it is a strong indication that there is room for improvement.[49]

SUMMARY

The analytical elements outlined above constitute the foundation of an effective and useful RIA. Adherence to these key elements will yield important improvements in the information provided to decisionmakers, resulting in better-designed regulations and potentially large net benefits to society as a whole. In addition improved analyses will help the public, Congress, and the courts understand agency regulatory decisions.

Last year's Regulatory Program started that OMB was in the process of drafting more specific guidance in preparing RIAs in order to provide continued improvements in regulatory analyses. Draft RIA guidelines are set out in Appendix V. OMB solicits comments on their completeness, usefulness, and appropriateness.

[48] Executive Order No. 12291 requires that net benefits (benefits minus costs) be calculated and that regulatory decisions be made that maximize net benefits to the extent permitted by law.

[49] See John Morrall, "Regulating Risk: A Review of the Record," *Regulation* (Nov/Dec 1986) p. 30 and John Mendeloff, *The Dilemma of Toxic Substance Regulation*, (Cambridge, Mass.: MIT Press, 1988) p. 22.

APPENDIX III

Additional Procedures Concerning OIRA Reviews Under Executive Order Nos. 12291 and 12498 [Revised]

June 13, 1986

MEMORANDUM FOR THE HEADS OF DEPARTMENTS AND AGENCIES SUBJECT TO EXECUTIVE ORDER NOS. 12291 AND 12498

From the time the President signed Executive Order No. 12291 on February 17, 1981, OMB has worked with the Departments and Agencies to develop and implement various procedures concerning the review of draft rules by the Office of Information and Regulatory Affairs (OIRA). We have also developed trial procedures and supported legislative proposals concerning our reviews as we have gained experience with these Executive Orders. For example last year, we implemented on a pilot basis with the Environmental Protection Agency additional procedures concerning OIRA's communications with persons outside the Federal Government.

We have also supported an American Bar Association Resolution that endorsed the President's regulatory review efforts and recommended that more information concerning our reviews be made available to Congress and the public.

The purpose of this memorandum is to advise you of additional procedures that we have determined, as a matter of administrative discretion, to implement concerning our review of draft rules under Executive Order No. 12291 and to set forth our policy on disclosure of agency regulatory program drafts under Executive Order No. 12498.

Current Procedures

These new procedures supplement our current procedures. As you are aware, Executive Order No. 12291 establishes certain procedures; the Administrative Procedure Act sets forth procedural and substantive requirements that govern agency action; other statutes establish procedures; and OIRA has adopted its own internal rules concerning its review of draft rules under Executive Order No. 12291. Furthermore, Departments and Agencies usually have established rules or practices to implement their rulemaking activities.

Attached to this memorandum are copies of some of the relevant materials concerning our reviews and procedures. Several of the most important features of these current procedures are:

Reviews Under Executive Order No. 12291

- Rules must meet statutory requirements. Executive Order No. 12291 reviews cannot result in rules not authorized by law or rules that do not carry out statutory requirements.
- Rulemaking decisions are made by agency heads. Executive Order No. 12291 makes it clear that the rulemaking authority of the agency head is not displaced by the Order.
- Rules must be based on the agency record. Executive Order No. 12291 cannot cause rulemaking decisions that are not supported by the agency rulemaking record. The law requires that all agency decisions must be rationally based on information in the agency record.
- Requirements of Executive Order No. 12291 apply only to the extent permitted by law. If there is a conflict between the Executive Order or the President's regulatory principles in Executive Order No. 12291 and the law, the law governs.

Current OIRA Procedures

- Only the Administrator and Deputy Administrator within OIRA (or someone specifically designated by them) may communicate with someone who is not employed by the Federal Government on regulations submitted to OIRA for review under Executive Order No. 12291.
- Written materials received from anyone not employed by the Federal Government are made available in OIRA's public reading room for review by the public.
- OMB has advised persons who wish to send us information about regulatory proposals to *send information to the rulemaking agency,* with a copy to us, so that the material may be made a part of the agency record.
- In general, OIRA provides *written reasons* to the agency whenever OIRA returns a regulation to an agency for further review because it is not

consistent with the President's regulatory principles.

- OIRA issues *full reports* annually on the disposition of all rules reviewed under Executive Order No. 12291, including a list of all returned rules.

New Procedures

1. OIRA will make available, upon written request made to OIRA after publication of an ANPRM or NPRM in the *Federal Register*, copies of any draft of the ANPRM or NPRM submitted for OIRA's review under Executive Order No. 12291;
2. Similarly, OIRA will make available, upon written request made to OIRA after publication of the final rule in the *Federal Register*, copies of any draft of the final rule submitted for OIRA's review under Executive Order No. 12291;
3. OIRA will make available, upon written request made to OIRA after the ANPRM, NPRM or the final rule is published in the *Federal Register*, all written correspondence concerning the draft submitted for OIRA's review under Executive Order No. 12291 that is exchanged between OIRA and the agency head. "Correspondence" means any documents exchanged between OIRA and the head of an agency.

These procedures are derived from provisions in S. 2433, as reported from the Senate Governmental Affairs Committee, with Administration support, in 1984. The Report on S. 2433 (No. 98-576, 98th Congress, 2d. Sess.) contains explanatory material as to how these provisions would have been interpreted had S. 2433 been enacted. We will be guided by that material in implementing these first three provisions.

4. OIRA will send EPA copies of all written material concerning EPA rules that OIRA receives from persons who are not employees of the Federal Government;
5. OIRA will advise EPA of all oral communications concerning EPA's rules, e.g., meetings, telephone calls, that OIRA (i.e., the Administrator and Deputy Administrator) has with persons who are not employees of the Federal Government; and
6. OIRA will invite EPA to all scheduled meetings with such persons concerning EPA's rules.

In May 1985, we instituted with EPA on a trial basis other procedures to better conform our Executive Order No. 12291 review procedures to EPA's somewhat unique internal procedures and statutory provisions concerning rulemaking. (See attached letter dated May 30, 1985, Attachment D.) These procedures are practical, and EPA believes that they are useful. This Memorandum revises those procedures with EPA and makes them a part of OIRA's current procedures.

(Note: These procedures do not apply to information collection requests under the Paperwork Reduction Act of 1980, even if such requests are a part of a proposed agency rule. Other procedures apply to such matters, see 5 CFR Part 1320.)

7. OIRA will apply these procedures (#4 through #6) to any other Department or Agency that is subject to Executive Order No. 12291 if that agency elects to institute these procedures, or any part of them.

Procedures #4 through #6 presently apply only to EPA. Although patterned upon EPA's statutory and internal procedures nonetheless, OIRA is prepared to extend these procedures to other agencies if the head of the agency so requests. A current list of agencies that have requested coverage will be maintained in the public reading room.

In addition,

8. OIRA will make available upon written request to OIRA made after the Regulatory Program is published, any agency draft submission sent to OIRA under Executive Order No. 12498. A copy will be available in the public reading room;
9. OIRA will continue to publish a complete annual accounting of Executive Order No. 12291 activities;
10. OIRA will make available upon written request to OIRA made after the end of a calendar month, a list of all draft ANPRMs, NPRMs and draft final rules for which OIRA has completed review under Executive Order No. 12291 during the preceding month (and the length of our review for each); and
11. OIRA will place in its public reading room: all written material received from persons outside the Federal Government concerning agency rules; a list of all meetings with persons outside the Federal Government pertaining to rules of an agency if that agency elects to participate in procedure #6; and a list of all other communications with persons outside the Federal Government pertaining to rules of any agency if that agency elects to participate in procedure #5.

Effective Date of New Procedures

The effective date of these new procedures is June 13, 1986, as explained below.

For purposes of new procedures #1 through #3, OIRA will make available in accordance with the conditions of those procedures, all drafts of the rule (and written correspondence referred to in procedure #3) if the review under Executive Order No. 12291 began on or after June 13, 1986, or was under review on that date. OIRA reviews of draft ANPRMs, NPRMs and final rules will be separate actions for purposes of disclosure. For example, copies of a draft NPRM under procedure #1 will be available in accordance with the conditions of procedure #1 after publication of the NPRM, if it was pending on or submitted after June 13, 1986, for review under Ex-

ecutive Order No. 12291. Disclosure of the draft NPRM would not be delayed until publication of a final rule. The reviews are distinct events for disclosure purposes. Similarly, if a review under Executive Order No. 12291 of a draft NPRM was completed prior to June 13, 1986, it would not be covered by these new procedures. Drafts of the final rule would be subject to procedure #2 if the final rule was pending on or submitted after June 13, 1986.

For purposes of procedures #4 through #6, the effective date will be the date of receipt of the request by the head of an agency to have these procedures apply. They apply as of June 13, 1986, for EPA. (Trial procedures with EPA have been effective since May 30, 1985.)

Procedure #8 will apply to drafts of the agency submissions for the *1986 Regulatory Program* and thereafter. The annual accounting referenced in procedure #9 is an appendix to the annual *Regulatory Program*. The lists referred to in procedures #10 and #11 will be available in OIRA's public reading room and upon written request on the 10th day of the month following the month for which the list is made. The first list will be available August 10, 1986. All written material pertaining to rules subject to Executive Order No. 12291 review received from persons not employed by the Federal Government as described in procedure #11 will be available within 3 to 5 days after receipt by OIRA.

These new procedures and OIRA's existing procedures are intended only to improve the internal management of the Federal Government, and are not intended to create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, its agencies, its officers or any person.

WENDY L. GRAMM
Administrator
Office of Information
and Regulatory Affairs

Attachments

A — Department of Justice/OLC Opinion dtd 2/13/81
B — Executive Order No. 12291 (see Appendix II)
C — Executive Order No. 12498 (see Appendix I)
D — OIRA Procedures #3

Attachment A

February 13, 1981

MEMORANDUM

Re: Proposed Executive Order entitled "Federal Regulation"

The attached proposed Executive Order was prepared by the Office of Management and Budget in consultation with this Office, and has been forwarded for the consideration of this Department as to form and legality by the Office of Management and Budget with the approval of the Director. The proposed Order is designed to reduce regulatory burdens, to provide for presidential oversight of the administrative process, and to ensure well-reasoned regulations. The Order sets forth a number of requirements that Executive Branch agencies must adhere to in exercising their statutory rulemaking authority. We conclude that the Order is acceptable as to form and legality.

The Order has the following major provisions. Agencies must take action only if the potential benefits outweigh the social costs; attempt to maximize social benefits; choose the least costly alternative in selecting among regulatory objectives; and set priorities with the aim of maximizing net benefits. All of these requirements must be followed "to the extent permitted by law." The Order would require agencies to prepare for each "major rule" a Regulatory Impact Analysis (RIA) setting forth a description of the potential costs and benefits of the proposed rule, a determination of its potential net benefits, and a description of alternative approaches that might substantially achieve regulatory goals at a lower cost. Agencies would be required to determine that any proposed regulation is within statutory authority and that the factual conclusions upon which the rule is based are substantially supported by the record viewed as a whole. The Director of the Office of Management and Budget and the Presidential Task Force on Regulatory Relief would be given authority, *inter alia*, to designate proposed or existing rules as major rules, to prepare uniform standards for measuring costs and benefits, to consult with the agencies concerning preparation of RIAs, to state approval or disapproval of RIAs and rules on the administrative record, to require agencies to respond to these views (and to defer rulemaking while so consulting), and to establish schedules for review and possible revision of existing major rules. The Order would require agencies to defer rules that are pending on the date of its issuance, including rules that have been issued as final rules but are not yet legally effective, and to reconsider them under the Order. By its terms, the Order would create no substantive or procedural rights enforceable by a party against the United States or its representatives, although the RIA would become part of the administrative record for judicial review of final rules.

I. LEGAL AUTHORITY: IN GENERAL

The President's authority to issue the proposed Executive Order derives from his constitutional power to "take Care that the Laws be faithfully executed." U.S. Const., Art. II, § 3. It is well established that this provision authorizes the President, as head of the Executive Branch, to "supervise and guide" Executive officers in "their construction of the statutes under which they act in order to secure that unitary and uniform execution of the laws which Article II of the Constitution evidently contemplated in vesting general executive power in the President alone." *Myers* v. *United States,* 272 U.S. 52, 135 (1926).[1]

The supervisory authority recognized in *Myers* is based on the distinctive constitutional role of the President. The "take Care" clause charges the President with the function of coordinating the execution of many statutes simultaneously: "Unlike an administrative commission confined to the enforcement of the statute under which it was created . . . the President is a constitutional officer charged with taking care that a 'mass of legislation' be executed," *Youngstown Sheet & Tube Co.* v. *Sawyer,* 343 U.S. 579, 702 (1952) (Vinson, C.J., dissenting). Moreover, because the President is the only elected official who has a national constituency, he is uniquely situated to design and execute a uniform method for undertaking regulatory initiatives that responds to the

[1] In *Buckley* v. *Valeo,* 424 U.S. 1, 140-41 (1976), the Supreme Court held that any "significant governmental duty exercised pursuant to a public law" must be performed by an "Officer of the United States," appointed by the President or the Head of a Department pursuant to Art. II, § 2, cl. 2. We believe that this holding recognizes the importance of preserving the President's supervisory powers over those exercising statutory duties, subject of course to the power of Congress to confine presidential supervision by appropriate legislation. *See also* n. 7, *infra.*

will of the public as a whole.[2] In fulfillment of the President's constitutional responsibility, the proposed Order promotes a coordinated system of legislation, ensuring a measure of uniformity in the interpretation and execution of a number of diverse statutes. If no such guidance were permitted, confusion and inconsistency could result as agencies interpret open-ended statutes in differing ways.

Nevertheless, it is clear that the President's exercise of supervisory powers must conform to legislation enacted by Congress.[3] In issuing directives to govern the Executive Branch, the President may not, as a general proposition, require or permit agencies to transgress boundaries set by Congress. *Youngstown Sheet & Tube Co.* v. *Sawyer,* 343 U.S. 579 (1952). It is with these basic precepts in mind that the proposed Order must be approached.

We believe that an inquiry into congressional intent in enacting statutes delegating rulemaking authority will usually support the legality of Presidential supervision of rulemaking by Executive Branch agencies. When Congress delegates legislative power to Executive agencies, it is aware that those agencies perform their functions subject to Presidential supervision on matters of both substance and procedure. This is not to say that Congress never intends in a specific case to restrict Presidential supervision of an Executive agency; but it should not be presumed to have done so whenever it delegates rulemaking power directly to a subordinate Executive official rather than the President. Indeed, after *Myers* it is unclear to what extent Congress may insulate Executive agencies from Presidential supervision. Congress is also aware of the comparative insulation given to the independent regulatory agencies, and it has delegated rulemaking authority to such agencies when it has sought to minimize Presidential interference. By contrast, the heads of non-independent agencies hold their positions at the pleasure of the President, who may remove them from office for any reason. It would be anomalous to attribute to Congress an intention to immunize from Presidential supervision those who are, by force of Art. II, subject to removal when their performance in exercising their statutory duties displeases the President.

Of course, the fact that the President has both constitutional and implied statutory authority to supervise decisionmaking by Executive Branch agencies does not delimit the extent of permissible supervision. It does suggest, however, that supervision is more readily justified when it does not purport wholly to displace, but only to guide and limit, discretion which Congress has allocated to a particular subordinate official. A wholesale displacement might be held inconsistent with the statute vesting authority in the relevant official. See *Myers* v. *United States, supra,* at 135: "Of course there may be duties so peculiarly and specifically committed to the discretion of a particular officer as to raise a question whether the President may overrule or revise the officer's interpretation of his statutory duty in a particular instance." This suggestion is based on the view that Congress may constitutionally conclude that some statutory responsibilities should be carried out by particular officers without the President's revision, because such officers head agencies having the technical expertise and institutional competence that Congress intended the ultimate decisionmaker to possess.[4] Under this analysis, of course, lesser incursions on administrative discretion are easier to support than greater ones. This Office has often taken the position that the President may consult with those having statutory decisionmaking responsibilities, and may require them to consider statutorily relevant matters that he deems appropriate, as long as the President does not divest the officer of ultimate statutory authority.[5] Of course, the President has the authority to inform an appointee that he will be discharged if he fails to base his decisions on policies the President seeks to implement.[6]

A. The Order would impose requirements that are both procedural and substantive in nature. Procedurally, it would direct agencies to prepare an RIA assessing the costs and benefits of major rules. We discern no plausible legal objection to this requirement, which like most procedural requisites is at most an indirect constraint on the exercise of statutory discretion. At least as a general rule, the President's authority of "supervis[ion] in his administrative control," *Myers* v. *United States,* supra, at 135, permits him to require the agencies to follow procedures that are designed both to promote "unitary and uniform execution of the laws" and to aid the President in carrying out his constitutional duty to propose legislation. See U.S. Const., Art. II, § 3. We believe that a requirement that the agencies perform cost-benefit analysis meets these criteria. Further, the President's constitutional right to consult with officials in the Executive Branch permits him to require them to inform him of the costs and benefits of proposed action.[7] In our view, a requirement that rulemaking authorities prepare an RIA is the least that *Myers* must mean with respect to the President's authority to "supervise and guide" Executive officials.

[2] *See* Bruff, *Presidential Power and Administrative Rulemaking,* 88 Yale L.J. 451, 461-62 (1978).

[3] In certain circumstances, statutes could invade or intrude impermissibly upon the President's "inherent" powers, but that issue does not arise here.

[4] *Cf.* H. Friendly, The Federal Administrative Agencies (1962) (discussing concept of "agency expertise" as reason for delegation of power to particular agencies). The *Myers* Court reaffirmed, however, that even such officers may be dismissed at the pleasure of the President. 272 U.S. at 135.

[5] *See generally,* 1 Ops. Office of Legal Counsel Nos. 77-21, 77-56 (1977).

[6] *See* note 4 *supra.*

[7] *See* U.S. Const., Art. II., §2 (President may "require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices").

B. Substantively, the Order would require agencies to exercise their discretion, within statutory limits, in accordance with the principles of cost-benefit analysis. More complex legal questions are raised by this requirement. Some statutes may prohibit agencies from basing a regulatory decision on an assessment of the costs and benefits of the proposed action. *See, e.g., EPA* v. *National Crushed Stone Ass'n,* 101 S. Ct. 295 (1980). The Order, however, expressly recognizes this possibility by requiring agency adherence to principles of cost-benefit analysis only "to the extent permitted by law." The issue is thus whether, when cost-benefit analysis is a statutorily authorized basis for decision, the President may require Executive agencies to be guided by principles of cost-benefit analysis even when an agency, acting without presidential guidance, might choose not to do so. We believe that such a requirement is permissible. First, there can be little doubt that, when a statute does not expressly or implicitly preclude it, an agency may take into account the costs and benefits of proposed action. Such a calculus would simply represent a logical method of assessing whether regulatory action authorized by statute would be desirable and, if so, what form that action should take. In our view, federal courts reviewing such actions would be unlikely to conclude that an assessment of costs and benefits was an impermissible basis for regulatory decisions.

Second, the requirement would not exceed the President's powers of "supervision." It leaves a considerable amount of decisionmaking discretion to the agency. Under the proposed Order, the agency head, and not the President, would be required to calculate potential costs and benefits and to determine whether the benefits justify the costs. The agency would thus retain considerable latitude in determining whether regulatory action is justified and what form such action should take. The limited requirements of the proposed Order should not be regarded as inconsistent with a legislative decision to place the basic authority to implement a statute in a particular agency. Any other conclusion would create a possible collision with constitutional principles, recognized in *Myers,* with respect to the President's authority as head of the Executive Branch.

C. We believe that the President would not exceed any limitations on his authority by authorizing the Task Force and the Director to supervise agency rulemaking as the Order would provide. The Order does not empower the Director or the Task Force to displace the relevant agencies in discharging their statutory functions or in assessing and weighing the costs and benefits of proposed actions.[8] The function of the Task Force and the Director would be supervisory in nature. It would include such tasks as the supplementation of factual data, the development and implementation of uniform systems of methodology, the identification of incorrect statements of fact, and the placement in the administrative record of a statement disapproving agency conclusions that do not appear to conform to the principles expressed in the President's Order. Procedurally, the Director and the Task Force would be authorized to require an agency to defer rulemaking while it responded to their views concerning proposed agency action. This power of consultation would not, however, include authority to reject an agency's ultimate judgment, delegated to it by law, that potential benefits outweigh costs, that priorities under the statute compel a particular course of action, or that adequate information is available to justify regulation. As to these matters, the role of the Director and the Task Force is advisory and consultative. The limited power of supervision embodied in the proposed Order is, therefore, consistent with the President's recognized powers to supervise the Executive Branch without displacing functions placed by law in particular agencies.

