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STATEMENT OF SALLY KATZEN
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BEFORE THE
SENATE COMMITTEE ON THE JUDICIARY

March 17, 1995

Good morning, Mr. Chairman and Members of the Subcommittee. I am pleased to be here today to discuss with you S. 343, the "Comprehensive Regulatory Reform Act of 1995," in the form it was voted out of the Subcommittee on Administrative Oversight and the Courts on Tuesday, March 14.

The stated goal of S. 343 is to produce a more rational rulemaking process by increasing the opportunities for public involvement, by focusing agencies' attention on the consequences of their regulations, by bringing greater scientific and economic rationality to the regulation of risks to our health, safety, and environment, and by requiring centralized review of important new regulations. These are laudable goals, which the Administration fully and actively supports. Indeed, we have spoken frequently and forcefully of the importance of basing regulatory decisionmaking on good data and good analysis of costs, benefits, and risk, of the benefits of centralized regulatory review, and of the desirability of an open and transparent process. More importantly, we have done a great deal to put these ideas into practice, beginning almost immediately after we took office.

Executive Order No. 12866, which President Clinton signed on September 30, 1993, represents the cornerstone of our efforts. It recognizes that there is an important role for regulation in

protecting the health, safety, environment, and well-being of the American people. At the same time, it emphasizes that Government has a basic responsibility to govern wisely and carefully, regulating only when necessary and only in the most cost-effective manner.

To implement this philosophy, the Order sets forth principles emphasizing the critical role of analysis (of costs, benefits, and risk) and of the use of that analysis in decisionmaking; consideration of different regulatory alternatives and of alternatives to regulation; the importance of private markets and the use of market incentives in regulating; the need for performance standards rather than command and control techniques; better consideration of the needs of small businesses and the roles of state and local governments; and the need for extensive consultation with all those affected by the regulation (both those who will benefit and those who will be burdened).

The Executive Order requires agencies to propose or adopt a regulation only after determining that the rule would achieve its objective in a cost-effective manner, and that its benefits would justify its costs. And it specifically calls for the use of risk analysis in regulatory decisionmaking. The Executive Order states that in developing regulations, agencies are to consider "how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency." It also provides that "[i]n setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction."

Recognizing that risk assessments and cost-benefit analyses are valuable tools in helping agencies make regulatory decisions

in a sensible and cost-effective manner, the Administration has expressed its support for risk and cost-benefit legislation. Indeed, three weeks ago, President Clinton stated, "[W]e're attempting to work with members of both parties in Congress to further reform regulation. . . . For example, we want all agencies to carefully compare the cost and benefits of regulations so that we don't impose any unnecessary burdens on business."[1] The President would like to sign risk/cost-benefit legislation that improves the regulatory process. He has supported -- indeed, encouraged -- members of the Administration to work with you to that end. At the same time, however, we cannot support legislation that is likely to burden the regulatory process with unnecessary or costly requirements that will cause delay or gridlock or are likely to have substantive consequences that are detrimental to the American public.

We have reviewed S. 343, as it was voted out of the Subcommittee. Regrettably, we have concluded that it is, in the President's words, an "extreme" proposal. "[L]iterally read, [S. 343] could pile so many new requirements on government that nothing would ever get done. It would add to the very things that people have been complaining about for years."

Before turning to our specific concerns, I want to address an issue that is being discussed by Committee Members about the origins of the bill. A number of Members recall S. 1080, a regulatory reform bill that passed the Senate, 94-0, in early 1982.[2] Many Members of this Committee helped work on this bill and supported its passage. The structure of S. 343, as voted out of Subcommittee, is based on the structure of S. 1080. Some

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[1] Remarks by President Clinton at a Regulatory Reform Event, Room 450, Old Executive Office Building, February 21, 1995.

[2] Cong. Rec., daily ed., S 2713-S 2721 (March 23, 1982).

provisions of S. 343 are identical to provisions in S. 1080. But there are significant differences as well. S. 343 adds provisions expanding the applicability of the bill, imposing decisional criteria, encouraging judicial review, adding various forms of petition processes, and prescribing detailed risk assessment and characterization procedures. Let me discuss these in turn.[3]

Section 621 -- the Definition of "Major Rule." One obvious problem with S. 343 is its scope. Its regulatory impact analysis and risk assessment requirements apply to each "major rule." A major rule is then defined as one that "is likely to have a gross annual effect on the economy of $50,000,000 or more" or is likely to result in "a substantial increase in costs or prices" or has "significant adverse effects" on competition, employment, investment, innovation, the environment, public health or safety, etc.