II. SUSPENSION OF PROPOSED AND FINAL REGULATIONS

The Order requires Executive Branch agencies (1) to suspend the effective date of rules that have been issued as final rules, but have not become legally effective; and (2) to reconsider rules that are proposed but have not yet been made final. After suspension of final rules, agencies must reconsider all such rules in accordance with the Order. These requirements are imposed only "to the extent permitted by law" and are thus inapplicable when a judicial or statutory deadline requires prompt action. Moreover, agencies must, in complying with these directives, adhere to the requirements of the Administrative Procedure Act (APA), 5 U.S.C. §551 *et seq.,* and all other laws.

For rules that have not yet been made final, the APA imposes no special procedural requirements. Agencies need not follow the notice and comment procedures of 5 U.S.C. §553, for nothing in that provision requires an agency to allow a period for comment on a decision to delay final adoption of a proposed rule. The agency's decision may, however, be subject to judicial review, and the agency may have to furnish a reasoned explanation for that decision. *See ASG Indust.* v. *CPSC,* 593 F.2d 1323, 1335 (D.C. Cir. 1979); *Action for Children's Television* v. *FCC,* 564 F.2d 458, 478-79 (D.C. Cir. 1977). The explanation here—that the agency needs time to prepare an RIA required by Executive Order—is, we believe, sufficient.

[8]The Paperwork Reduction Act of 1980, Pub. L. No. 96-511, 94 Stat. 2812, provides some implied statutory support for the Order by giving OMB a direct role in coordinating agency regulations that impose paperwork burdens on the public. With respect to non-independent agencies the Act gives the Director authority to disapprove "unreasonable" agency collection of information requests. §3504(h)(5)(C). The Act does not authorize him, however, to disapprove the accompanying rule itself insofar as the two are separable. *See* §3518(e); S. Rep. No. 930, 96th Cong., 2d Sess. 56 (1980).

The second category of regulations covered by the Executive Order raises somewhat different legal issues. Under 5 U.S.C. §553(b), notice and comment procedures must be followed for "rulemaking" unless "the agency for good cause finds (and incorporates the findings and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. §551(5), the term "rulemaking" is defined as "agency process for formulating, amending, or repealing a rule." The initial question, then, is whether an agency's decision to "suspend" a final but not effective rule is "rulemaking" which triggers the procedural safeguards of §553.

In a recent memorandum, this Office concluded that a 60-day suspension of the effective date of a final rule should not, in general, be regarded as rulemaking within the meaning of the APA.[9] We based our conclusion on "the clear congressional intent to give agencies discretion to extend the effective date provision beyond 30 days" and the absence of statutory language or history suggesting "that a delay in effective date is the sort of agency action that Congress intended to include within the procedural requirements of §553(b)." Nevertheless, we believe that a short-term suspension of the effectiveness of a final rule is not the equivalent of an indefinite suspension coupled with a process designed to review the basis for the rule, with a view to establishing a new rule. Although the former seems fairly characterized as a mere extension of an effective date under §553(d), the latter should probably be characterized as "agency process for formulating, amending, or repealing a rule" for purposes of §553(b).

The difference between these two measures for purposes of §553 becomes clear upon examination of the sequence of events that is expected to take place under each of them. Under the President's Memorandum of January 29, 1981, agencies are to defer the effective dates of final rules for sixty days in order to review them. The completion of that review will point to either of two dispositions. The rule might be allowed to take effect as published in final form, or it might be withdrawn for some proposed change. The first disposition would require no new procedures. The second disposition would surely contemplate an amendment or repeal of the earlier rule subject to §553's public procedures, but the earlier deferral of the rule's effective date would remain just that.[10]

Under the proposed Order, the situation is analogous to the second possible disposition under the President's Memorandum. The Order, by requiring careful cost-benefit analysis of rules through the RIA process, would contemplate notices of proposed rulemaking on the preliminary RIA and a reexamination of the rule at the appropriate time. The issue to be decided at the time the rule is suspended indefinitely for the Order's process to take place is whether the rule, which has already been promulgated in final form, should be allowed to have interim effect while it is under review by the agency. We believe that this decision is one of "formulating, amending, or repealing a rule" that requires either notice and comment procedures or good cause for dispensing with them under §553(b). Admittedly, the difference between a short deferral of the effectiveness of a rule and an indefinite suspension for reexamination is in part one of degree. But there is also a difference in kind: once a decision to begin the process of amending a rule is made, there is no longer a plausible argument that a rule that was to take effect is merely to be delayed for a brief period.

Notice and comment procedures on the issue of the interim effectiveness of a rule that is due to undergo reexamination under the Order should take the following form. The agency should defer the rule's effective date for a period sufficient to allow a short time for notice and comment, an opportunity for the agency to consider the comments and decide the issue of interim effectiveness, and an interval before the rule takes effect sufficient to meet the purposes of §553(d).

In deciding on the interim effectiveness of final rules subject to the Order's procedures, the final question is whether and under what circumstances agencies will have good cause to dispense with notice and comment procedures. Public procedures on interim effectiveness might be "unnecessary, impracticable, or contrary to the public interest," where the question whether there should be any rule at all was fully ventilated in the rule's comment process, or where it is clear that interim effect could impose substantial but short-term compliance costs. On the other hand, notice and comment might be needed where the rule's proponents had advanced substantial arguments for its early effectiveness, and where compliance costs are not likely to be wasted.

Such arguments must, of course, be assessed on a case-by-case basis. If the available record indicates that the costs of the rule at issue are not substantial and that the failure to allow the rule to become effective may itself be controversial, the likelihood that a court will require notice and public comment increases. The procedural requirements of the APA will, therefore, vary with the size and immediacy of the burdens imposed by the rule and the need for public comment on a decision to withdraw a final but not effective rule.

[9]Memorandum of January 28, 1981, for Honorable David Stockman, Director, Office of Management and Budget, from Larry L. Simms, Acting Assistant Attorney General, Office of Legal Counsel.

[10]Admittedly, one of the purposes of the 30-day effective date provision is to allow agencies to correct errors or oversights in final regulations. *See* Final Report, Attorney General's Committee on Administrative Procedure 114-15 (1941); *Sannon* v. *United States*, 460 F. Supp. 458, 467 (S.D. Fla. 1978). This purpose, however, does not suggest that agencies may make corrections, let alone withdraw rules, during the period between a rule's publication and its effective date without offering public procedures or showing good cause for dispensing with them. Proposed corrections—or even repeals—would of course be amendments for purposes of §553(b).

III. REGULATORY REVIEW BY AGENCY HEADS

Section 4 of the proposed Order would require agency heads to make express determinations that regulations they issue are authorized by law and are supported by the materials in the rulemaking record. These requirements are meant to assure agency compliance with existing legal principles that rules must be authorized by law, and that they should be adequately supported by a factual basis. Accordingly, we find no legal difficulty with them. In particular, they do not purport to change generally applicable statutory standards for judicial review of agency action, *see* 5 U.S.C. §706, and could not have such an effect. They also do not purport to alter any specially applicable standards, such as those concerning the evidentiary standard that must be met to uphold a given rule, appearing in statutes governing a particular agency.

On the other hand, the section would add the significantly new procedural requirements that agency heads expressly determine that the legal and factual requisites for a rule have been met. The first requirement reflects the principle, central to administrative law, that agency action must be guided by the "supremacy of law." *St. Joseph Stock Yards Co.* v. *United States,* 298 U.S. 38, 84 (1936) (Brandeis, J.). This principle protects against excess of power and abusive exercise of power by administrators. *See Report of the U.S. Attorney General's Comm. on Administrative Procedure, Administrative Procedure in Government Agencies,* S. Doc. No. 8, 77th Cong., 1st Sess. 76 (1941). The requirement that agency heads determine that a rule has "substantial support" in the materials before the agency means that a rule's necessary factual basis must be found to exist. This second requirement should not be confused with a "substantial evidence" standard of judicial review, which could be imposed only by statute. It embodies Recommendation 74-4 (subpart 3) of the Administrative Conference of the United States, 1 CFR §305.74.4, which urges that for a rule to be considered rational, it should be adequately grounded in a factual basis. This requirement is consistent with the approach of courts that have carefully reviewed agency action under the "arbitrary and capricious" standard of the Administrative Procedure Act, 5 U.S.C. §706(2)(A). *See, e.g., Ethyl Corp.* v. *EPA,* 541 F.2d 1 (D.C. Cir.) (en banc), *cert. denied,* 426 U.S. 941 (1976).

IV. JUDICIAL REVIEW

The Order states that it is not intended to create any rights or benefits enforceable by a party to litigation against the United States, its agencies, or any other person. At the same time, it provides that determinations of costs and benefits, and the RIA itself, are meant to form part of the agency record for purposes of judicial review. The effect of this provision is to preclude direct judicial review of an agency's compliance with the Order. The provision makes clear the President's intention not to create private rights, an intention that should be controlling here. *See Independent Meat Packers Ass'n* v. *Butz,* 526 F.2d 228 (8th Cir. 1975), *cert. denied,* 424 U.S. 966 (1976) (no judicial enforcement of Executive Order requiring consideration of inflationary impact of regulations, in part because such Order had not been issued pursuant to delegation from Congress); *Legal Aid Soc. of Alameda County* v. *Brennan,* 608 F.2d 1319 (9th Cir. 1979) (judicial review available of compliance with an Executive Order that had been ratified by Congress). Even without the provision, compliance with the Order would probably be immunized from review because the Order has not been promulgated pursuant to a specific grant of authority from Congress to the President and thus lacks the "force and effect of law" concerning private parties. *See Independent Meat Packers Ass'n* v. *Butz, supra; National Renderers Ass'n* v. *EPA,* 541 F.2d 1281, 1291-1292 (8th Cir. 1976); *Hiatt Grain Feed, Inc.* v. *Bergland,* 446 F. Supp. 457, 501-502 (D. Kan. 1978). The bar on judicial review of agency compliance with the Order does not, of course, prohibit a court from hearing a constitutional or statutory attack on the legality of the Order itself or of agency action taken pursuant to its requirements.

Because the regulatory impact analysis that will be required by the Order will become part of the agency record for judicial review, courts may consider the RIA in determining whether an agency's action under review is consistent with the governing statutes. This, of course, is true of all matters appearing in the rulemaking record.

V. CONCLUSION

The proposed Executive Order is acceptable as to form and legality.

Larry L. Simms
Acting Assistant Attorney General
Office of Legal Counsel

Attachment D

May 30, 1985

MEMORANDUM FOR OIRA STAFF

Subject: OIRA Procedures #3

The purpose of this memorandum is to remind you of the policies of the Office of Information and Regulatory Affairs under the Paperwork Reduction Act of 1980, Executive Order No. 12291, and Executive Order No. 12498, with respect to:

- records maintenance;
- public access to records; and
- meetings with the public.

These policies are intended to ensure that our responsibilities are discharged as efficiently and openly as practicable, consistent with both the law and the need for confidential communications between the President and his executive officers. Because OIRA's role in implementing the Paperwork Reduction Act is very different from its role in implementing Executive Order No. 12291 and Executive Order No. 12498, different procedures are necessary for our actions under each of these three programs. The differences derive primarily from the different authorities involved. The rules for Executive Order No. 12291 reviews will be applied to the Executive Order No. 12498 process to the extent they are relevant in that context.

BACKGROUND

OIRA's Role Under the Paperwork Reduction Act. In summary, the Paperwork Reduction Act requires OMB to review and approve or disapprove agency requests for information from the public. In this regard, the Paperwork Reduction Act essentially recodified the clearance authority that was originally assigned to OMB (actually the old Bureau of the Budget) by the Federal Reports Act of 1942.

OMB is responsible for determining whether agency information collection requirements meet the standards of the Act. Reviews under the Act determine whether the proposed information collection request is necessary for the proper performance of agency functions, including whether the information has "practical utility," whether it is too burdensome on respondents, and whether there is a need for the information. As a result, our actions may have legal, judicially reviewable consequences and must be based upon a complete record. The Act and our implementing rule specify the procedures that OIRA must follow. The bottom line is that we are responsible for ensuring that the record is complete and constitutes a justifiable basis for our decision, and that we adhere to the required procedures in developing the record and making our decision.

OIRA's Role Under E.O. 12291 and E.O. 12498. In contrast, our review under Executive Orders No. 12291 and No. 12498 derives from the President's constitutional authority over, and responsibility for actions taken by, his executive officers in carrying out the law. He has delegated his authority to review regulations to the Director of OMB. Thus, we conduct our reviews on behalf of the Director and the President.

In conducting an Executive Order review, OMB does not make final regulatory decisions—those are assigned by law to the heads of the respective agencies and must in all cases remain the regulatory agency's responsibility. The decision is made by the regulatory agency and the agency is accountable for both the adequacy of the record of its rulemaking and for justifying the substantive validity of the decision under the applicable statutes. We review the draft regulations of departments and agencies and advise whether the draft rules and their analysis meet the President's regulatory principles, as set forth in Executive Orders No. 12291 (Section 2) and No. 12498 (Section 1). As the Executive Orders note, our review is not intended to provide any third party with any procedural or substantive right concerning the regulations.

Since some regulations contain collections of information from the public, they are subject to our review and approval under the Paperwork Reduction Act as well as under Executive Order No. 12291.

THE DECISIONMAKING RECORD

The law generally requires that agencies must compile a record of materials that justify their rulemaking actions and that will serve as a basis for judicial review. The regulatory agency is also required under the Administrative Procedure Act to provide a concise general explanation for any regulations adopted by informal rulemaking and to explain, for example, significant substantive differences between an NPRM and a final rule, including new facts or data that the agency has relied upon.

For most rulemakings the law requires only that public comments on a proposed rule and certain un-

derlying scientific and empirical data be included with a text of the notice of proposed rulemaking and a final rule in the rulemaking record. The agency may, and usually does, include in a preamble to a rule other material in the record that is significant and relevant to the rulemaking. But the rule must be based upon and justified by the whole rulemaking record. Factual material that is not in the rulemaking record may not be used as a basis for supporting a rule.

For paperwork reviews, OIRA is the decisionmaking agency; *we* open and maintain that record. Our decision to approve or disapprove is based upon this record and must be justified by it. The record we compile is the material that may be reviewed as the law provides by the courts.

For reviews of regulations under Executive Orders No. 12291 and No. 12498, the agency is the decisionmaker; for judicial review, its rulemaking file, not factual material available to us, is the relevant material. In accordance with the Director's Memorandum of June 11, 1981 (attached), we make available materials we receive from the public to the regulatory agency so it may consider such material and include it in its records if it chooses to do so.

When we conduct reviews and give advice under the Executive Orders, we and the agencies treat our discussions in the same way we handle such consultation on other subjects—they are not generally disclosed. We will, however, make available upon request to the public all written information that we receive from any member of the public that we consider in our review, our final recommendation letter (if any) to the agency under E.O. 12291, and, of course, any material we submit for inclusion in an agency rulemaking record.

The following additional policies should be used as guidance in implementing our responsibilities under the Paperwork Reduction Act of 1980 and Executive Orders No. 12291 and No. 12498.

RECORDS MAINTENANCE

Each OIRA supervisor is responsible for ensuring that the relevant documents are placed in the proper files on matters under their supervision.

Any supervisor (including the Administrator and Deputy Administrator) who receives written comments directly from a member of the public will promptly send a copy of the comments to the appropriate Desk Officer.

Any comments that would otherwise be included in the public record but for which the commentor proposes to limit public access should not be accepted without the approval of the Deputy Administrator. Jim MacRae is responsible for periodic review and disposition of all files for the purpose of retention, storage, or destruction, in accordance with the policies set forth below. Except in unusual circumstances, all documents that are not required by law to be retained should be disposed of when the documents that are required to be retained are transferred to the Federal Records Center.

- *Paperwork Reduction Act of 1980*
  - — Because the written materials in our dockets are the documentary basis for our paperwork decisions and also constitute a basis for the public to review and comment to us on the proposed agency action, paperwork clearance dockets must be kept accurate, timely, and complete. To that end, Desk Officers should place in the docket, promptly after its receipt at OMB, any material that should be in the record.
  - — The record should include the following material:
    - – Agency proposal and any revisions;
    - – OMB worksheet;
    - – All written comments from the public and other government agencies;
    - – Evidence of final OMB action.
  - — After final action (approval or disapproval), the record should be retained in the reading room for at least 6 months. At least twice a year the Reports Management staff will review the files and send to the Federal Records Center all records for which final action has been completed for at least six months. The records will be classified as "temporary" for the Federal Records Center.

- *Executive Order No. 12291*
  - — Because the head of the regulatory agency, not OMB, is the decisionmaker on all rulemaking issues that come to us under E.O. 12291, we will routinely make available to the appropriate regulatory agency copies of all written materials that we receive from members of the public during the rulemaking proceeding and that are relevant to a particular informal rulemaking.
  - — The Desk Officer should also send to the public reading file within three days after receipt a copy of any such comments received from members of the public.
  - — The Desk Officer should send a copy of the final OMB written recommendation to the agency (if any) to the public reading file within three days after transmittal to the agency.
  - — The following material will not be made public, but, in addition to the final written OMB recommendations/views to the agency (if any), will be retained as part of the regulatory files:
    - – draft and proposed agency materials;
    - – OMB worksheets; and
    - – internal OMB and interagency documents as described by 5 U.S.C. 552(b)(5).

— After completion of the OIRA review, the regulatory files should be retained for at least six months. At least twice a year, the Reports Management staff, assisted by the other Branches, will review the files and segregate all files for which the reviews have been completed for at least six months. All files of rules that were "consistent, with no change" will be sent to the Federal Records Center. All other files will be retained within the NEOB for one year, then sent to the Federal Records Center. All files sent to the Federal Records Center will be classified as "temporary."

PUBLIC ACCESS TO OUR DOCKETS AND RECORDS

FOIA requests should be handled in accordance with OMB FOIA procedures. In addition, we have customarily made our paperwork dockets and written information from the public available for inspection.

Notwithstanding the increased Secret Service security precautions in the New Executive Office Building, we must continue to make access to our public records as simple as possible. All clearances should be arranged through Jim MacRae's office, ext. 6880.

To avoid confusion and misunderstanding, visitors should be told at the time clearance is sought that their clearance is limited to the public reading room. If the individual who has been cleared does not arrive at the reading room shortly after their scheduled clearance time, Jim MacRae should be notified. Jim will alert the Secret Service, which will take appropriate action. We cannot permit individuals who are cleared into the building for the reading room to roam through the building.

- *Paperwork Reduction Act of 1980*

— Current and recent records of paperwork clearance actions will be maintained in such a way as to be readily accessible to members of the public (with exceptions as provided in 5 CFR 1320.18). These files, which are the complete and official record for clearance purposes, will be kept in NEOB 3201, the reading room. They will be accessible to the public during normal business hours—9:00 am–5:30 pm.

- *Executive Order No. 12291 and No. 12498*

— We will maintain two types of documents in our public files relating to regulatory reviews—all comments received from any member of the public, and all our final recommendation letters to agencies under Executive Order No. 12291. These files will also be accessible to the public in the reading room during normal business hours.

MEETINGS WITH MEMBERS OF THE PUBLIC (including telephone contacts)

- *Paperwork Reduction Act of 1980*

— Any Desk Officer or supervisor may meet with members of the public to discuss and receive data and facts that are relevant to a paperwork clearance decision.

— Consistent with the policies of this memorandum and available time, OIRA staff must be equally accessible to all members of the public.

— In making our paperwork decision, we will consider only information that we receive *in writing*. The OIRA staff should make this policy clear during any conversation with members of the public, and should advise them to submit their comments in writing to *both* OMB and the agency concerned.

— OIRA staff may provide the public with information regarding the status of our paperwork decisionmaking process and the material and factual basis of our review, but should refrain from discussing their views of the issues or speculating on the outcome of the review.

— If an information collection requirement is contained in a proposed rule, any discussion with members of the public must be limited exclusively to the information collection request.

— Other procedures concerning paperwork reviews are set forth in 5 CFR 1320 and the Act itself.

- *Executive Orders No. 12291 and No. 12498*

— Inquiries from persons outside of the executive branch about regulatory matters under Executive Orders No. 12291 and No. 12498 shall be referred to the Deputy Administrator's Office or the appropriate agency.

— Consistent with the policies of this memorandum and available time the Administrator and Deputy Administrator will be accessible to all members of the public.

— No one within OIRA except the Administrator or Deputy Administrator will meet or talk with members of the public on Executive Orders No. 12291 and No. 12498 matters, unless specifically authorized by the Administrator or Deputy Administrator.

— Members of the public should be advised to submit their comments in writing to the appropriate agency if they wish to submit them to OMB, as provided in the Director's letter of June 11, 1981. They should also be advised that any materials submitted to us will be made part of the public file and made available to the appropriate agency.

ROBERT P. BEDELL
Deputy Administrator
Office of Information
and Regulatory Affairs

June 11, 1981

MEMORANDUM FOR HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

Subject: Certain Communications Pursuant to Executive Order 12291, "Federal Regulation"

Regulatory relief is one of the cornerstones of President Reagan's program of economic recovery. As an important step in achieving regulatory relief, on February 17, 1981, the President issued Executive Order 12291, "Federal Regulation." This memorandum explains how the Presidential Task Force on Regulatory Relief and the Office of Management and Budget (OMB) will communicate with the public and the agencies regarding proposed regulations covered by E.O. 12291. It also describes certain obligations of the public and agencies in this regard.

A major purpose of the Executive Order is to ensure that, to the extent permitted by law, regulatory decisions are based upon sound analysis of the potential consequences. Toward this end, a comprehensive factual basis is essential to assist agencies and other interested parties in assessing the economic and other ramifications of proposed regulations.

Under the Executive Order, both the Task Force and OMB will be reviewing factual materials related to regulatory proposals. Both the public and the agencies should understand that the primary forum for receiving factual communications regarding proposed rules is the agency issuing the proposal, not the Task Force or OMB. Factual materials that are sent to the Task Force or OMB regarding proposed regulations should indicate that they have also been sent to the relevant agency. Pursuant to this policy, the Task Force and OMB will regularly advise those members of the public with whom they communicate that relevant factual materials submitted to them should also be sent to the agency for inclusion in the rulemaking record. Accordingly, agencies receiving such materials from the public should take care to see that they are placed in the record.

On occasion, the Task Force staff and OMB will receive or develop factual material which they believe should be considered by an agency during a particular informal rulemaking. In accordance with advice provided by the Department of Justice, such material, when submitted to an agency for its consideration, will be identified as material appropriate for the whole record of the agency rulemaking.

Two additional matters should be noted. First, our procedures will be consistent with the holding of and policies discussed in *Sierra Club* v. *Costle,* No. 79-1565, slip op. at 212-20 (D.C. Cir. April 29, 1981). Second, these procedures apply only to informal rulemaking proceedings and are not in any sense intended to affect the more stringent ex parte rules applicable to agency adjudications and formal rulemakings. (Such proceedings are expressly intended by Congress to be more in the nature of formal judicial proceedings and involve bars against various forms of ex parte communication.)

David Stockman
Director
Office of Management and Budget

May 30, 1985

MR. A. JAMES BARNES
Deputy Administrator
Environmental Protection Agency

In recent discussions, you have asked us to review our present practices to ensure that factual information pertaining to EPA's rulemaking activities that is made available to us by members of the public is also made available to EPA in a timely manner.

We have reviewed our procedures and we believe that our general policies and practices under Executive Order No. 12291 are sound. However, in response to your request, we would propose certain additional procedures, beyond our existing policies and practices, which, if they are acceptable to you, we would be willing to undertake on an experimental basis.

Background

Our existing procedures implement guidance provided to us by the Attorney General in an opinion of April 24, 1981, entitled "Contacts between OMB and Executive Branch Agencies Pursuant to Executive Order 12291." It complements an earlier analysis by the Attorney General of the legal basis of the Executive Order (Memorandum re: Proposed Executive Order entitled "Federal Regulation," dated February 13, 1981). Both opinions of the Attorney General are enclosed (Tabs A and B).

The earliest of these two opinions of the Attorney General concluded that Executive Order No. 12291, which established the regulatory review process administered by the Office of Information and Regulatory Affairs was a lawful exercise of the President's Constitutional authority—

> "to 'supervise and guide' Executive Officers in 'their construction of the statutes under which they act in order to secure that unitary and uniform execution of the laws which Article II of the Constitution evidently contemplated in vesting general executive power in the President alone' *Myers* v. *United States*, 272 U.S. 52, 135 (1926)."

The second opinion of the Attorney General of April 24, 1981, concluded, in part that:

- The Office of Information and Regulatory Affairs, to which the authority of the Director of OMB under Executive Order No. 12291 has been delegated, "may freely contact agencies regarding the substance of proposed regulations, and may do so by way of telephone calls, meetings, or other forms of communication unavailable to members of the public."
- "[D]isclosure obligations, if any, lie with the rulemaking agency and not with [OIRA]."
- "[OIRA] is therefore under no legal disability with respect to contact with rulemaking agencies. At most, [OIRA] could adopt procedures as a matter of policy to assist the agencies in complying with our recommendation or with rules fashioned by the agencies themselves" (p.4).

This opinion, written before the seminal decision of the United States Court of Appeals for the District of Columbia Circuit in *Sierra Club* v. *Costle*, 657 F.2d 298 (1981), concluded that the judicial decisions issued until that time were "confused" as to whether an agency must include in its rulemaking record for judicial review factual information received by the agency from officials of the Executive Office of the President (EOP). The Attorney General therefore recommended that agencies include such factual information in their records in order to avoid the possibility of judicial reversal. The Attorney General did not, however, require or recommend inclusion of communications under the Executive Order that form part of the agency's deliberative process, i.e., legal and policy arguments, analyses of the facts, and factual data that cannot reasonably be segregated from deliberative material.

To implement the recommendations of the Attorney General, OMB Director David A. Stockman issued a Memorandum for the Heads of Executive Departments and Agencies on June 11, 1981, entitled "Certain Communications Pursuant to Executive Order No. 12291, 'Federal Regulation'" (Tab C). That Memorandum emphasized "that the primary forum for receiving factual communications regarding proposed rules is the agency issuing the proposal, not the Task Force or OMB."

This emphasis on the agency as the forum for receiving factual communications merely reflects, of course, the fact that the Executive Order does not divest an agency head of authority provided by law or the legal requirement that agency rules must be based upon the rulemaking record.

Since these procedures were implemented, the court's decision in *Sierra Club* has clearly established the propriety of contacts between EOP officials and agencies concerning rulemaking—indeed, it has demonstrated their importance for proper policy guidance of this critical aspect of government activity—and demonstrated that the procedures recommended by the Attorney General and implemented by the Director's Memorandum go well beyond what is required by law.

Written Materials from Persons Outside the Executive Branch

The Director's Memorandum provided that:

- Factual materials that are sent to the Presidential Task Force on Regulatory Relief or OIRA regarding proposed regulations should indicate that they have also been sent to the relevant

agency. Pursuant to this policy, the Memorandum noted that the Task Force and OIRA would regularly advise those members of the public with whom they communicated that relevant factual materials submitted to them should also be sent to the agency for inclusion in the rulemaking record.

— Accordingly, agencies receiving such materials from the public should take care to see that they are placed in the record.

— On occasion, the Task Force staff and OIRA would receive or develop factual material that they believed should be considered by an agency during a particular informal rulemaking. The Memorandum provided that, in accordance with advice provided by the Department of Justice, such material, when submitted to an agency for its consideration, would be identified as material appropriate for inclusion in the record of the agency rulemaking.

To further implement the recommendations of the Attorney General, OIRA established additional procedures, as a matter of policy, beyond the requirements of law and the recommendations of the Attorney General. Thus, we have uniformly and consistently made available to Members of Congress, the agencies, and the public copies of documents concerning an agency rulemaking that we have received from persons who are not officials or employees of the executive branch. We also strive to maintain copies of all such documents in our materials that are available for public review.

In addition to such materials being lodged in our public files and copies being made available upon request, you have asked whether copies of such documents that pertain to EPA rules could be routinely sent to EPA to help ensure that such materials are included, if appropriate, in EPA rulemaking dockets. In order to accommodate you, we will send to the General Counsel of EPA copies of all such documents that we receive from persons outside the executive branch. We will seek to provide these copies within five working days of their receipt in OIRA.

Non-written Communications with Persons Outside the Executive Branch

As you know, our practice with regard to non-written communications with persons outside the Federal Government, e.g., telephone calls and meetings, is to constrain communications that pertain to proposed agency rules. Only the Administrator and I (or OIRA employees specifically authorized by us in unusual circumstances) are authorized to communicate with persons outside the Federal Government on the substance (as opposed to the status) of rules that are subject to review under Executive Order No. 12291. These restrictions also apply to our review of rulemaking activities pursuant to Executive Order No. 12498. These restrictions do not apply to the other functions and activities of OIRA, such as our review of information collection requests under the Paperwork Reduction Act of 1980, even if an information collection request is contained in a proposed rule. In this latter circumstance, different procedures apply. See 5 CFR Part 1320 (Tab D) and OIRA Procedures Memorandum #3 (Tab E). The limitations noted above do, however, apply to the parts of a rule that do not contain an information collection request.

Obviously, senior officials in OIRA must be able to communicate freely with members of the public and persons within the Federal Government, just as the senior officials in EPA do.[1] We have, however, limited such communications essentially to the Administrator and Deputy Administrator. Furthermore, even Doug and I usually do not communicate with persons outside the Federal Government on proposed agency rules while they are under review pursuant to Executive Order No. 12291.

Notwithstanding these procedures applicable to all rules subject to the Order, you have asked whether specific additional procedures could be fashioned to apprise EPA of factual information that becomes available to us as a result of non-written communications with persons outside the Federal Government and that pertain to proposed EPA rules. Before describing what we believe is appropriate, it is useful first to deal with an approach we have rejected and the reasons why.

"Logging"

Although you have not suggested it, we believe that a general "logging" program or some variant thereof, particularly between and within executive agencies and entities, would not be an acceptable solution and would, as a general matter, be bad policy. The Attorney General's opinion of April 24, 1981, confirms this at pages 7-9 (Tab A). This view is also reflected in *Sierra Club* v. *Costle*, 657 F.2d 298, 404-408 (1981); prior congressional consideration of the issue (see pp. 3-4, Tab A); and, EPA's own stated position on the matter (Tab F).

In a nutshell, here is why we think a general "logging" system is a bad idea.

- It is unnecessary. There would be no adverse legal consequence even if we were to have information that is not in the agency record. An agency rule must be based on material in the

[1] As the court stated in *Sierra Club* v. *Costle*, "Under our system of government, the very legitimacy of general policymaking performed by unelected administrators depends in no small part upon the openness, accessibility, and amenability of these officials to the needs and ideas of the public from whom their ultimate authority derives, and upon whom their commands must fall. . . .Furthermore, the importance to effective regulation of continuing contact with a regulated industry, other affected groups, and the public cannot be underestimated. Informal contacts may enable the agency to win needed support for its program, reduce future enforcement requirements by helping those regulated to anticipate and shape their plans for the future, and spur the provision of information which the agency needs." 657 F.2d 298, 400-1 (1981).

record. Since EPA cannot rely on information it does not have to support a rule, see 657 F.2d 401, factual information that might be available to us from persons outside the Federal Government, that is not also made available to EPA, is not pertinent. Furthermore, an agency has no use for who-talked-to-whom entries.

- Imposition of a logging requirement would improperly interfere with the communication of policy views within the executive branch and the deliberative process itself. The court in *Sierra Club* rejected this approach. This was also a basis for Congress' rejection of the proposal to apply "ex parte" requirements to informal rulemaking. See pages 3 and 4 of Tab A, particularly footnotes 5-8.
- It is contrary to the "legislative model" of informal rulemaking[2] adopted by the Congress.
- It would divert attention from whether the agency's decision is a good one—the substantive issue—to how the agency made the decision.
- It would establish a paperwork blizzard if all participants in all discussions were required to "log" all communications on the thousands of rules considered every year. This would be nothing short of a bureaucratic nightmare to administer.
- A "logging requirement" would be impossible to "define." When would it begin? Who would it cover? When would it end? What would it consist of? There are neither practical nor principled answers to these questions.
- Such a procedure would logically require the agency to log all of its internal deliberative discussions also—a practical impossibility.

[2]Where agency action resembles judicial action, where it involves formal rulemaking, adjudication, or quasi-adjudication among "conflicting private claims to a valuable privilege," the insulation of the decisionmaker from *ex parte* contacts is justified by basic notions of due process. But where agency action involves informal rulemaking of a policymaking sort, the concept of *ex parte* contacts is of more questionable utility.

Additional Procedures

Nonetheless, in order to increase the amount of factual information that is available to EPA for its rulemaking decisions, and to respond to your request, we propose the following procedure which, if acceptable to you, we would try for a period of time and then reassess with you.

Whenever the Administrator or I have a meeting or a telephone call with a person outside of the executive branch concerning a proposed EPA rule subject to Executive Order No. 12291, and that meeting or telephone call provides factual information that we are not confident has also been provided to EPA, either the Administrator or I will call the General Counsel of EPA and advise him of the communication and of the relevant factual information. EPA can then do whatever it deems appropriate with regard to the information reported to the General Counsel. Furthermore, with respect to scheduled meetings, if any, we will try for a period of time and for a few rulemakings to provide an opportunity for senior officials of EPA to attend and participate, if they choose to do so. After some experience, we will reassess this procedure, as well.

Please let me know if you believe that we should initiate these procedures.

ROBERT P. BEDELL
Deputy Administrator
Office of Information and Regulatory Affairs

Enclosures

APPENDIX IV

Executive Order No. 12291 Annual Report for 1987

TABLE OF CONTENTS

Exhibits

I. INTRODUCTION

This report provides information on the implementation of President Reagan's Executive Order No. 12291 for the year ending December 31, 1987. It also describes trends in regulatory activity during the past decade.

Executive Order No. 12291, signed on February 17, 1981, established within the Executive branch a mechanism for improving Federal regulatory activities. The purposes of the Executive Order are to control the growth of Federal regulation and to ensure that individual regulations are well reasoned, economically sound, and coordinated with the policies of other agencies. In particular, the Order requires that all new regulations, to the extent permitted by law, adhere to the following principles:

- Agencies must base regulations upon adequate information concerning the need for and the consequences of the proposed action.
- Agencies must not issue regulations unless the potential benefits to society outweigh the potential costs to society.
- Of the alternative approaches to a given regulatory objective, an agency must select the alternative involving the least net cost to society.

To ensure compliance with these principles, the President ordered executive agencies to submit all proposed and final regulations to the Office of Management and Budget (OMB) for review before publication.

These review policies and procedures are conducted within statutory authorities. The Executive Order guides Federal regulatory officials in exercis-

ing the discretion given them by statute. This statutory discretion is often very broad, and may be ambiguous or contradictory, but may be exercised only to the extent permitted by law. Where statutes clearly exclude economic considerations by their terms, any Executive-Order policies to the contrary are overridden. The Order applies to general policymaking, such as "informal rulemaking" under the Administrative Procedure Act. It does not apply to adjudicatory proceedings.

This is the seventh annual report on the Order's implementation. Section II describes the requirements and procedures of the Order. Section III presents detailed information on the types of rules reviewed and the types of actions taken by OMB in 1987. Comparisons are then made between 1987 data and those of 1981 through 1986. Section IV examines the nature and extent of regulatory activity since 1977 by analyzing certain statistics of *Federal Register* activity.

II. IMPLEMENTATION OF THE EXECUTIVE ORDER

The Office of Information and Regulatory Affairs (OIRA) in OMB oversees agency compliance with Executive Order No. 12291. OIRA seeks to ensure, on a day-to-day basis, that agency regulatory activity reflects the President's regulatory policies described in the Order.

OIRA reviews "major" regulations with special attention. Regulations so designated have economic costs of over $100 million annually, or are projected to have significant effects on employment, inflation, or industry viability. A regulatory impact analysis (RIA) must accompany major regulations at both proposed and final rulemaking stages. An RIA assesses the costs and benefits of the action and its alternatives. OMB may waive the RIA requirement in special cases—for example, in order to expedite publication of an emergency regulation. Agencies must submit major proposed rules to OMB at least 60 days before publication, and major final rules at least 30 days before publication.

Executive agencies must transmit nonmajor regulations to OMB at least 10 days prior to planned publication. Executive Order No. 12291 does not require agencies to prepare RIAs for nonmajor actions, but it does require agencies to assure that their rules are consistent with the Executive Order's principles, to the extent permitted by law. Many agencies perform an initial analysis of the economic impact of nonmajor rules if they believe the rule will have a significant effect, or if it will be useful in assessing the impact.

III. REVIEW OF REGULATIONS

A. Types of Rules Reviewed in 1987

OMB reviewed 2,314 agency rules in 1987 under Executive Order No. 12291. Nine agencies accounted for 78 percent of the rules reviewed (see Exhibit 1). These agencies were: the Department of Agriculture (420 rules), the Department of Health and Human Services (314 rules), the Environmental Protection Agency (205 rules), the Department of Transportation (202 rules), the Department of the Interior (186 rules), the Department of Education (174 rules), the Department of Commerce (134 rules), the Office of Personnel Management (97 rules), and the Department of Justice (84 rules).

Exhibit 2 shows the number of rules reviewed during 1987 by each agency. Rules are classified as either proposed or final, and either major or nonmajor. Of the rules OMB reviewed in 1987, 47.3 percent were proposed and 52.7 percent were final. Major rules constituted only 3 percent of all rules. Nonmajor final rules were the predominant type of rule reviewed, constituting 51.4 percent of the total of all rules reviewed. The Environmental Protection Agency had the largest number of major proposed rules (12), followed by the Department of Agriculture (11), and the Department of Labor (3). The Department of Agriculture had the largest number of major final rules (8), followed by the Environmental Protection Agency (7). Exhibit 3 lists by name all major proposed and final regulations reviewed in 1986.

Exhibit 4 displays changes over the last 7 years in the types of rules reviewed. The total number of rules OMB reviewed in 1987 rose 15.4 percent from 1986 but was 17.5 percent lower than the number reviewed in 1981. The number of proposed rules in 1987 increased 35.4 percent from 1986 and 9.9 percent from 1981. The number of final rules reviewed in 1987 rose 1.9 percent from 1986 but dropped 31.2 percent from 1981. The number of major rules in 1987 was 2.8 percent less than the number in 1986, but rose 12.9 percent from 1981. The percentage-change comparisons with 1981 activity understate somewhat the decline in rulemaking actions, since the Executive Order review process operated for less than a full year in 1981.

Exhibit 5 shows, by agency, the number of rules reviewed during each of the last 7 years. Comparing 1987 with 1981, the greatest percentage declines in the total number of rules occurred at the Environmental Protection Agency (−72.1 percent), the Department of Energy (−62.3 percent), the Department of Agriculture (−36.2 percent), and the Department of Transportation (−29.1). The Department of Defense experienced the largest percentage increase since 1981 (325 percent), followed by Health and Human Services (168.4 percent), the Office of Personnel Management (155.3 percent), and the Department of Education (126 percent).

EXHIBIT 1.