Consider first the numerical threshold. Since President Ford, every President has had an executive order establishing regulatory review. An essential ingredient of these orders is a distinction between that which is important and that which is more routine or administrative. For over 20 years, that distinction has been drawn at an aggregate annual effect on the economy of $100 million; that is also the threshold set in S. 1080.[4]

In developing Executive Order No. 12866, the Administration consciously retained $100 million as the threshold for requiring a cost-benefit analysis, having determined that the resources devoted to regulatory analysis should be commensurate with the

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[3] I am not discussing here the amendments to the Regulatory Flexibility Act.

[4] Cong. Rec., daily ed., S. 2715 (March 23, 1982).

significance of the decision to be made. Allocating resources where they are most productive (i.e., getting the biggest bang for the buck) is a tenet of proponents of cost-benefit analysis. S. 343, by setting the threshold for such analyses at one half of what President Reagan used (14 years ago) in his Executive Order, dilutes this distinction. Indeed, for a large number of rules, there would be newly imposed procedural and paperwork requirements that can only cause delay and gridlock.

We are also concerned that S. 343 goes beyond the numerical threshold, in its definition of rules requiring a cost-benefit analysis. These are open-ended phrases -- "substantial increase in costs or prices" and "significant adverse effects" -- that start you down a slippery slope. Is there a "substantial increase" in price if there is a 5¢ increase in a 15¢ item? A 5¢ increase in a $1.00 item? What if you use a 1,000 of those $1.00 items? Is it still "substantial" if the 1,000 items account for less than 1% of your cost of service? Are there not some cases where the cost of undertaking a rigorous cost-benefit analysis or following the detailed risk assessment and communication procedures would overwhelm the benefits to be derived from such analysis? How are agencies to know where the line is to be drawn and what criteria would be used by the courts in reviewing whatever decision is made?

I am not asking these questions just as a stylistic device. The broader the scope of the definition of "major rule," the greater the number of rules that will require formal, structured analysis. The amount of analytic and other administrative effort devoted to a rulemaking has to be kept in proportion to the importance of that rule. Stated another way, it does not make sense to sweep into the system large numbers of regulations that do not warrant, and could not conceivably profit from, a full-blown cost-benefit analysis. At that point there is overload. As the President stated, "Why bother [to seek the repeal of

consumer or environmental statutes] if you can paralyze the government by process? Surely, after years and years and years of people screaming about excessive governmental process, we won't just go to an even bigger round of process to tilt the process itself in another direction."

Section 624 -- "Decisional Criteria." S. 343 provides that no final major rule can be issued unless the agency finds that the potential benefits of the rule "justify" the potential costs of the rule and that the rule will provide greater net benefits to society "than any of the reasonable alternatives" identified during the rulemaking process. To be explicit on the intended effect of this provision, the language voted out of Subcommittee states that unless an existing statute "expressly requires" promulgation of a rule without regard to or without satisfying one or both of these decisional criteria, these criteria "shall supplement any other decisional criteria otherwise provided by law."

The potential effects of Section 624 are hard to itemize, but the significance of the contemplated change cannot be overstated. For more than 30 years, Congress has passed -- and Presidents from both parties have signed -- publicly acclaimed legislation for which the decisionmaking criteria are different from that suggested here. Some legislation -- much of it seeking to redress long-standing wrongs to minority groups and persons with disabilities -- is based on social and procedural, rather than economic, standards of equity, fairness, and due process. Other legislation -- including legislation involving safety to workers -- reflects Congressional judgments that while both safety and health standards properly consider costs, in the latter case those costs may not be weighed against benefits once a significant risk has been determined. Still other legislation -- much of it designed to protect the environment -- is based upon standards tied to the most advanced technology being used by

industry. And other legislation -- underpinning entitlements, benefits, and formula grant programs -- views certain individuals and groups as worthy of society's support exceeding a level that a marginal analysis of aggregate social needs might suggest.