EXECUTIVE ORDER 12291
TOTAL REVIEWS - BY AGENCY
1987

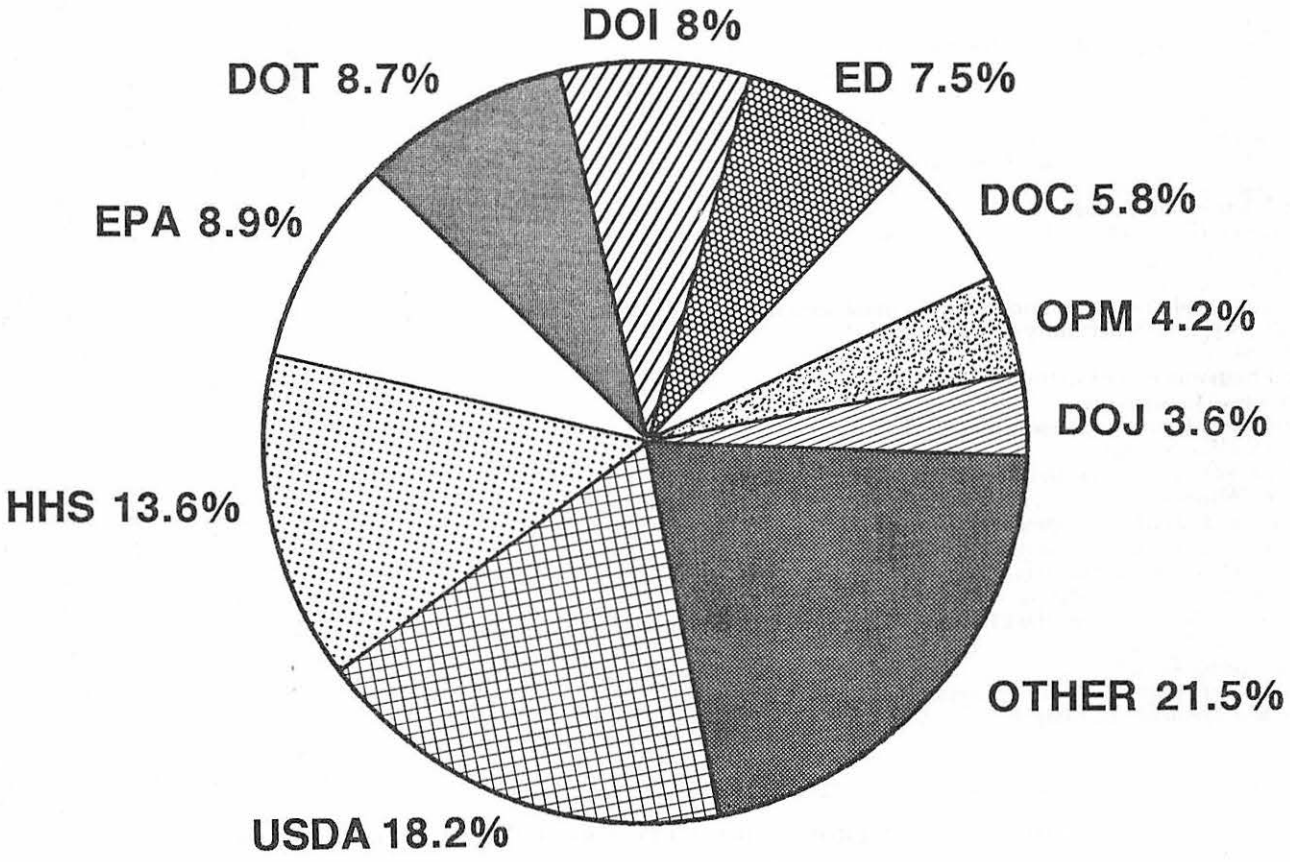

EXHIBIT 2. TYPES OF RULES REVIEWED DURING 1987 BY AGENCY

Agency	Total rules	Nonmajor		Major	
		NPRM	Final	NPRM	Final
Agriculture	420	188	213	11	8
Health and Human Services	314	162	149	2	1
Environmental Protection Agency	205	101	85	12	7
Transportation	202	85	113	2	2
Interior	186	93	90	1	2
Education	174	88	86	0	0
Commerce	134	54	80	0	0
Office of Personnel Management	97	28	69	0	0
Justice	84	37	45	1	1
Veterans Administration	67	37	30	0	0
Housing and Urban Development	64	24	35	3	2
Labor	64	24	34	3	3
General Services Administration	59	13	46	0	0
Treasury	29	13	16	0	0
Federal Emergency Management Agency	26	18	8	0	0
Energy	20	11	9	0	0
State	19	7	12	0	0
Defense	17	7	7	2	1
Small Business Administration	16	8	4	2	2
National Aeronautics and Space Administration	15	2	13	0	0
Other Temporary Commissions	12	3	9	0	0
Railroad Retirement Board	11	8	3	0	0
National Archives and Records Administration	9	4	5	0	0
U.S. Information Agency	8	6	2	0	0
ACTION	7	5	2	0	0
Architectural and Transportation Barriers Compliance Board	7	4	3	0	0
Equal Employment Opportunity Commission	7	2	3	1	1
Peace Corps	5	2	3	0	0
National Endowment for the Humanities	4	4	0	0	0
Panama Canal Commission	4	0	4	0	0
Pension Benefit Guaranty Corporation	4	2	2	0	0
Selective Service System	4	2	2	0	0
United States International Development Cooperation Agency	4	1	3	0	0
Institute of Museum Services	3	1	2	0	0
Pennsylvania Avenue Development Corporation	3	1	2	0	0
Federal Mediation and Conciliation Service	2	2	0	0	0
National Endowment for the Arts	2	2	0	0	0
African Development Foundation	1	1	0	0	0
Committee for Purchase from the Blind and Other Severely Handicapped	1	1	0	0	0
Inter-American Foundation	1	1	0	0	0
National Science Foundation	1	1	0	0	0
Navajo and Hopi Indian Relocation Commission	1	0	1	0	0
Office of Management and Budget	1	1	0	0	0
Total	2,314	1,054	1,190	40	30
Percentage of total	100.0	45.6	51.4	1.7	1.3

EXHIBIT 3. MAJOR PROPOSED AND FINAL RULES REVIEWED DURING 1987

1. Major Proposed Rules

UNITED STATES DEPARTMENT OF AGRICULTURE
- 1988 Wheat Program
- Common Program Provisions
- 1988 Feed Grain Program
- 1988 Upland Cotton Program
- 1987 Crop Soybean Preliminary Loan and Purchase Rate
- Safflower Crop Insurance Corporation
- General Crop Insurance Regulations
- Cranberry Crop Insurance
- Rural Housing Loan Policies
- Operating Loan Policies
- 1988 Rice Program

DEPARTMENT OF DEFENSE
- Champus Organization-Based Payment System
- Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments

DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Capital Payments under the Inpatient Hospital Prospective System
- Tests and Requirements for Certification of Permissibility of Respiratory Protective Devices

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
- Procedure for Calculating Maximum Mortgage Amounts
- Housing Voucher Program
- Housing Voucher Program

DEPARTMENT OF THE INTERIOR
- 1987-88 Migratory Game Bird Hunting

DEPARTMENT OF JUSTICE
- Control of Employment of Aliens

DEPARTMENT OF LABOR
- Davis-Bacon and Related Acts
- Hazardous Waste Operations and Emergency Response
- Electrical Safety-Related Work Practices

DEPARTMENT OF TRANSPORTATION
- Construction-Differential Subsidy Payment
- Light Truck Average Fuel Economy Standards for Model Years 1990-91

ENVIRONMENTAL PROTECTION AGENCY
- Emergency Planning and Community Right-To-Know Programs
- Requirements for Underground Storage Tanks
- RCRA Financial Responsibility for Underground Storage Tanks
- Notification Requirements for Industrial Non-hazardous Facilities
- Residential Wood Heaters
- Volatility for 1989 & Later Commercial Gasoline and Vehicle Evaporation Controls
- Refueling Emission for 1990 & Later Light-Duty Vehicles
- NAAQS — Fine Particulates
- Post-1987 Ozone and Carbon Monoxide Plan
- Protection of Stratospheric Ozone
- Toxic Chemical Release Inventory Form
- Asbestos-Containing Materials in Schools

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
- Pension Accruals Past Normal Retirement Age

SMALL BUSINESS ADMINISTRATION
- Small Business Size Standards
- Disaster Home Loan Program

2. Major Final Rules

UNITED STATES DEPARTMENT OF AGRICULTURE
- Grains and Similarly Handled Commodities
- Conservation Reserve Program
- 1987 Crop Soybean
- 1987 Wheat, Feed Grains, Rice and Cotton Programs
- 1987 Crop Sugar Beets and Sugarcane Price Support Loan Rates
- General Administrative Regulations — Suspension and Debarment
- General Administrative Regulations — Appeals Procedures
- Thrifty Food Plan and Deductions

DEPARTMENT OF DEFENSE
- Civilian Health and Medical Program

DEPARTMENT OF HEALTH AND HUMAN SERVICES
- Limits on Payments for Drugs

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
- Lead-Based Paint Hazard Elimination in FHA and Section 8 Programs
- Lead-Based Paint Hazard Elimination in Community Development Block Grants

DEPARTMENT OF THE INTERIOR
- Frameworks for Selecting Early Hunting Seasons
- Late Season Migratory Bird Hunting

DEPARTMENT OF JUSTICE
- Control of Employment of Aliens

DEPARTMENT OF LABOR
- Standard for Occupational Exposure to Benzene
- Occupational Exposure to Formaldehyde
- Grain Handling Facilities

DEPARTMENT OF TRANSPORTATION
- Intervals for Drydocking and Tailshaft Examinations
- Light Truck Fuel Economy Standards for Model Year 1989

ENVIRONMENTAL PROTECTION AGENCY
- Organic Chemicals, Plastics and Synthetic Fibers
- Coliform Maximum Contaminant Level
- California List
- Emergency and Hazardous Chemical Inventory Forms and Community Right-To-Know Reporting Requirements
- NAAQS — Particulate Matter
- NSPS for Industrial-Commercial-Institutional Steam Generating Units
- Asbestos Containing Materials in Schools

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
- Pension Accruals Past Normal Retirement Age

SMALL BUSINESS ADMINISTRATION
- Loans to State and Local Development Companies
- Disaster Home Loans, Debt Collection

EXHIBIT 4. COMPARISON OF RULES REVIEWED DURING 1981-87 BY TYPE

	Number							Percentage change						
Type of rule	1981	1982	1983	1984	1985	1986	1987	1981-82	1982-83	1983-84	1984-85	1985-86	1986-87	1981-87
Nonmajor:														
Proposed	971	1,024	1,044	945	1,053	783	1,054	5.5	2.0	−9.5	11.4	−25.6	34.6	8.5
Final	1,735	1,528	1,377	1,101	1,100	1,150	1,190	−11.9	−9.9	−20.0	−0.1	4.5	3.5	−31.4
Total	2,706	2,552	2,421	2,046	2,153	1,933	2,244	−5.7	−5.1	−15.5	5.2	−10.2	16.1	−17.1
Major:														
Proposed	24	29	22	33	20	25	40	20.8	−24.1	50.0	−39.4	25.0	60.0	66.7
Final	38	51	39	25	38	47	30	34.2	−23.5	−35.9	52.0	23.7	−36.2	−21.1
Total	62	80	61	58	59	72	70	29.0	−23.8	−4.9	1.7	22.0	−2.8	12.9
All:														
E.O. Not Applicable	35	1	0	0	0	0	0	−97.1	−100.0	NA	NA	NA	NA	−100.0
Proposed	995	1,053	1,066	978	1,073	808	1,094	5.8	1.2	−8.3	9.7	−24.7	35.4	9.9
Final	1,773	1,579	1,416	1,126	1,138	1,197	1,220	−10.9	−10.3	−20.5	1.1	5.2	1.9	−31.2
Total	2,803	2,633	2,482	2,104	2,211	2,005	2,314	−6.1	−5.7	−15.2	5.1	−9.3	15.4	−17.4

EXHIBIT 5. TWENTY MOST ACTIVE RULE-PRODUCING AGENCIES, COMPARISON OF RULES REVIEWED 1981–1987

	Number							Percentage change						
Agency	1981	1982	1983	1984	1985	1986	1987	1981-82	1982-83	1983-84	1984-85	1985-86	1986-87	1981-87
USDA	657	692	551	480	406	418	420	5.3	−20.4	−12.9	−15.4	3.0	0.5	−36.1
HHS	117	272	294	198	212	281	314	132.5	8.1	−32.7	7.1	32.5	11.7	168.4
EPA	734	340	268	302	302	197	205	−53.7	−21.2	12.7	0.0	−34.8	4.1	−72.1
DOT	285	225	225	217	253	196	202	−21.1	0.0	−3.6	16.6	−22.5	3.1	−29.1
DOI	147	248	240	132	161	144	186	68.7	−3.2	−45.0	22.0	−10.6	29.2	26.5
DOC	162	147	121	107	113	129	134	−9.3	−17.7	−11.6	5.6	14.2	3.9	−17.3
ED	77	52	50	104	109	99	174	−32.5	−3.8	108.0	4.8	−9.2	75.8	126.0
OPM	38	49	65	45	69	72	97	28.9	32.7	−30.8	53.3	4.3	34.7	155.3
HUD	74	130	111	108	90	68	64	75.7	−14.6	−2.7	−16.7	−24.4	−5.9	−13.5
VA	69	70	69	70	65	62	67	1.4	−1.4	1.4	−7.1	−4.6	8.1	−2.9
DOL	83	49	49	35	38	56	64	−41.0	0.0	−28.6	8.6	47.4	14.3	−22.9
DOJ	53	51	72	46	78	46	84	−3.8	41.2	−36.1	69.6	−41.0	82.6	58.5
GSA	56	62	85	62	85	41	59	10.7	37.1	−27.1	37.1	−51.8	43.9	5.4
SBA	10	16	20	31	19	30	16	60.0	25.0	55.0	−38.7	57.9	−46.7	60.0
FEMA	16	6	29	16	26	24	26	−62.5	383.3	−44.8	62.5	−7.7	8.3	62.5
TREAS	34	33	53	44	26	21	29	−2.9	60.6	−17.0	−40.9	−19.2	38.1	−14.7
DOE	53	49	34	25	19	16	20	−7.5	−30.6	−26.5	−24.0	−15.8	25.0	−62.3
NASA	10	11	13	11	25	15	15	10.0	18.2	−15.4	127.3	−40.0	0.0	50.0
NARA	NA	NA	NA	NA	9	13	9	NA	NA	NA	NA	44.4	−30.8	NA
DOD	4	9	13	7	17	9	17	125.0	44.4	−46.2	142.9	−47.1	88.9	325.0

B. Types of Actions Taken on Rules

Exhibits 6 through 9 summarize the actions taken on agency rules under Executive Order No. 12291 during 1987. Exhibit 10 compares OMB's action during 1987 with actions in previous years.

Exhibit 6 shows the number of rules in these categories that OMB reviewed during 1987 by each agency. Of the 2,314 rules reviewed during 1987, OMB found that 70.5 percent were consistent with the principles of the Executive Order as submitted, 23.7 percent were consistent with the Order after the agency adopted changes during the review period, 0.4 percent were inconsistent with the Order and returned to the agency for reconsideration, and another 2.5 percent were withdrawn by agencies. Emergency rules and rules subject to statutory or judicial deadlines constituted 2.5 percent of all 1987 rules, and 0.2 percent were sent improperly or were exempt.

Exhibit 7 shows the percentage of rules in each category for the 20 most active rulemaking agencies.

Exhibit 8 lists by name each of the 10 rules returned for reconsideration in 1987. Exhibit 9 lists by name each of the 59 rules withdrawn by agencies during OMB review in 1987. OMB may return regulations for reconsideration if it finds them to be inconsistent with the principles of the Executive Order. Agencies may withdraw rules during review because they have concluded that the rules are inconsistent with the Executive Order or for other reasons. An agency may, for example, wish to incorporate newly acquired information into a rule.

Exhibit 10 compares OMB actions on agency rules during the past seven years. The percentage of rules OMB found consistent with the Executive Order declined rather steadily, from 87.3 percent in 1981 to 68.3 percent in 1986, but increased slightly to 70.5 percent in 1987. At the same time, the percentage of rules OMB found consistent after change increased sharply, from 4.9 percent in 1981 to 23.7 percent in 1987. The percentage of rules that agencies withdrew through 1985 increased to 3.1 percent from 1.8 percent in 1981, then declined to 2.5 percent in 1987. The percentage of rules that OMB returned for agency reconsideration has fluctuated over the years but reached a low point of 0.4 percent in 1987 compared to 1.6 percent in 1981. Through 1985, the percentage of rules issued by agencies under emergency, statutory, or judicial deadlines did not appreciably change from the 1.4 percent recorded in 1981, but it increased significantly in 1986 to 4.3 percent before declining to 2.5 percent in 1987.

Exhibit 11 shows OMB's average regulatory review time by agency from 1981 to 1987 for all major and nonmajor rules. Generally, review time for major rules is longer than for nonmajor rules because of their greater complexity and importance. In 1981 OMB's average review time for all major rules was 13 days; in 1987, it was 32 days. OMB's average review time in 1981 for nonmajor rules was 9 days, as compared with an average of 25 days in 1987. The 1987 average review time for all rules was 25 days—slightly higher than 1986's average of 24 days.

C. Exemptions

Executive Order No. 12291 authorizes the Director of OMB to exempt classes of regulations from any or all of the requirements of the Order. The exemptions granted by OMB fall into four broad categories: (1) rules that are essentially nonregulatory; (2) rules that delegate regulatory authority to States; (3) rules that largely or entirely affect individual entities and that do not involve broader policy issues; and

(4) rules for which a delay of even a few days could impose substantial costs and that are unlikely to involve significant policy issues.

At the end of 1987, OMB had granted a total of 29 exemptions (some covering more than one of the categories above) to eight agencies. Exhibit 12 lists these exemptions. Most of the exemptions were established during the initial years of the operation of the Executive Order. In each case, OMB determined that the exempted regulations, as a class, were consistent with the goals and requirements of the Executive Order. OMB continues to review all major rules as defined by the Executive Order regardless of class exemptions. OMB may request that agencies submit specific rules within an exempt class and may revoke exemptions at any time.

IV. TRENDS IN REGULATORY ACTIVITY

Because there are no precise or agreed-upon measures of regulatory activity, we cannot measure the precise effect Executive Order No. 12291 has had on regulatory activity. It is useful, however, to compare the number of pages and the number of total rule documents (proposed-rule documents plus final-rule documents) published in the *Federal Register* during different time periods.

Exhibit 13 shows the number of pages published in the *Federal Register* from its inception in 1936 through 1987. There was little year-to-year change until the 1970s, when the size of the *Federal Register* increased dramatically. But in 1981, the year Executive Order No. 12291 went into effect, the growth in the *Federal Register* ended.

In fact the exhibit shows that since 1981, with but two exceptions, the size of the *Federal Register* has declined precipitously on an annual basis. In 1981 through 1984, the number of pages published in the *Federal Register* decreased—there were 41.4 percent fewer pages in the *Federal Register* in 1984 than in 1980. In 1985, the number of pages rose modestly by 4.87 percent over 1984 levels. But in 1986, the number of *Federal Register* pages declined 11.3 percent to its lowest level since 1974. In 1987 the number of published pages increased 4.7 percent above the 1986 level. Nevertheless, the overall trend of the past seven years is significantly downward sloping.

Exhibit 14 further depicts the effects of Executive Order No. 12291 on the size of the *Federal Register*. It does this by showing the number of pages published in the *Federal Register* each month since 1977. The dramatic break with the upward trend in the 1970s is clearly evident.

Exhibit 15 depicts the total number of proposed and final rule documents published since 1977. This chart parallels the exhibit for pages published. It also indicates that since Executive Order No. 12291 was issued, Federal regulatory activity as represented by documents issued has decreased.

Exhibits 16, 17, and 18 provide various measures of regulatory activity since 1980.

EXHIBIT 6. TYPES OF ACTIONS TAKEN ON AGENCY RULES DURING 1987

Agency	Total reviews	Consistent without change	Consistent with change	Withdrawn by agency	Returned for reconsideration	Returned sent improperly	Emergency	Statutory or judicial deadline
Agriculture	420	345	58	5	2	0	6	4
Health and Human Services	314	187	114	12	0	1	0	0
Environmental Protection Agency	205	123	60	9	0	1	0	12
Transportation	202	127	64	7	4	0	0	0
Interior	186	153	28	2	0	0	1	2
Education	174	106	64	4	0	0	0	0
Commerce	134	96	11	1	0	0	5	21
Office of Personnel Management	97	89	3	3	2	0	0	0
Justice	84	71	13	0	0	0	0	0
Veterans Administration	67	48	19	0	0	0	0	0
Labor	64	31	31	0	0	0	1	1
Housing and Urban Development	64	38	14	7	1	0	0	4
General Services Administration	59	41	15	3	0	0	0	0
Treasury	29	21	7	0	1	0	0	0
Federal Emergency Management Agency	26	14	10	2	0	0	0	0
Energy	20	12	8	0	0	0	0	0
State	19	15	2	1	0	1	0	0
Defense	17	13	4	0	0	0	0	0
Small Business Administration	16	9	6	0	0	0	1	0
National Aeronautics and Space Administration	15	11	4	0	0	0	0	0
Other Temporary Commissions	12	8	3	1	0	0	0	0
Railroad Retirement Board	11	7	1	1	0	2	0	0
National Archives and Records Administration	9	8	0	0	0	0	1	0
U.S. Information Agency	8	7	1	0	0	0	0	0
ACTION	7	6	1	0	0	0	0	0
Architectural and Transportation Barriers Compliance Board	7	5	1	1	0	0	0	0
Equal Employment Opportunity Commission	7	5	1	0	0	0	0	1
Peace Corps	5	5	0	0	0	0	0	0
National Endowment for the Humanities	4	3	1	0	0	0	0	0
Panama Canal Commission	4	3	1	0	0	0	0	0
Pension Benefit Guaranty Corporation	4	4	0	0	0	0	0	0
Selective Service System	4	3	1	0	0	0	0	0
U.S. International Development Corporation	4	3	1	0	0	0	0	0
Institute of Museum Services	3	3	0	0	0	0	0	0
Pennsylvania Avenue Development Corporation	3	3	0	0	0	0	0	0
Federal Mediation and Conciliation Service	2	2	0	0	0	0	0	0
National Education Administration	2	1	1	0	0	0	0	0
African Development Fund	1	1	0	0	0	0	0	0
Committee for Purchase from the Blind and Other Severely Handicapped	1	1	0	0	0	0	0	0
Inter-American Foundation	1	1	0	0	0	0	0	0
Navajo and Hopi Commission	1	0	1	0	0	0	0	0
National Science Foundation	1	1	0	0	0	0	0	0
Office of Management and Budget	1	1	0	0	0	0	0	0
Total	2,314	1,631	549	59	10	5	15	45
Percentage of total	100.0	70.5	23.7	2.5	0.4	0.2	0.6	1.9

EXHIBIT 7. TYPES OF ACTIONS TAKEN ON AGENCY RULES DURING 1987 BY PERCENTAGE

Agency	Total reviews	Percentage						
		Consistent without change	Consistent with change	Withdrawn by agency	Returned for reconsideration	Returned sent improperly	Emergency	Statutory or judicial deadline
Agriculture	420	82.1	13.8	1.2	0.5	0.0	1.4	1.0
Health and Human Services	314	59.6	36.3	3.8	0.0	0.3	0.0	0.0
Environmental Protection Agency	205	60.0	29.3	4.4	0.0	0.5	0.0	5.9
Transportation	202	62.9	31.7	3.5	2.0	0.0	0.0	0.0
Interior	186	82.3	15.1	1.1	0.0	0.0	0.5	1.1
Education	174	60.9	36.8	2.3	0.0	0.0	0.0	0.0
Commerce	134	71.6	8.2	0.7	0.0	0.0	3.7	15.7
Office of Personnel Management	97	91.8	3.1	3.1	2.1	0.0	0.0	0.0
Justice	84	84.5	15.5	0.0	0.0	0.0	0.0	0.0
Veterans Administration	67	71.6	28.4	0.0	0.0	0.0	0.0	0.0
Labor	64	48.4	48.4	0.0	0.0	0.0	1.6	1.6
Housing and Urban Development	64	59.4	21.9	10.9	1.6	0.0	0.0	6.3
General Services Administration	59	69.5	25.4	5.1	0.0	0.0	0.0	0.0
Treasury	29	72.4	24.1	0.0	3.4	0.0	0.0	0.0
Federal Emergency Management Agency	26	53.8	38.5	7.7	0.0	0.0	0.0	0.0
Energy	20	60.0	40.0	0.0	0.0	0.0	0.0	0.0
Defense	17	76.5	23.5	0.0	0.0	0.0	0.0	0.0
Small Business Administration	16	56.3	37.5	0.0	0.0	0.0	6.3	0.0
National Aeronautics and Space Administration	15	73.3	26.7	0.0	0.0	0.0	0.0	0.0
National Archives and Records Administration	9	88.9	0.0	0.0	0.0	0.0	11.1	0.0
All Other	112	78.6	14.3	3.6	0.0	2.7	0.0	0.9
Total	2,314	70.5	23.7	2.5	0.4	0.2	0.6	1.9

EXHIBIT 8. REGULATIONS RETURNED TO AGENCIES FOR RECONSIDERATION DURING 1987

Agency/Title of regulation	Type	Received	Reviewed
United States Department of Agriculture:			
Reimbursing Workfare's administrative costs	Final	12/17/85	06/25/87
Food Stamp Program: administrative review process	Final	04/06/87	11/19/87
Department of Housing and Urban Development:			
Housing Voucher Program	NPRM	04/16/87	06/15/87
Department of Transportation:			
Powered Ultralights, airman certification requirements	NPRM	11/27/85	02/18/87
Ultralight aircraft registration and markings	NPRM	03/18/86	02/18/87
Cargo preference	Final	02/12/87	03/23/87
Cargo preference	Final	05/29/87	06/05/87
Treasury Department:			
Country of origin marking	NPRM	07/17/87	11/27/87
Office of Personnel Management			
Service and enrollment areas for comprehensive medical plans	NPRM	01/09/87	07/29/87
Federal Employees Retirement System—disability retirement	NPRM	03/25/87	12/18/87

EXHIBIT 9. REGULATIONS WITHDRAWN BY AGENCIES DURING 1987

Agency/Title of regulation	Rule Type	Date Received	Date Withdrawn
United States Department of Agriculture:			
Animal Welfare—Definition of Terms	NPRM	12/15/86	02/06/87
Animal Welfare—Regulations	NPRM	12/12/86	02/06/87
Food Stamp Program—Demonstration and Evaluation Project Agenda	NPRM	11/17/86	02/20/87
Food Stamp Program—Income and Resource Eligibility and Verification	NPRM	02/11/87	04/20/87
Service Community Program Loans Sold to the Private Sector	NPRM	08/20/87	08/21/87
Department of Commerce:			
Electronic Data Dissemination Policies and Guidelines	NPRM	05/08/87	07/10/87
Department of Education:			
Territorial Teacher Training Assistance Program	NPRM	03/24/87	05/07/87
Transition Program for Refugee Children	NPRM	02/26/87	05/29/87

EXHIBIT 9. REGULATIONS WITHDRAWN BY AGENCIES DURING 1987—Continued

Agency/Title of regulation	Rule Type	Date Received	Date Withdrawn
Formula Grants—Local Educational Agencies and Tribal Schools	NPRM	03/20/87	07/10/87
Pell Grant Program	Final	06/29/87	07/23/87
Department of Health and Human Services:			
Area Health Education Center Progam	Final	11/25/86	02/10/87
Scholarship Eligibility Under Indian Health Scholarship Program	NPRM	01/30/87	03/09/87
Effect of Pension from Noncovered Employment	Final	02/03/87	03/24/87
Covered Surgical Procedures for Ambulatory Surgical Centers	NPRM	03/20/87	04/21/87
Presumptive Disability, Categories of Impairments—AIDS	Final	06/15/87	07/21/87
Presumptive Disability, Categories of Impairments—Renal Disease	NPRM	06/15/87	08/12/87
Health Education Assistance Program—Stay of Litigation Requirement	NPRM	08/04/87	08/14/87
Recognition of College of American Pathologists Accreditation Program	NPRM	04/13/87	08/24/87
Supplementary Payments to Individuals in Medicaid Facilities	Final	06/19/87	09/21/87
Supplemental Security Income for the Aged, Blind, and Disabled	NPRM	06/15/87	09/27/87
Alertness Aid Drug Products for Over-the-Counter Human Use	Final	07/17/87	10/19/87
Utilization and Quality Control Peer Review Program	NPRM	10/26/87	11/25/87
Department of Housing and Urban Development:			
Procedure for Calculating Maximum Mortgage Amounts	NPRM	01/30/87	05/04/87
Manufactured Home Construction—Vapor Barrier Penetration	NPRM	02/10/87	05/28/87
Condominium Ownership Mortgage Insurance	Final	06/24/87	07/02/87
Manufactured Home Construction and Safety Standards	Final	08/05/87	08/07/87
Manufactured Home Design Inspection System	NPRM	06/11/87	08/19/87
Increase in the Single-Person Occupancy Limitation	NPRM	08/26/87	11/25/87
HUD-Determined Maintenance Wage Rates	NPRM	10/22/87	11/25/87
Department of the Interior:			
Financial Assistance and Social Services Program	NPRM	05/08/87	09/14/87
Special Grants for Economic Development	NPRM	01/07/87	11/05/87
State Department			
Ineligible Classes of Aliens—Immigration and Nationality Act	Final	03/02/87	04/15/87
Department of Transportation:			
Daytime Running Lamps	NPRM	01/07/87	01/14/87
Administration of Contracts	NPRM	01/30/87	04/08/87
Automatic Train Control, Northeast Corridor Carriers	NPRM	05/07/87	05/18/87
Reporting Unsafe Conditions on Gas and Hazardous Liquid Pipelines	NPRM	07/10/87	07/14/87
Report of Financial Data for Commuter Carriers	NPRM	08/05/87	08/10/87
Counting UMTA Reduced-Fare Program Costs Toward 504 Cost Cap	NPRM	09/08/87	09/18/87
Truck Size and Weight, Reasonable Access	NPRM	11/27/87	12/01/87
Environmental Protection Agency:			
Colorado Carbon Monoxide Plan for the Denver Area	NPRM	05/27/87	06/16/87
Disapproval of Atlanta O_3-State Implementation Plan	NPRM	05/28/87	06/16/87
Notification Requirements—Industrial Nonhazardous Disposal Facility	NPRM	06/30/87	08/12/87
Stack Height Emissions Balancing	Final	06/16/87	06/26/87
Fuel Economy Test	Final	09/04/87	09/09/87
Reportable Quantity Adjustments—Saccharin	Final	10/22/87	12/07/87
NSPS—Sewage Treatment Plants	Final	06/30/87	09/17/87
Small-Volume Manufacturer Certification	NPRM	09/18/87	12/18/87
America Mining Congress v. EPA Interpretation	Final	10/28/87	12/08/87
Architectural and Transportation Barriers Compliance Board:			
Information Availability—Procedures	NPRM	03/24/87	04/02/87
Federal Emergency Management Agency:			
Guidance for Implementing Disaster Relief Act Amendments of 1974	NPRM	02/02/87	02/10/87
Administration of Grants, Audits of State and Local Governments	Final	11/25/87	12/03/87
General Services Administration:			
GSA Board of Contract Appeals ADP Protests	Final	07/02/86	03/05/87
Electronic Recordkeeping	NPRM	12/24/86	10/15/87
Centralized Services in Federal Buildings	Final	08/29/86	11/18/87
Office of Personnel Management:			
Special Provisions for Certain Annuitants Employed by INS	Final	06/12/87	12/03/87
Severance Pay	NPRM	02/26/87	12/10/87
Severance Pay	NPRM	11/06/87	12/18/87
Other Temporary Commissions:			
Nondiscrimination on the Basis of Handicap	NPRM	01/20/87	01/29/87
Railroad Retirement Board:			
Determining Disability	NPRM	04/06/87	10/07/87

EXHIBIT 10. TYPES OF ACTIONS TAKEN ON AGENCY RULES—PERCENTAGE COMPARISON 1981–1987

Action taken	Percentage in							Percentage change						
	1981	1982	1983	1984	1985	1986	1987	81-82	82-83	83-84	84-85	85-86	86-87	81-87
Consistent without change....	87.3	84.1	82.3	78.0	70.7	68.3	70.5	−3.2	−1.8	−4.3	−7.3	−2.4	2.2	−16.8
Consistent with change.....	4.9	10.3	12.7	15.1	23.1	22.9	23.7	5.4	2.4	2.4	8.0	−0.2	0.8	18.8
Withdrawn by agency.....	1.8	1.2	1.6	2.4	3.1	2.8	2.5	−0.6	0.4	0.8	0.7	−0.3	−0.3	0.7
Returned for reconsideration..	1.6	2.1	1.3	2.7	1.5	1.4	0.4	0.5	−0.8	1.4	−1.2	−0.1	−1.0	−1.2
Sent improperly or exempt....	3.1	0.9	0.0	0.0	0.3	0.2	0.2	−2.2	−0.9	0.0	0.3	−0.1	0.0	−2.9
Emergency, statutory, or judicial deadline.....	1.4	1.4	2.0	1.7	1.2	4.3	2.5	0.0	0.6	−0.3	−0.5	3.1	−1.8	1.1
Total (column entries are rounded figures)	100.1	100.0	99.9	99.9	99.9	99.9	99.8							

EXHIBIT 11. AVERAGE REVIEW TIME OF RULES UNDER EXECUTIVE ORDER NO. 12291
(in days)

	1981			1982			1983			1984		
	Major	Nonmajor	All	Major	Nonmajor	All	Major	Nonmajor	All	Major	Nonmajor	All
USDA	22	8	8	17	10	10	15	13	13	11	19	19
DOC	8	8	8	22	9	10	5	11	11	316	14	17
DOD	NA	9	9	NA	6	6	NA	16	16	NA	30	30
ED	NA	8	8	32	12	13	NA	11	11	39	18	19
DOE	7	7	7	26	6	7	45	7	9	77	9	12
HHS	8	7	7	21	10	11	35	18	19	3	33	33
HUD	NA	14	14	NA	11	11	12	15	15	10	18	17
DOI	6	8	8	13	10	10	12	17	17	7	17	17
DOJ	NA	6	6	NA	7	7	NA	14	14	NA	10	10
DOL	26	6	9	37	10	12	121	18	29	NA	43	43
STATE	NA	9	9	NA	7	7	28	10	16	NA	5	5
DOT	8	8	8	37	12	12	24	15	15	42	20	21
TREAS	1	8	8	60	13	14	NA	12	12	17	18	18
EPA	12	9	9	88	17	19	14	22	22	58	30	31
Other agencies	5	10	10	40	13	14	35	14	14	26	20	20
All government	13	9	9	28	11	12	28	15	16	31	22	22

	1985			1986			1987			1981-87		
	Major	Nonmajor	All	Major	Nonmajor	All	Major	Nonmajor	All	Major	Nonmajor	All
USDA	15	19	19	13	18	18	18	19	19	16	14	14
DOC	NA	12	12	127	15	15	NA	19	19	41	12	13
DOD	NA	30	30	30	28	28	4	12	11	11	20	19
ED	NA	16	16	14	13	13	NA	15	15	34	14	14
DOE	30	7	8	34	15	17	NA	24	24	31	9	10
HHS	74	46	47	19	37	36	24	38	38	33	28	28
HUD	NA	27	27	44	32	33	33	21	22	24	19	19
DOI	5	19	19	7	11	11	12	20	19	9	15	14
DOJ	NA	9	9	NA	8	8	2	6	6	2	9	9
DOL	173	55	61	76	47	49	91	52	54	71	34	37
STATE	NA	16	16	NA	5	5	NA	12	12	28	10	10
DOT	80	34	36	32	19	19	21	32	31	39	20	21
TREAS	16	13	13	NA	7	7	NA	16	16	24	13	13
EPA	78	33	35	41	41	41	49	35	37	58	22	23
Other agencies	105	23	25	74	24	25	37	26	26	45	19	19
All government	64	26	27	29	24	24	32	25	25	32	18	19

EXHIBIT 12. AGENCY RULES EXEMPTED FROM REVIEW PROCEDURES

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service—Special Nutrition program notices that revise reimbursement rates and eligibility criteria for the School Lunch, Child Care Food, and other nutrition programs.

Food and Nutrition Service—Food Stamp program notices that set eligibility criteria and deduction policies.

Agricultural Marketing Service—Regulations that establish voluntary standards for grading the quality of food.

Animal and Plant Health Inspection Service—Rules and notices concerning quarantine actions and related measures to prevent the spread of animal and plant pests and diseases.

Animal and Plant Health Inspection Service—Rules affirming actions taken on an emergency basis if no adverse comments were received.

Rural Electrification Administration—Rules concerning standards and specifications for construction and materials.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration—Certain time-sensitive preseason and in-season Fishery Management Plan regulatory actions that set restrictions on fishing seasons, catch size, and fishing gear.

DEPARTMENT OF ENERGY

Power Marketing Administrations—Regulations issued by various power administrations relating to the sale of electrical power that they produce or market.

DEPARTMENT OF THE INTERIOR

Office of Surface Mining—Actions to approve, or conditionally approve, State regulatory mining actions or amendments to such actions.

Office of Surface Mining—Approval of State mining reclamation plans or amendments.

Office of Surface Mining—Cooperative agreements between OSM and States.

United States Fish and Wildlife Service—Certain parts of the annual migratory bird hunting regulations.

DEPARTMENT OF TRANSPORTATION

All Offices of DOT—Amendments that postpone the compliance dates of regulations already in effect.

Coast Guard—Regatta regulations, safety zone regulations, and security zone regulations.

Coast Guard—Anchorage, drawbridge operations, and inland waterways navigation regulations.

Coast Guard—Regulations specifying amount of separation required between cargoes containing incompatible chemicals.

Federal Aviation Administration—Standard instrument approach procedure regulations, en route altitude regulations, routine air space actions, and airworthiness directives.

National Highway Traffic Safety Administration—Federal Motor Vehicle Safety Standard 109 table of tire sizes.

DEPARTMENT OF THE TREASURY

Internal Revenue Service, Bureau of Alcohol, Tobacco and Firearms, and Customs Service—Revenue rulings and procedures, Customs decisions, legal determinations, and other similar ruling documents. Major legislative regulations are covered fully.

ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticides and Toxic Substances—Actions regarding pesticide tolerances, temporary tolerances, tolerance exemptions and food additives regulations, except those that make an existing tolerance more stringent.

Office of Pesticides and Toxic Substances—Unconditional approvals of TSCA Section 5 test marketing exemptions, and of experimental use permits under FIFRA.

Office of Pesticides and Toxic Substances—Decision documents defining and establishing registration standards; decision documents and termination decisions for the RPAR process; and data call-in requests made under Section 3(c)(2)(B) of FIFRA.

Office of Air, Noise, and Radiation—Rules that unconditionally approve revisions to State Implementation Plans.

Office of Air, Noise, and Radiation—Unconditional approvals of equivalent methods for ambient air quality monitoring, and of NSPS, NESHAPS, and PSD delegations to States; approvals of carbon monoxide and nitrogen oxide waivers; area designations of air quality planning purposes; and deletions from the NSPS source categories list.

Office of Water—Unconditional approvals of State Water Standards.

Office of Water—Unconditional approval of State underground injection control programs; delegations of NPDES authority to States; deletions from the 307(a) list of toxic pollutants; and suspensions of Toxic Testing Requirements under NPDES.

Office of Solid Waste and Emergency Response—Unconditional approvals of State authorization under RCRA, of State solid waste management plans, and of hazardous waste delisting petitions under RCRA.

PENSION BENEFIT GUARANTY CORPORATION

Interest Rates—Changes in interest rates on late premium payments and delinquent employer liability payments under Sections 6601 and 6621 of the Internal Revenue Code as amended by the Tax Equity and Fiscal Responsibility Act of 1982.

GOVERNMENTWIDE

Office of Federal Procurement Policy—All regulations, except those concerning acquisition of automatic data processing and telecommunications equipment; those implementing and supplementing Federal Acquisition Regulation Subparts 15.6 (Source Selection) and 32.5 (Progress Payments Based on Costs); and those implementing and supplementing the Competition in Contracting Act of 1984 (Public Law 98-3691), the Defense Procurement Reform Act of 1984 (Title XII, Public Law 98-525), and the Small Business and Federal Procurement Competition Enforcement Act of 1984 (Public Law 98-577).

EXHIBIT 13.