All of this legislation was vigorously debated and carefully considered at the time of enactment, and it has served as the underpinning of American society since at least World War II. While each statute set forth the factors that should be considered, it is not surprising that few, if any, expressly precluded consideration of the decisional criteria that have only recently been articulated in this form. It may be appropriate to review and/or reconsider some of these statutes, but any fundamental changes in underlying standards should be debated and decided on the merits and not in the guise of procedural reform. To override this history in 33 lines of text, without identifying the statutes and regulatory programs involved, and without a reasoned discussion by the responsible Committees and by the full Senate and House of the myriad of social and economic policies that are implicated cannot be fairly characterized as good government.

Sections 553, 625, 634, and 706 -- Judicial Review. S. 343 invites judicial review of any agency's compliance or noncompliance with the analytic requirements of the bill, including both the numerical and non-numerical criteria used in determining whether or not the rule is a major rule.[5] Because S. 343 does not preclude judicial review, the Administrative Procedure Act, which authorizes judicial review of final agency

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[5] While Section 625 does not explicitly permit court review of whether or not a rule should be considered "major," the amendment to 5 U.S.C. 553(e) does. Under new 5 U.S.C. 553(e)(2), any person may file a petition suggesting the need for an agency to perform the analyses required for "major" rules. Under new 5 U.S.C. 553(e)(3), an agency decision to deny such a petition is subject to immediate court review.

action, would apply. In addition, Sections 625(b), 634(b) and 639(c) require that cost-benefit analyses, risk assessments and peer review reports be made part of the administrative record for purposes of judicial review of final agency action. There is also the explicit provision in Section 625 that agency compliance or noncompliance with these decisional criteria discussed above is subject to review in the Federal courts.[6]

The objective of cost benefit and risk assessment legislation should be to improve the regulatory decisionmaking process, not to create unproductive paper record requirements or additional opportunities for litigation. Nevertheless, this bill authorizes Federal judges to focus on whether the agencies chose the right path to follow in developing a rule and whether they followed each of the many procedural steps. Similarly, the open-ended definition of "major" discussed invites endless opportunities for litigation, producing uncertainty and delay -- with all of the attendant costs.

In addition, as noted above, each regulation issued under an existing statute (with its own decision criteria, agency practice, and court precedent) would become subject to the new decisional criteria in Section 624. For present purposes, the important point is that the bill (specifically Section 625(b)) makes Federal judges, rather than the Congress, responsible for deciding what changes in social and economic policy are to be made.

Last year the Administration and the Senate reached agreement, in the context of the Johnston Amendment to the Safe

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[6] Section 625 is reinforced, in new 5 U.S.C. 706(c)(2)(B), by having the reviewing Federal court find as an abuse of agency discretion an agency interpretation of a statute "that does not give the agency the broadest discretion to develop rules that will satisfy the decisional criteria of section 624."

Drinking Water Act, that risk analysis should not be subject to judicial review. The Executive, with oversight by Congress, should be responsible for determining the processes by which agencies make their decisions, particularly when the decisions are to be informed by substantial doses of science and economics. We should think twice before inviting generalist judges to evaluate the quality of the science and scientific judgment used in risk assessments; before we give economists the opportunity to serve as expert witnesses opining on the sufficiency or accuracy of the cost and cost-effectiveness estimates an agency made before promulgating a regulation; and before requiring Federal agencies to spend added time satisfying (with the extra margin needed to assure affirmance in court) each step, producing even more paper and an even larger record -- efforts that would consume a great deal of time and resources without producing sounder regulations.

We are also troubled by the amendment to 5 U.S.C. 706, which requires a reviewing court to hold as unlawful "an agency interpretation [of a statute] that is other than the interpretation of the statute clearly intended by Congress" or as an abuse of discretion an agency failure to explain "in a reasoned analysis why it selected the interpretation [it did] and why it rejected other permissible interpretations of the statute". As this Committee well knows, there is an enormous body of law and lore on the subject of statutory construction and on the more arcane issue near and dear to the hearts of administrative lawyers on the subject of an agency's interpretation of its statutory mandate. This section begins by appearing to codify the Chevron[7] decision, but then it introduces a number of new twists. It is not at all clear what changes are being made, what other seminal administrative law decisions are being overturned or significantly modified, and, again, what the

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[7] Chevron v. NRDC, 467 U.S. 837 (1984).

implications will be for the host of organic statutes whose interpretations (by the agencies or by the courts under a different standard of review) have up to now been considered settled law. These are matters that should not be lightly brushed aside, particularly in the name of improving the regulatory system.[8]

If there is one thing that the last 30 years of administrative law has taught us, it is that courts are not always good at second guessing agency rulemaking. Judicial interpretations that emerge in the context of an individual, hard-fought litigation do not always make sense in the broader context of setting priorities and reducing risks in a cost-effective manner. Given the ready availability of congressional oversight, the cost of adding a judicial component to risk/cost-benefit legislation far exceeds the benefits that judicial enforcement is likely to provide.