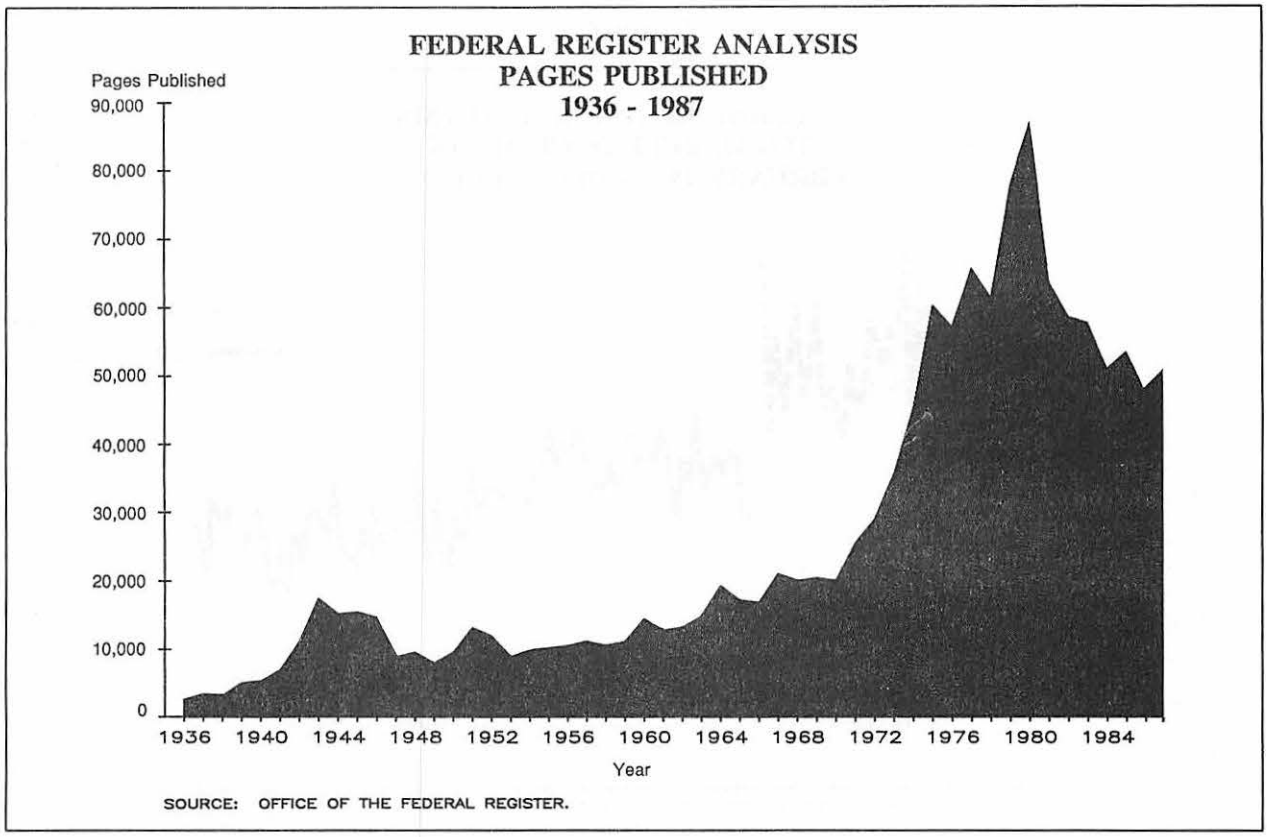

EXHIBIT 14.

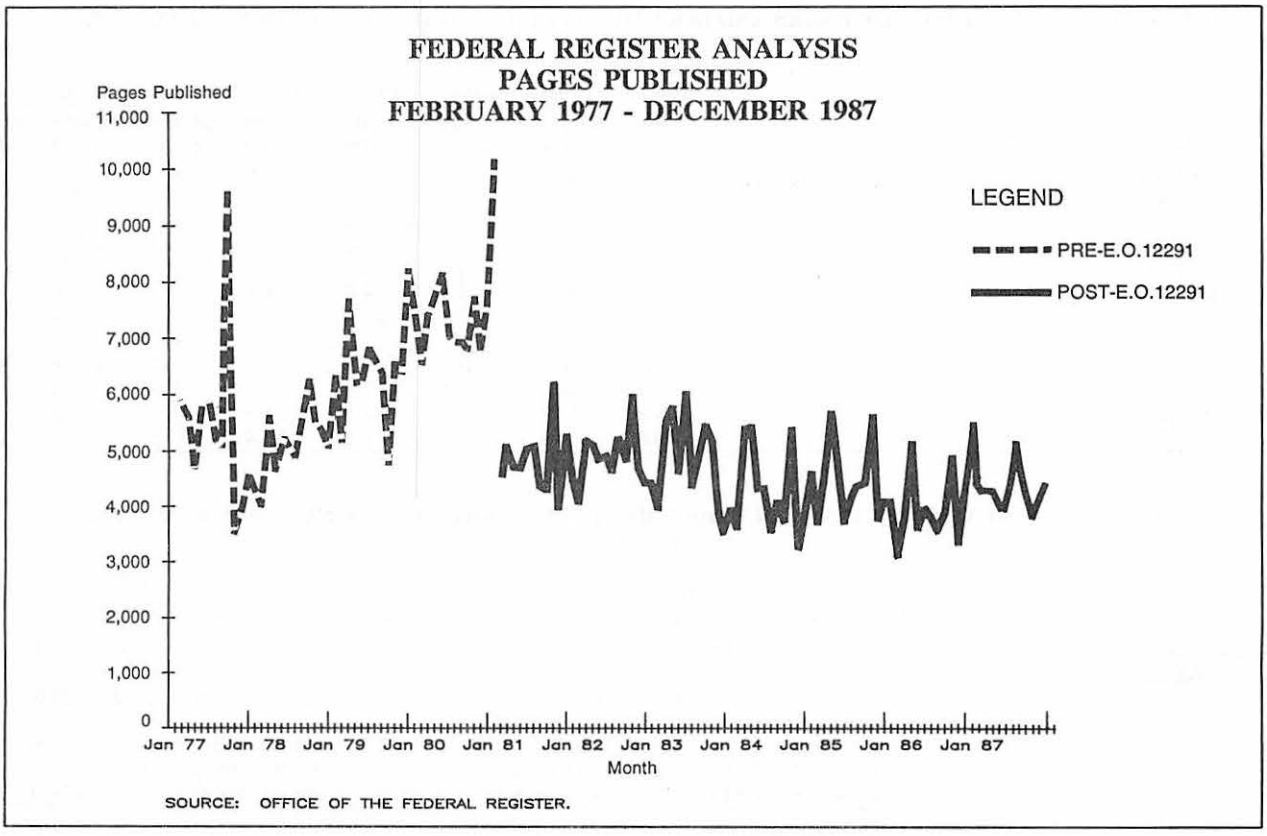

EXHIBIT 15.

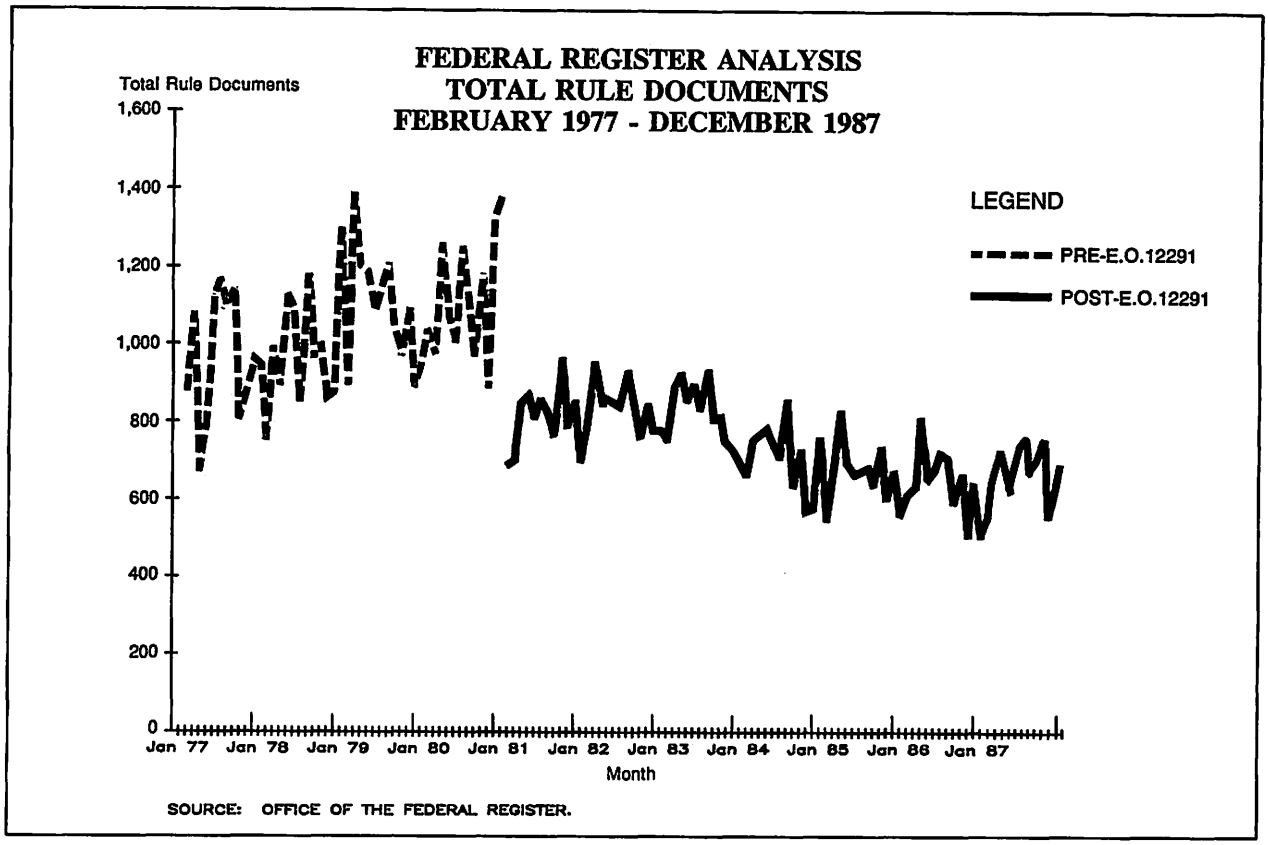

EXHIBIT 16. COMPARISON OF PAGES AND DOCUMENTS PUBLISHED IN THE *FEDERAL REGISTER*
1980–1987

	1980	1981	1982	1983	1984	1985	1986	1987
Total pages published	87,012	63,554	58,494	57,704	50,998	53,480	47,418	49,654
Average pages per month	7,251	5,296	4,875	4,809	4,250	4,457	3,952	4,138
Percentage change year to year	NA	−27.0	− 8.0	− 1.4	−11.6	4.9	−11.3	4.7
Percentage change from 1980	NA	−27.0	−32.8	−33.7	−41.4	−38.5	−45.5	−42.9
Proposed rule documents	5,347	3,862	3,729	3,906	3,350	3,381	3,185	3,423
Average documents per month	446	322	311	326	279	282	265	285
Percentage change year to year	NA	−27.8	− 3.4	4.7	−14.2	0.9	− 5.8	7.5
Percentage change from 1980	NA	−27.8	−30.3	−26.9	−37.3	−36.8	−40.4	−36.0
Final rule documents	7,745	6,401	6,288	6,049	5,155	4,843	4,589	4,581
Average documents per month	645	533	524	504	430	404	382	382
Percentage change year to year	NA	−17.4	− 1.8	− 3.8	−14.8	− 6.1	− 5.2	− 0.2
Percentage change from 1980	NA	−17.4	−18.8	−21.9	−33.4	−37.5	−40.7	−40.9

EXHIBIT 17. ANALYSIS OF FINAL RULE DOCUMENTS PUBLISHED IN THE *FEDERAL REGISTER*
1982–1987

	Final Rules						Percentage of Total					
	1987	1986	1985	1984	1983	1982	1987	1986	1985	1984	1983	1982
New requirements	451	366	358	260	248	294	9.8	7.6	7.4	5.0	4.1	4.7
Revision to existing requirements	1,241	1,267	1,255	1,350	1,430	1,530	27.1	24.2	25.9	26.2	23.6	24.3
Elimination of existing requirements	85	142	177	162	217	299	1.9	3.3	3.7	3.1	3.6	4.8
All other	2,804	2,814	3,053	3,383	4,154	4,165	61.2	64.9	63.0	65.6	68.7	66.2
Total	4,581	4,589	4,843	5,155	6,049	6,288	100.0	100.0	100.0	100.0	100.0	100.0

EXHIBIT 18. FINAL RULE DOCUMENTS BY AGENCY PUBLISHED IN THE *FEDERAL REGISTER* 1982–1987

Agency	Number of documents						Percentage of documents					
	1987	1986	1985	1984	1983	1982	1987	1986	1985	1984	1983	1982
Agriculture	556	554	611	684	638	674	11.3	11.1	11.8	12.9	10.5	10.6
Commerce	285	292	254	202	213	205	5.8	5.9	4.9	3.8	3.5	3.2
Defense	172	198	113	102	109	111	3.5	4.0	2.2	1.9	1.8	1.8
Education	68	51	40	35	25	36	1.4	1.0	0.8	0.7	0.4	0.6
Energy	15	21	14	27	37	52	0.3	0.4	0.3	0.5	0.6	0.8
Health and Human Services	380	405	450	422	573	561	7.7	8.1	8.7	8.0	9.5	8.9
Housing and Urban Development	89	95	96	141	128	124	1.8	1.9	1.9	2.7	2.1	2.0
Interior	246	240	258	320	461	477	5.0	4.8	5.0	6.0	7.6	7.5
Justice	122	116	108	113	159	102	2.5	2.3	2.1	2.1	2.6	1.6
Labor	56	55	68	56	63	63	1.1	1.1	1.3	1.1	1.0	1.0
State	18	12	7	7	8	15	0.4	0.2	0.1	0.1	0.1	0.2
Transportation	859	923	903	748	865	908	17.4	18.5	17.4	14.1	14.3	14.3
Treasury	184	236	219	247	244	180	3.7	4.7	4.2	4.7	4.0	2.8
Environmental Protection Agency	438	487	518	624	605	805	8.9	9.8	10.0	11.8	10.0	12.7
Equal Employment Opportunity Commission	18	8	13	14	16	7	0.4	0.2	0.3	0.3	0.3	0.1
Federal Emergency Management Agency	66	71	84	91	261	398	1.3	1.4	1.6	1.7	4.3	6.3
Government Services Administration	83	74	107	74	95	80	1.7	1.5	2.1	1.4	1.6	1.3
National Aeronautics and Space Administration	33	36	28	15	20	18	0.7	0.7	0.5	0.3	0.3	0.3
Office of Management and Budget	2	0	0	1	2	1	0.0	0.0	0.0	0.0	0.0	0.0
Office of Personnel Management	74	44	39	38	43	25	1.5	0.9	0.8	0.7	0.7	0.4
Small Business Administration	14	34	26	39	26	26	0.3	0.7	0.5	0.7	0.4	0.4
Veterans Administration	49	51	49	54	53	54	1.0	1.0	0.9	1.0	0.9	0.9
Other	257	275	241	261	335	337	5.2	5.5	4.7	4.9	5.5	5.3
Commodity Futures Trading Commission	25	19	32	38	51	19	0.5	0.4	0.6	0.7	0.8	0.3
Consumer Product Safety Commission	8	9	17	30	22	25	0.2	0.2	0.3	0.6	0.4	0.4
Federal Communications Commission	444	306	400	405	359	393	9.0	6.1	7.7	7.7	5.9	6.2
Federal Deposit Insurance Corporation	16	16	14	20	24	17	0.3	0.3	0.3	0.4	0.4	0.3
Federal Energy Regulatory Commission	95	82	127	139	156	120	1.9	1.6	2.5	2.6	2.6	1.9
Federal Home Loan Bank Board	30	29	39	32	41	53	0.6	0.6	0.8	0.6	0.7	0.8
Federal Maritime Commission	17	6	9	43	19	26	0.3	0.1	0.2	0.8	0.3	0.4
Federal Reserve System	32	28	40	37	66	75	0.6	0.6	0.8	0.7	1.1	1.2
Federal Trade Commission	49	77	84	82	116	80	1.0	1.5	1.6	1.6	1.9	1.3
Interstate Commerce Commission	48	51	59	53	103	127	1.0	1.0	1.1	1.0	1.7	2.0
Nuclear Regulatory Commission	47	36	49	42	55	51	1.0	0.7	0.9	0.8	0.9	0.8
Securities and Exchange Commission	40	54	66	54	65	84	0.8	1.1	1.3	1.0	1.1	1.3
Total[a]	4,935	4,991	5,182	5,290	6,056	6,329	100.0	100.0	100.0	100.0	100.0	100.0

[a]Totals may include final rules issued jointly by two or more agencies.

APPENDIX V

Regulatory Impact Analysis Guidance[1]

A Regulatory Impact Analysis (RIA) should demonstrate that a proposed regulatory action satisfies the requirements of Section 2 of Executive Order No. 12291. To do so, it should show that:

- There is adequate information concerning the need for and consequences of the proposed action;
- The potential benefits to society outweigh the potential costs; and
- Of all the alternative approaches to the given regulatory objective, the proposed action will maximize net benefits to society.

The fundamental test of a satisfactory RIA is whether it enables independent reviewers to make an informed judgment that the objectives of Executive Order No. 12291 are satisfied. An RIA that includes all the elements described below is likely to fulfill this requirement. Although variations consistent with the spirit and intent of the Executive Order may be warranted for some rules, most RIAs should include these elements.

The guidance in this document is not in the form of a mechanistic blueprint, for a good RIA cannot be written according to a formula. Competent professional judgment is indispensable for the preparation of a high-quality analysis. Different regulations may call for very different emphases in analysis. For one proposed regulation, the crucial issue may be the question of whether a market failure exists, and much of the analysis may need to be devoted to that key question. In another case the existence of a market failure may be obvious from the outset, but extensive analysis might be necessary to estimate the magnitude of benefits to be expected from proposed regulatory alternatives. The amount of analysis (whether scientific, statistical, or economic) that a particular issue requires depends on how crucial that issue is to determine the best alternative and on the complexity of the issue.

Regulatory analysis inevitably involves uncertainties and requires informed professional judgments. Whenever an agency has questions about such issues as the appropriate analytical techniques to use or the alternatives that should be considered, it should consult with the Office of Management and Budget as early in the analysis stage as possible.

This document is written primarily in terms of proposed regulatory changes. However, it is equally applicable to the review of existing regulations. In the latter case, the regulation under review should be compared to a baseline case of no regulation and to reasonable alternatives.

Elements of a Regulatory Impact Analysis

Preliminary and final Regulatory Impact Analyses of major rules should contain five elements. They are: (1) a statement of the potential need for the proposal, (2) an examination of alternative approaches, (3) an analysis of benefits and costs, (4) the rationale for choosing the proposed regulatory action, and (5) a statement of statutory authority. These elements are explained in sections I-V below.

I. STATEMENT OF POTENTIAL NEED FOR THE PROPOSAL

In order to establish the potential need for the proposal, the analysis should demonstrate that (a) market failure exists that is (b) not adequately resolved by measures other than Federal regulation.

A. Market Failure

The analysis should determine whether there exists a market failure that is likely to be significant. Once such market failure has been identified, the analysis should show how adequately the regulatory alternatives to be considered address the specified market failure. The three major types of market failure are externality, natural monopoly, and inadequate information.

1. *Externality.* An externality occurs when one party's actions impose uncompensated benefits or costs on another outside the marketplace. Environmental problems are a classic case of externality. Another example is the case of common property resources that may become congested or overused, such as fisheries or the broadcast spectrum. A third example is a "public good," such as defense or scientific research, whose distinguishing characteristic is that it is inefficient, or impossi-

[1]This appendix was mainly written by Michael Mazur as one of his last projects before his untimely death last year. Those who knew Mike will appreciate his hard work and careful analysis that made this guidance possible.

ble, to exclude individuals from its benefits.

2. *Natural monopoly.* Natural monopoly exists where a market can be served at lowest cost only if production is limited to a single producer. Local telephone, gas, and electricity services are examples.
3. *Inadequate information.* The optimum, or ideal, level of information is not necessarily the maximum possible amount, because information, like other goods, should not be produced when the costs of doing so exceed the benefits. The free market does not necessarily supply an optimal level of information, because information once generated can be disseminated at little or no marginal cost and because it is commonly infeasible to exclude nonpayers from reaping benefits from the provision of information by others. Where market failure due to inadequate information is the rationale for government intervention, a regulatory acton to improve the availability of information will ordinarily be the preferred alternative.

The current state of knowledge about the economics of information is not highly developed. Therefore, regulatory intervention to address an information problem should only be undertaken where there is substantial reason to believe that private incentives to provide information are seriously inadequate and that the specific regulatory intervention proposed will provide net benefts for society.

In many circumstances, the availability of information, while perhaps not optimal, is reasonably adequate, so that attempts to regulate information are as likely to make things worse as to make them better. Information about a particular characteristic of a product, for example, would be reasonably adequate if buyers could determine the existence of the characteristic by inspection of the product before purchase or (in the case of a frequently purchased product) by use of the product. Even if the characteristic could not be determined by buyers, government intervention would not be warranted where sellers have incentives to reveal the existence of the characteristic to buyers. Sellers will have substantial incentives to supply information about any characteristic that is important to buyers and valued positively by them, particularly if the level of the characteristic varies between the products of one seller and another. In these circumstances sellers whose products rank highly in the valued characteristic can increase their sales by informing buyers of the superiority of their products. If the level of the characteristic does not vary between the products of one seller and another, individual sellers have less incentive to inform buyers about the characteristic. Even so, the incentives of individual sellers or of a trade association to supply information may be substantial.

Sellers are least likely to supply adequate information about a particular characteristic of their product where the characteristic is negatively valued by consumers and the level of the characterstic does not vary between the products of one seller and those of another (e.g., cholesterol in eggs). Even in such circumstances, substantial information about the characteristic may be available to buyers. For example, sellers of rival products may supply the information (e.g., while sellers of butter may have no incentive to tell buyers about cholesterol in butter and its possible consequences, sellers of margarine do have such an incentive). Where the negative characteristic involves a health or safety hazard, the threat of future product liability lawsuits may give sellers adequate incentives to reveal information about the potential hazard. News media, consumer groups, public health agencies, and similar services may supply information not supplied by sellers. In summary, while it is possible to identify situations in which market failure due to inadequate information is more likely to warrant regulatory intervention, each situation must be examined on a case-by-case basis.

There should be a presumption against the need for certain types of regulatory actions, except in special circumstances. A particularly demanding burden of proof is required to demonstrate the potential need for any of the following types of regulations:

- Price controls in competitive markets
- Controls on producton or sales in competitive markets
- Mandatory uniform quality standards for goods or services, unless they have hidden safety or other defects and the problem cannot be adequately dealt with by voluntary standards or information disclosing the hazard to potential buyers or users
- Controls on entry into employment or

production, except
(a) where indispensable to protect health and safety (e.g., FAA tests for commercal pilots), or
(b) to manage the use of common public resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

B. Other Alternatives

Even where a market failure exists, there may be no need for Federal regulatory intervention if other means of dealing with the market failure resolve the problem adequately or better than the proposed Federal regulation would. Among the alternative means that may be applicable are the judicial system (particularly liability cases to deal with health and safety), antitrust enforcement, and workers' compensation systems.

An important alternative that may often be relevant is regulation at the State or local level. In determining whether there exists a potential need for a proposed Federal regulation, the analysis should examine whether regulation at the Federal level is more appropriate than regulation at the State or local level. This analysis may support regulation at the Federal level where rights of national citizenship (such as legal equality among the races) or considerations of interstate commerce are involved. If interstate commerce is involved, the analysis should attempt to determine whether the burdens on interstate commerce arising from different State and local regulations are so great that they outweigh the advantages of diversity and local political choice. In some cases the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, pollution that spills across state lines (such as acid rain whose precursors are transported widely in the atmosphere) is probably best controlled by Federal regulation, while localized pollution (such as garbage truck noise) is probably more efficiently handled by local government regulation.

In general, because demands among localities for different governmental services differ and because competition among governmental units for taxpayers and citizens may encourage efficient regulation, the smallest unit of government capable of correcting the market failure should be chosen. This must, however, be balanced against the possibility of higher costs because national firms would be required to comply with more than one set of regulations and because administering similar regulations in more than one governmental unit involves some costs of duplication. Thus, some analysis may be necessary to determine which level of government can most efficiently regulate a specific market failure.

If the analysis does suggest a potential need for a Federal action, it should also consider alternatives of nonregulatory Federal measures. For example, as an alternative to requiring an action or the use of a particular product, it may be more efficient to subsidize it. Similarly, a fee or charge may be a preferable alternative to banning or restricting a product or action. An example would be an effluent discarge fee, which has been recommended as an efficient way to limit pollution because it causes pollution sources with different marginal costs of abatement to control effluents in an efficient manner. In addition, legislative measures that make use of economic incentives, such as changes in insurance provisions or changes in property rights, should be considered.

II. AN EXAMINATION OF ALTERNATIVE APPROACHES

The RIA should show that the agency has considered the most important alternative approaches to the problem and must provide the agency's reasoning for selecting the proposed regulatory change over such alternatives. Ordinarily, it will be possible to eliminate some alternatives by a preliminary analysis, leaving a manageable number of alternatives to be evaluated by quantitative benefit-cost analysis according to the principles to be described in Section III. The number and choice of alternatives to be selected for detailed benefit-cost analysis is unavoidably a matter of judgment. There must be some balance between thoroughness of analysis and practical limits to the agency's capacity to carry out analysis.

Alternative regulatory actions that should be explored include the following:

1. *More performance-oriented standards for health, safety, and environmental regulations.* Performance standards are generally to be preferred to engineering or design standards because they allow the regulated parties to achieve the regulatory objective in the most cost-effective way. In general, a performance standard should be preferred wherever that performance can be measured or reasonably imputed. Performance standards should also be applied as broadly as possible without creating too much variation in regulatory benefits; for example, by set-

ting emission standards on a plant-wide or firm-wide basis rather than source by source. It is misleading and inappropriate, however, to characterize a standard as a performance standard if it is set so that there is only one feasible way to meet it; as a practical matter, such a standard is a design standard.

2. *Different requirements for different segments of the regulated population.* For example, there might be different requirements for large and small firms. If such a differentiation is made, it should be based on perceptible differences in the costs of compliance or in the benefits to be expected from compliance. For example, some worker safety measures may exhibit economies of scale, that is, lower costs per worker protected in large firms than in small firms. A heavier burden should not be placed on one segment of the regulated population on the grounds that it is better able to afford the higher cost; this is a sure formula for loading disproportionate costs on the most productive sectors of the economy.
3. *Alternative levels of stringency.*In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although costs will eventually increase more rapidly than benefits). It is important to consider alternative levels of stringency to better understand the relationship between stringency and benefits and costs. This approach will increase the information available to the decisionmaker on the option that maximizes net benefits.
4. *Alternative effective dates of compliance.*The timing of a regulation may also have an important effect on its net benefits. For example, costs of a regulation may vary substantially over different compliance dates for an industry that requires a year or more to plan its production runs efficiently. In this instance a regulation whose requirements provide sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.
5. *Alternative methods of ensuring compliance.* Compliance alternatives include the appropriate entity (local, State or Federal) to enforce compliance, whether compliance is enforced by on-site inspection or periodic reporting, and structuring compliance penalties so that they provide the most appropriate incentives.
6. *Informational measures.* Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be made mandatory or left voluntary), mandatory disclosure reguirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hot-lines, or public interest broadcast announcements). If intervention is necessary to address a market failure arising from inadequate information, informational remedies will generally be the preferred approaches. As an alternative to a mandatory standard, a regulatory measure to improve the availability of information has the advantage of being a more market-oriented approach. Thus, providing consumers information about concealed characteristics of consumer products gives consumers a greater choice than banning these products (for example, consumers are likely to benefit more from information on energy efficiency than from a prohibition on sale of appliances or automobiles falling below a specified standard of energy efficiency).

Except for prohibiting indisputably false statements (whose banning can be presumed beneficial), specific informational measures must be evaluated in terms of their benefits and costs. Paradoxically, the current state of knowledge does not generally permit the benefits and costs of informational remedies to be measured very accurately. Nonetheless, it is essential to consider carefully the costs and benefits of alternative informational measures, even if they cannot be quantified very precisely. Some effects of informational measures can easily be overlooked. For example, the costs of a mandatory disclosure requirement for a consumer product include not only the obvious cost of gathering and communicating the required information, but also the loss of any net benefits of information displaced by the mandated information, the cost of any inaccurate consumer interpretation of the mandated information, and any inefficiencies arising from the incentive that mandatory disclosure of a particular characteristic gives to producers to overinvest in improving that specific characteristic of their products.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, as will often be the case, the least intrusive alternative suffi-

cient to accomplish the regulatory objective should be chosen. For example, it will often be sufficient for government to establish a standardized testing and rating system without mandating its use, because firms that score well according to the system will have ample incentive to publicize the fact.

7. *More market-oriented approaches.* In general, alternatives that provide for more market-oriented approaches, with the use of economic incentives replacing command-and-control requirements, should be explored. Market-oriented alternatives that may be considered include fees, subsidies, penalties, marketable rights or offsets, changes in liabilities or property rights, and required bonds, insurance or warranties (in many instances, implementing these alternatives will require legislation).

III. ANALYSIS OF BENEFITS AND COSTS

A. General Principles

The preliminary analysis called for by Sections I and II should have narrowed the number of alternatives to be considered by quantitative benefit-cost analysis to a workable number. Ordinarily, one of the alternatives will be to promulgate no regulation at all, and this alternative will commonly serve as the base from which increments in benefits and costs are calculated for the other alternatives. Even if the alternative of no regulation is not permissible statutorily, it is often desirable to evaluate benefits and costs to determine if statutory change would be desirable.

In some cases the desirability of specific alternatives outside the scope of the agency's regulatory authority may be determined by use of basic economic concepts in light of the principles enumerated in Section I. In other instances, however, only a quantitative benefit-cost analysis can resolve the question, and such alternatives will need to be included in the analysis of this section. In addition, alternative forms of agency regulation will need to be evaluated by quantitative benefit-cost analysis.

1. *Evaluation of Alternatives.* Except where prohibited by law, the primary criterion for choice among alternatives is expected net benefit (benefits minus costs). Other criteria may sometimes produce equivalent results, but they must be used with care to avoid the potentially serious pitfalls to be explained in Part B of this section and in Section IV. Both benefits and costs should be expressed in discounted constant dollars. Appropriate discounting procedures are discussed in the following section.

The distinction between benefits and costs in benefit-cost analysis is somewhat arbitrary, since a positive benefit may be considered a negative cost, and vice versa, without affecting the net benefit (benefits minus costs) decision criterion. This implies that the considerations applicable to benefit estimates also apply to costs and vice versa. The different issues are considered separately under benefits or costs in Sections B and C below according to where they most often arise.

If the proposed regulation is composed of a number of distinct provisions, it is important to evaluate the benefits and costs of the different provisions separately. The interaction effects between separate provisions (such that the existence of one provision affects the benefits or costs arising from another provision), may complicate the analysis, but does not eliminate the need to examine provisions separately. In such a case, the desirability of a specific provision may be appraised by determining the net benefits of the proposed regulation with and without the provision in question. Where the number of provisions is large and interaction effects are pervasive, it is obviously impractical to analyze all possible combinations of provisions in this way. Some judgment must be used to select the most significant or suspect provisions for such analysis.

2. *Discounting.* The monetary values of benefits and costs occurring in different years should be discounted to their present values so that they are comparable. This is not the same as correcting for inflation. An inflation adjustment is made with a price index, whereas discounting to present value is done with a discount rate. Benefits and costs expressed in constant (i.e., unaffected by inflation) dollars must further be discounted to present values before benefits and costs in different years can be added together to determine overall net benefits.

Discounting takes account of the fact that resources (goods or services) in a given year are worth more than identical resources in a later year. The underlying reason for this is that resources can be invested so as to return more resources

later. Partly because of this productivity of investment, individuals value consumption in earlier years higher than consumption in later years.

Modern analysis of discounting for public programs stresses the distinction between two rates of return:

- The *before-tax* rate, also known as the opportunity cost of capital. This is the real rate of return to marginal private investments. Estimates of the opportunity cost of capital in the U.S. economy vary substantially. The 10 percent discount rate specified by OMB Circular A-94 for use in evaluating government programs is intended to represent the opportunity cost of capital.
- The *after-tax* rate, also known as the consumption rate of interest. This represents the rate at which consumers would be willing to exchange present for future consumption, that is, the rate at which consumers must be compensated for postponing their consumption. As with the opportunity cost of capital, alternative estimates of the consumption rate of interest vary significantly. A rate of four percent is reasonably representative of the range of alternative estimates and consistent with a 10 percent before-tax rate of return.

The basic concept underlying the academic literature on public-sector discounting is that economic welfare is ultimately determined by consumption and only indirectly by investment. Therefore, the value of investment must be measured by the value of the subsequent increase in consumption it permits. Any effect that a government program has on investment must be converted to an equivalent time-stream of consumption before being discounted. In practice, this results in a complex procedure that uses the before-tax and after-tax discount rates, a "shadow price of capital," and the impacts of benefits and costs on investment. It is recommended that agencies continue to use the well-understood procedure of discounting by a single rate (as specified by OMB Circular A-94) and, when appropriate, perform additional analysis using the more complex shadow-price-of-capital methodology.

There are two circumstances when it is important to perform sensitivity analysis using the shadow price of capital approach:

(a) Where the costs of the regulation are almost entirely current costs borne by consumers. In such circumstances a low rate close to four percent is called for. (This assumes, as is normally the case, that the benefits are all in the form of disposable income or other benefits directly to individuals.)

(b) Where some of the costs are capital costs financed out of saving *and* there is a long period between the time when most costs are incurred and the time when most benefits accrue. In general, the *smaller* the fraction of costs that are capital costs financed out of saving and the *longer* the time period between costs and benefits, the greater the likelihood that the shadow price of capital approach will be correct.

It is conceptually incorrect to adjust the discount rate as a device to account for the uncertainty of expected future benefits and costs. This procedure will virtually never lead to a correct adjustment of benefits and costs. Therefore, risk and uncertainty should be dealt with according to the principles in Section 3 below and not by changing the discount rate.

3. *Treatment of Risk and Uncertainty.* Where uncertainties exist about important parameters affecting the expected benefits or costs of an alternative under consideration, it is essential to carry out a *sensitivity analysis* to determine the effect on net benefits of plausible variations in the value of the parameters. One form of sensitivity analysis involves calculation of the "switch-point" value of the parameter under examination, that is, the value of the parameter at the break-even point at which the net-benefit decision criterion switches over from favoring one alternative to favoring another. When this break-even point of the parameter value is determined, the analysis may then consider the probability that the true parameter value is above or below the break-even value. For example, if the major uncertainty about a proposed regulation were its cost, the analysis could calculate how high the cost would need to be in order to reduce the net benefit of the proposal to zero. If it is judged to be highly unlikely that the actual cost would be that high or higher, it may be concluded that the choice of the proposed alternative is not sensitive to uncertainties about its cost.

A primary objective of sensitivity analysis is to identify where additional analy-

sis may be most needed. If the choice of a specific regulatory action is sensitive to alternative parameter values that are about equally likely to be true, more research to better determine the true parameter value could be very valuable.

Wherever parameter estimates are uncertain, for either benefits or costs, most-likely estimates (in statistical terms, unbiased estimates or expected values) should be presented. Hypothetical best-case or worst-case estimates may be presented as alternatives for sensitivity analysis. Where possible, information about the probability distribution of the parameter estimate should be presented.

A common situation that arises in estimating both benefits and costs is that a number of different studies may exist which together provide a range of different estimates for a particular parameter. In general, it is not appropriate to use the midpoint of the range of extreme values provided by the studies. Such a technique ignores the information provided by all studies except those providing the extreme values, which may be the least reliable. The preferred approach to deriving a most-likely estimate of a particular parameter in this situation would be to derive it as a weighted average of the estimates of the individual studies, with the weight of each estimate being based on the reliability (in the best judgment of the agency) of the study that produced it.

Where expected future benefits or costs are uncertain, their value to those who receive them may be different from their value if they were certain. (Often, but not always, a certain future benefit is worth more to people than an uncertain future benefit with the same expected value.) As noted in the previous section, it is incorrect to adjust the discount rate as a device to account for the riskiness of future benefits or costs. Any allowance for risk should be made by adjusting the monetary values (for the year in which they occur) of the uncertain benefits and costs so that they are expressed in terms of their "certainty-equivalents."

For an uncertain benefit in future year X, the certainty-equivalent is the number of certain dollars in year X that the uncertain benefit is worth to its recipient. For example, suppose that a particular regulation reduces the probability of fire in a particular type of facility. As part of a benefit-cost analysis for this regulation, the dollar value of the expected reduction in fire loss would be calculated. The owners of the protected facilities place a higher dollar value on the risk of a fire than the expected dollar value of the loss. This is demonstrated by their willingness to pay for fire insurance. Therefore, their relative net cost (the percentage difference between insurance premiums and insurance company claim payments) for fire insurance can be used to increase the expected dollar value of the reduction in fire loss to its certainty-equivalent value.

In the example of the preceding paragraph, the adjustment for risk would involve an increase in the value of the benefit, whereas uncertainty of a benefit is normally thought to reduce its certainty-equivalent value. The reason is that even though this benefit by itself is uncertain, it acts to reduce the overall level of risk that would prevail in the absence of the regulation. This illustrates the important principle that what matters is not the variability or riskiness of a regulation's net benefits by themselves, but the regulation's effect on risk and uncertainty overall.

While an adjustment to account for risk may be called for in the fire-risk example given, a similar adjustment for the value of reductions in fatalities and injuries would not be appropriate. Assuming that the values of fatalities and injuries have been derived by the willingness-to-pay methodology recommended in section B.2 below, they would already represent the certainty-equivalent value of the uncertain risk. This is because the estimated dollar values represent the certain dollar amounts that individuals would sacrifice to reduce these risks.

Probably in most cases it will not be advisable to adjust for risk and uncertainty. As a theoretical matter, no adjustment for risk is necessary wherever the net benefits are widely dispersed among many individuals and are not correlated with disposable income. And in cases where this does not apply, risk may be relatively unimportant or may already be taken into account by use of the willingness-to-pay methodology. In other cases, there may be no practical way to quantify the value of changes in risk.

4. *Assumptions.* Where benefit or cost estimates are heavily dependent on certain assumptions, it is essential to make these assumptions explicit and, where alternative assumptions are plausible, to carry out sensitivity analyses based on plausi-

ble alternative assumptions. If the decision criterion proves to be sensitive to alternative plausible assumptions, this may necessitate further research to develop more evidence on which of the alternative assumptions is the most appropriate. Because the adoption of a particular estimation methodology sometimes implies major hidden assumptions, it is important to analyze estimation methodologies carefully to make hidden assumptions explicit.

5. *International Trade Effects.* In calculating the benefits and costs of a proposed regulatory action, generally no explicit distinction needs to be made between domestic and foreign resources. If, for example, compliance with a proposed regulation requires the purchase of specific equipment, the opportunity cost of that equipment is ordinarily best represented by its domestic cost in dollars, regardless of whether the equipment is produced domestically or imported. The relative value of domestic and foreign resources is correctly represented by their respective dollar values, because the foreign exchange value of the dollar is determined by a free exchange market. Nonetheless, an awareness of the role of international trade may be quite useful for assessing the benefits and costs of a proposed regulatory action. For example, the existence of foreign competition usually makes the demand curve facing a domestic industry more elastic than it would be otherwise. Elasticities of demand and supply frequently can significantly affect the magnitude of the benefits or costs of a regulation.

A regulation that discriminates unjustifiably against foreign exporters is a form of economic protectionism. The economic loss to the U.S. due to the fact that protectionism is economically inefficient will be reflected in the net benefit estimate of any properly conducted benefit-cost analysis. However, a benefit-cost analysis will generally not be able to measure the potential U.S. loss from the threat of future retaliation by foreign governments. Therefore, special attention should be given to any possibility that a regulation would unjustifiably discriminate between domestic and foreign producers and consumers—both discrimination against foreigners and discrimination in favor of foreigners.

The fact that a regulation has a differential effect on foreigners as compared to Americans does not necessarily constitute discrimination. If, for example, an automobile safety standard could be complied with less expensively by large cars than by small cars, such a standard would be more favorable to American car producers, who produce relatively more large cars compared to the fleet mix of foreign producers. Nonetheless, such a differential effect would not be discriminatory if the difference in compliance cost between large and small cars was necessary to achieve legitimate regulatory objectives in the most efficient way.

If a regulation has an adverse differential effect on foreign producers or consumers relative to domestic producers and consumers that is not necessary to realize regulatory goals efficiently, then a discriminatory effect on foreign trade exists. The RIA should identify any substantial differential effect on international trade and explain why it is necessary to achieve legitimate regulatory goals in the most efficient way. One means for reducing the likelihood of international discrimination would be for a U.S. product standard for an internationally traded good to be based on an international standard, wherever an international standard exists and is compatible with the health, safety, or environmental needs of the U.S. International harmonization can be beneficial for regulations directly setting standards for internationally traded goods or services. For example, it would be appropriate to consider international harmonization in setting safety standards for automobiles. There is no similar advantage to international harmonization where a regulation does not directly affect the quality of an internationally traded good or service, even if it indirectly affects its costs (e.g., environmental controls for automobile plants).

B. Benefit Estimates

The RIA should state the beneficial effects of the proposed regulatory change and its principal alternatives. In each case, there should be an explanation of the mechanism by which the proposed action is expected to yield the anticipated benefits. An attempt should be made to quantify all potential real incremental benefits to society in monetary terms to the maximum extent possible. A schedule of monetized benefits should be included that would show the type of benefit and when it would accrue; the numbers in this table should be expressed in constant,

undiscounted dollars. Any expected incremental benefits that cannot be monetized should be explained.

The RIA should identify and explain in detail the data or studies on which benefit estimates are based. Where benefit estimates are derived from a statistical study, the RIA must provide sufficient information so that an independent observer can determine the representativeness of the sample, whether it was extrapolated from properly in developing aggregate estimates, and whether the results are statistically significant.

For regulations addressing health and safety risks, the calculation of potential benefits should derive from the agency's estimate of the mean expected value of the reduction in risk attributable to the standard. Estimates of the prevailing level of risk and of the reduction in risk to be anticipated from a proposed standard should be unbiased most-likely estimates rather than hypothetical worst-case estimates. Extreme safety or health results should be weighted (along with intermediate results) by the probability of their occurrence to estimate the expected result implied by the available evidence. In addition, to the extent possible, the distribution of probabilities for various possible results should be presented separately, so as to allow for an explicit margin of safety, where required, in final decisions. If a margin of safety is to be provided, the proper place for it is the final stage of the decision-making process, not by adjusting the risk or benefit estimates in a conservative direction at the information-gathering or analytical stages of the process. Conservative estimates should be presented as alternatives to best estimates for sensitivity analysis, but should not substitute for them.

It is important to guard against double-counting of benefits. For example, if a regulation improved the quality of the environment in a community, the value of real estate in the community might rise, reflecting the greater attractiveness of living in the improved environment. It would ordinarily be incorrect to include the rise in property values among the benefits of the regulation. Ordinarily, the value of environmental benefits (e.g., reduced health risks, scenic improvements) will already be included among the benefits. The rise in property values reflects the capitalized value of these improvements. Therefore, to count as benefits both the value of the environmental improvements and the corresponding increase in property values is to count the same benefits twice. Only where a direct estimate of the benefits has not been included would it be appropriate to include the increase in property values among the benefits.

1. *Principles for Valuing Benefits.* Ordinarily, goods and services are to be valued at their market prices. However, in some instances, the market value of a good or service may not reflect its true value to society. If a regulatory alternative involves changes in such a good or service, its monetary value for purposes of benefit-cost analysis should be derived using an estimate of its true value to society (often called its "shadow price"). For example, suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant will be the value of the crop saved as a result of the controls. If the price of that crop is held above the free-market equilibrium price by a government price-support program, it would overstate the value of the benefit of controlling the pollutant if the crop saved were valued at the market price established by the support program. The social value of the benefit should be calculated using a shadow price for crops subject to price supports. The estimated shadow price should reflect the value to society of marginal uses of the crop (e.g., the world price if the marginal use is for exports). If the marginal use is to add to very large surplus stockpiles, the shadow price would be the value of the last units released from storage, minus storage cost. Therefore, where stockpiles are large and growing, the shadow price is likely to be low and could well be negative.

   In some important instances, a benefit does not correspond to a good or service traded in the marketplace. Important examples include reductions in health and safety risks, savings in time, and environmental amenities such as scenic vistas. To estimate the monetary value of a benefit that is not traded directly in the marketplace, the willingness-to-pay valuation methodology is conceptually superior, because the amount that people are willing to pay for a good or service is the best measure of its value to them. As noted in the following section, where there are practical obstacles to the accurate application of the willingness-to-pay methodology, alternative methods may be used. Methods for estimating the value of travel time include estimates based on wage rates and statistical studies of travelers'

choices among alternative travel modes. Methods for estimating the value of environmental and recreational amenities include travel-cost and contingent-valuation estimation methods. The following section outlines the principles for valuing the most important type of nonmarketed benefit: reductions in health and safety risks.

2. *Valuation of Health and Safety Benefits.* For health and safety benefits, a distinction should be made between risks of nonfatal illness or injury and fatality risks.
   (a) *Nonfatal illness and injury.* Although the willingness-to-pay approach is conceptually superior, the current state of empirical research in the area is not sufficiently advanced to assure that estimates derived by this method are necessarily superior to direct-cost valuations of reductions in risks of nonfatal illness or injury. Any injury-value estimate from a willingness-to-pay study is necessarily an average over a specific combination of injuries of varying severity. If the average injury severity in such a study is greatly different from that for the regulatory action under study, then the study's estimated injury value may not be appropriate for evaluating that action. Accordingly, the agency should use whichever approach it considers most appropriate for the decision at hand. The primary components of the direct-cost approach are medical costs and the value of lost production. Possibly important costs that may be omitted by the use of the direct-cost approach are the value of pain and suffering, and the value of time lost from leisure and other activities that are not economically directly productive.
   (b) *Fatality.* Reductions in fatality risks are best monetized according to the willingness-to-pay approach. The value of changes in fatality risk is sometimes expressed in terms of the "value of life." This is something of a misnomer, since the value of a life really refers to the sum of many small reductions in fatality risk. For example, if the annual risk of death is reduced by one in a million for each of two million people, that represents two "statistical lives" saved per year (two million × one millionth = two). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives saved. The conclusion that the fatality risk reductions in these two cases are equivalent implies an assumption. The implicit assumption—that equal increments in risk are valued equally—allows different risk increments to be added together and compared directly. As a different example, suppose there are two alternative reductions in the annual risk faced by an individual:

A: from $.10\times10^{-5}$ to $.09\times10^{-5} = .01\times10^{-5}$
B: from 1.00×10^{-5} to $.99\times10^{-5} = .01\times10^{-5}$

Since in both cases the reduction in annual risk is the same ($.01\times10^{-5}$), the value of A and B should be considered the same.

The assumption that equal increments in fatality risk are of equal value is a legitimate one, so long as the level of fatality risk is below 10^{-4} annually. There is evidence that the willingness-to-pay value for increments in fatality risk does not change significantly over a wide range of risk exposure below 10^{-4} annually.

For levels of annual risk exposure of 10^{-4} and above, it cannot be assumed that equal increments of risk are valued equally. At these higher risk levels, it is particularly important to distinguish between situations of voluntary risk assumption and those of involuntary risk. Where the high risk is involuntary, it is appropriate to value reductions in risk from that high level more highly than equal risk reductions at lower risk levels. In general, the greater the risk that an individual bears, the higher will be the value the individual places on marginal changes in risk. On the other hand, where a high risk is chosen voluntarily those assuming the risk tend to be persons who place a relatively low value on averting safety risks. Empirical studies of risk premiums in high-risk occupations suggest that reductions in voluntarily assumed high risks should be valued less than equal risk reductions at ordinary risk levels.

Estimates of the value of fatality risks refer only to changes in an uncertain risk of death. They have no application to the certain prevention

of the death of an identifiable individual.

3. *Alternative Frameworks for Health and Safety Benefits.* Several alternative ways of incorporating fatality risks into the framework of benefit-cost analysis may be appropriate. These may involve either explicit or implicit valuation of fatality risks.

One acceptable explicit valuation approach would be for the agency to select a single value for reductions in fatality risk at ordinary risk levels (below 10^{-4} annually) and use this value consistently for evaluating all its programs that affect ordinary fatality risks. Another acceptable explicit valuation approach would be to use a range of values for reductions in fatality risk and apply sensitivity analysis as with other parameters that have alternative plausible values. The range of alternative values should be a reasonable one, not one that includes the most extreme upper and lower values of fatality risk reduction that have been estimated. Extreme values are more appropriate for instances of extraordinarily high risks (above 10^{-4} annually), with the extreme low values being appropriate where voluntary assumption of high risk leads to self-selection and the extreme high values being appropriate where the high risk is involuntarily assumed.

Where the analysis uses a range of alternative values for reductions in fatality risk, it may be useful to calculate break-even values, as in other sensitivity analyses. This requires calculating the borderline value of reductions in fatality risk at which the net benefit decision criterion would switch over from favoring one alternative to favoring another (i.e., the value of fatality risk at which the net benefits of the two alternatives are equal). This method will frequently be infeasible because of its computational demands or because alternatives are continuous rather than discrete (e.g., alternative stringencies for exposure levels), but where appropriate, it is a useful supplement to the sensitivity analysis.

An implicit valuation approach could entail calculations of the cost per unit of reduction in fatality risk (cost per "statistical life saved"), with costs defined as costs minus monetized benefits. This must be used with care, since there is a serious potential pitfall: It is *not* correct to choose between two mutually exclusive alternatives by selecting the alternative with lowest cost per statistical life saved. The alternative with higher cost per life saved may nonetheless be the alternative with the higher net benefit to society.

The way to avoid this pitfall while retaining the implicit valuation approach is to make all calculations of cost per life saved in terms of increments between alternatives. Alternatives should be arrayed in order of their total reduction in expected fatalities and the incremental cost per life saved calculated between each adjacent pair of alternatives. In contrast to explicit valuation approaches, this avoids the necessity of specifying in advance a value for reductions in fatality risks. However, a range of values will be implied by the final selection of an alternative. This range should be consistent with estimated values of reductions in fatality risks calculated according to the willingness-to-pay methodology.

Another way of expressing reductions in fatality risks is in terms of life-years saved. For example, if a regulation protected individuals whose average remaining life expectancy was 40 years, then a risk reduction of one fatality would be expressed as 40 life-years saved. Such a refinement may be desirable for regulations that disproportionately protect young people (e.g., motor vehicle safety regulations) or elderly people (e.g., regulations controlling carcinogens). To derive the value of a life-year saved from an estimate of the value of life, first determine the average remaining life expectancy of the sample population in the study from which the estimate was drawn. Assuming that the average age of the sample population is known, the average remaining life expectancy may be derived from actuarial tables giving life expectancy in relation to age. Using standard compound interest tables, the value of a life-year saved can then be determined as the estimated value of life annualized over a period equal to the number of years of remaining average life expectancy.

C. Cost Estimates

1. *General Considerations.* The important economic concept of *opportunity cost* is relevant to benefit-cost analyses of regulations, as it is to other types of economic analyses. The opportunity cost of an alternative is the value of the benefits foregone as a consequence of that alternative. For example, the opportunity cost of banning

a product (e.g., a drug, food additive or hazardous chemical) is the foregone net benefit of that product. It is measured by changes in producers' and consumers' surpluses. (Producers' surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the distance between the price and the supply curve for that unit. Consumers' surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the distance between the price and the demand curve for that unit.) As another example, even if a resource required by regulation does not have to be paid for because it is already owned by the regulated firm, nonetheless the use of that resource to meet the regulatory requirement has an opportunity cost equal to the net benefit it would have provided in the absence of the requirement. Any such foregone benefits for an alternative should be monetized wherever possible and either added to the costs or subtracted from the benefits of that alternative. Any costs that are averted as a result of an alternative should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

All costs calculated should be incremental, that is, they should represent changes in costs that would occur if the regulatory alternative is chosen compared to costs in the base case (ordinarily no regulation or the existing regulaton). Future costs that would be incurred even if the regulation is not promulgated, as well as costs that have already been incurred (sunk costs), are not part of incremental costs. If marginal cost is not constant for any component of costs, incremental costs should be calculated as the area under the marginal cost curve over the relevant range.

Costs include private-sector compliance costs, government administrative costs and costs of reallocating workers displaced as a result of the regulation. Costs that are not monetary outlays must be included and should be attributed a monetary value wherever possible. Such costs may include the value (opportunity cost) of benefits foregone, losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time. A schedule of monetized costs should be included that would show the type of cost and when it would occur; the numbers in this table should be expressed in constant, undiscounted dollars. Any expected incremental costs that cannot be monetized should be explained. An important type of cost that often cannot be quantified is a slowing in the rate of innovation or of adoption of new technology. For example, regulations requiring a costly and time-consuming approval process for new products or new facilities may have such costs, as may regulations setting much more stringent standards for new facilities than existing ones.

Two accounting cost concepts that should not be counted as costs in benefit-cost analysis are interest and depreciation. The time value of money is already accounted for by the discounting of benefits and costs. Depreciation is already taken into account by the time distribution of benefits and costs; the only legitimate use for depreciation calculations in benefit-cost analysis is to estimate the salvage value of a capital investment.

2. *Real Costs versus Transfer Payments.* An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not genuine costs, but payments for which no real good or service is received in return. Several examples of problems that may arise from the confusion between transfer payments and real costs (or benefits) may help to identify situations in which further analysis of the problem may be warranted. Monopoly profits, insurance payments, government subsidies and taxes, and distribution expenses are four potential problem areas.

   (a) *Monopoly profits.* If, for example, sales of a competitively produced product were restricted by a government regulation so as to raise prices to consumers, the resulting monopoly profits are not a benefit of the rule, nor is their payment by consumers a cost. The real benefit-cost effects of the regulation would be represented by changes in producers' and consumers' surpluses.

   (b) *Insurance payments.* Potential pitfalls in benefit-cost analysis may also arise in the case of insurance payments, which are transfers. Suppose, for example, a worker safety regulation, by decreasing employee injuries,

led to reductions in firms' insurance premium payments. It would be incorrect to count the amount of the reduction in insurance premiums as a benefit of the rule. The proper measure of benefits is the value of the reduction in worker injuries, monetized as described previously, plus any reduction in real costs of administering insurance (such as the time of insurance company employees needed to process claims) due to the reduction in worker insurance claims. Reductions in insurance premiums that are matched by reductions in insurance claim payments are changes in transfer payments, not benefits.

(c) *Indirect taxes and subsidies.* A third instance where special treatment may be needed to deal with transfer payments is the case of indirect taxes (tariffs or excise taxes) or subsidies on specific goods or services. Suppose a regulation requires firms to purchase a $10,000 piece of imported equipment, on which there is a $1,000 customs duty. For purposes of benefit-cost analysis the cost of the regulation for each firm ordinarily would be $10,000, not $11,000, since the $1,000 customs duty is a transfer payment from the firm to the Treasury, not a real resource cost. This approach, which implicitly assumes that the equipment is supplied at constant costs, should be used except in special circumstances. Where the taxed equipment is not supplied at constant cost, the technically correct treatment is to calculate how many of the units purchased as a result of the regulation are supplied from increased production and how many from decreased purchases by other buyers. The former units would be valued at the price without the tax and the latter units would be valued at the price including tax. This calculation is usually difficult and imprecise, because it requires estimates of supply and demand elasticities, which are often difficult to obtain and inexact. Therefore, this treatment should only be used where the benefit-cost conclusions are likely to be sensitive to the treatment of the indirect tax. While costs ordinarily should be adjusted to remove indirect taxes on specific goods or services as described here, similar treatment is not warranted for other taxes, such as general sales taxes applying equally to most goods and services or income taxes.

(d) *Distribution expenses.* The treatment of distribution expenses is also a source of potential error. For example, suppose a particular regulation raises the cost of a product by $100 and that wholesale and retail distribution expenses are on average 50 percent of the factory-level cost. It would ordinarily be incorrect to add a $50 distribution markup to the $100 cost increase to derive a $150 incremental cost per product for benefit-cost analysis. Most real resource costs of distribution do not increase with the price of the product being distributed. In that case, either distribution expenses would be unchanged or, if they increased, the increase would represent distributor monopoly profits. Since the latter are transfer payments, not real resource costs, in neither case should additional distribution expenses be included in the benefit-cost analysis. However, increased distribution expenses should be counted as costs to the extent that they correspond to increased real resource costs of the distribution sector as a result of the change in the price or characteristics of the product.

D. Expenditure Rules

Regulations establishing terms or conditions of Federal grants, contracts, or financial assistance call for a different form of regulatory analysis than do other types of regulation. In some instances, a full-blown benefit-cost analysis may be appropriate to inform Congress and the President more fully about the desirability of the program, but this would not ordinarily be required in a Regulatory Impact Analysis. The primary function of the RIA for this type of regulation should be to verify that the terms or conditions are the minimum necessary to achieve the purposes for which the funds were appropriated. They should not contain conditions in pursuit of goals that are not germane to the purpose for which the funds were authorized and appropriated. Beyond controls to prevent abuse and to ensure that funds appropriated to achieve a specific purpose are channeled efficiently toward that end, maximum discretion should be allowed in the use of Federal funds, particularly when the recipient is a State or local government.

IV. RATIONALE FOR CHOOSING THE PROPOSED REGULATORY ACTION

The RIA should include an explanation of the reasons for choosing the selected regulation. Ordinarily, the regulatory alternative selected should be the one that achieves the greatest net benefits. If legal constraints prevent this choice, they should be identified and explained, and their net cost should be estimated.

Where uncertainties are substantial or a large proportion of benefits cannot be monetized, other methods of summarizing the benefit-cost analysis besides in the form of net benefits may sometimes be appropriate. When alternative forms of presentation are used, the objective must continue to be the maximization of net benefits (except where prohibited by law). Alternative criteria must be used with care because of the potential for errors or misinterpretation.

Agencies need not calculate the internal rate of return for a regulation. The internal rate of return is often difficult to compute and is problematical when multiple rates exist. It must not be used as a criterion for choosing between mutually exclusive alternatives. As a criterion for choosing between alternatives that are not mutually exclusive it has no advantages over the criterion of maximizing the present value of net benefits.

Benefit-cost ratios, if used at all, must be used with care to avoid a common pitfall. It is a mistake to choose among mutually exclusive alternatives by selecting the alternative with the highest ratio of benefits to costs. An alternative with a lower benefit-cost ratio than another may have the higher net benefits. Whether a regulation's benefits are greater (or less) than its costs can be determined by whether its benefit-cost ratio is greater (or less) than one. The benefit-cost ratio may be used as a very simplified indicator of the likely sensitivity of the result: If the benefit-cost ratio is much greater than one, the conclusion that regulation's benefits exceed its costs probably is not sensitive to likely alternative parameter values. If the ratio is only slightly greater than one, the conclusion probably is sensitive. The benefit-cost ratio may sometimes be acceptable as a rough substitute for genuine sensitivity analysis where it is not feasible to carry out a full sensitivity analysis (e.g., if the number of regulatory parameters to be tested by sensitivity analysis is large). When so used, the benefit-cost ratio should be recognized as only a crude approximation to a genuine sensitivity analysis and the analyst should be aware of its limitations (e.g., the benefit-cost ratio is sensitive to the arbitrary classification of an item as a benefit or an averted cost).

Where the benefits of proposed regulatory alternatives include reductions in fatality risks, an acceptable alternative to direct calculation of net benefits is the indirect approach of calculating incremental costs per life saved between adjacent alternatives. This is done by ranking all the alternatives according to the number of lives they save and then calculating the change in costs and the change in lives saved between each alternative and the one with the next highest number of lives saved. If the alternative selected is the one whose incremental cost per life saved is closest to the willingness-to-pay value of life, this decision criterion is analytically equivalent to that of maximizing net benefit.

In cases where important benefits cannot be assigned monetary values, cost-effectiveness analysis should be used where possible to evaluate alternatives that generate equivalent nonmonetizable benefits. Costs should be calculated net of monetized benefits. Between two alternatives with equivalent nonmonetizable benefits, the alternative with the lower net costs should be selected. Cost-effectiveness analysis should also be used to compare regulatory alternatives in cases where the level of benefits is specified by statute.

V. STATUTORY AUTHORITY

The RIA should include a statement of determination and explanation that the proposed regulatory action is within the agency's statutory authority.

Further Reading

Edith Stokey and Richard Zeckhauser, *A Primer for Policy Analysis.* Chapters 9 and 10 provide a good introduction to basic concepts.

E. J. Mishan, *Economics for Social Decisions: Elements of Cost-Benefit Analysis.* Assumes some knowledge of economics. Chapters 5-8 should be helpful on the important subjects of producers' and consumers' surpluses (not discussed extensively in this guidance document).

W. Kip Viscusi, *Risk By Choice.* Chapter 6 is a good starting point for the topic of valuing health and safety benefits. Other, more technical, sources are given in the bibliography.