Section 623 and 637 -- Look-Back. Section 623, "Petition for cost-benefit analysis," provides that anyone may petition the relevant agency or the OMB Director to perform a cost-benefit analysis for an existing major rule if one had not been previously performed that met the requirements of S. 343, and then the agency must conduct a detailed cost-benefit analysis as provided in S. 343. As a matter of principle, this

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[8] Also, to the extent that the agencies (and the courts) are locked into the intent of Congress, the weight will likely be given to the intent of the Congress that passed the statute -- 10, 20, 30, or more years ago -- augmented by the intent of subsequent Congresses only to the extent they have manifested that intent in the form of amendments, riders, etc. What will be the weight accorded the informal oversight process -- the expression of preferences by Congressional leadership, chairmen, and individual Members -- in the more recent past, currently, or as it may be expressed in the future? Is it really the will of the Congress to instruct the Federal judiciary to ignore the results of this traditional and highly effective Congressional oversight process?

Administration supports -- indeed, encourages -- agencies to review the effectiveness and efficiency of existing rules -- particularly those that have been on the books for a number of years. But Section 623 is unworkable and, if enacted as drafted, could transfer the management of the agencies from both the Executive and Legislative branches of government to special interests pursuing their own agendas.

Section 623 authorizes individuals to file a petition to have an agency review a major rule, any portion of a major rule, or agency guidance or general statement of policy that is equivalent to a major rule. The agency or OMB is to decide whether there is "a reasonable likelihood that the costs ... outweigh the benefits, or that reasonable questions exist as to whether the rule provides greater net benefits to society than any reasonable alternative ...". If the agency or OMB denies the petition, that action is immediately reviewable in court. If the agency or OMB grants the petition, the agency must promptly undertake the requisite cost-benefit analysis of the subject of the petition, and determine whether the rule "satisfies the decisional criteria" in Section 624. If the rule does not satisfy these decisional criteria, the agency is to "take immediate action either to revoke or amend the rule" to conform to these decisional criteria.

Similarly, Section 637 would establish a petition process for revising a previously conducted risk assessment to meet the requirements of Subchapter III. Section 637 requires the agency to decide whether or not to do so within 90 days, and requires that the risk assessment be completed within 180 days thereafter.

As noted earlier, this Administration strongly supports the idea that agencies should review the effectiveness and efficiency of existing rules -- particularly those that have been on the books for a number of years. On February 21, the President

specifically instructed the Federal regulatory agencies "to go over every single regulation and cut those regulations which are obsolete." The issue, then, is not principle; we agree on the objective. The issue is how to do it (and continue to have it done) in the most effective way.

We believe the petition processes in Sections 623 and 637 are unworkable and, if enacted as drafted, would, in the President's words, "paralyze the government by process." First, the task facing an agency is likely to be formidable. As to the petition process for cost-benefit analyses established by Section 623, there is little in the field of regulation that would not give rise to some "reasonable questions" concerning net benefits. Moreover, since the threshold for defining a "major" rule would be half of what it has been for the past 20 years (without even taking account of inflation), there are undoubtedly a very large number of regulations that have never been subject to the requisite cost-benefit analysis. Similarly, it is likely that many, if not most, of the risk assessments already completed did not follow each and every one of the steps outlined in Subchapter III, and thus petitions could be filed for virtually all previously completed risk assessments under Section 637.

Second, for both kinds of petitions, the time pressures will be severe, both to decide whether or not to grant the petition and, if so, then to complete the requisite analysis. Recall also that if an agency were to deny a petition, under S. 343, judicial review would be available to the petitioning party, thus exacerbating the strain on agency resources.

Most significantly, however, the agencies' task will <u>not</u> be determined by the President or the people he appoints, <u>or</u> by the Congress. Rather, the agencies' priorities will be set by the special interests who are the first to flood the agencies with their petitions and sufficiently well-financed to keep the

petitions coming. Thus the management of the agencies will be turned over to those pursuing their own parochial interests.

Subchapter III -- Risk Assessments. Subchapter III creates risk assessment and peer review requirements for agencies in connection with regulatory programs designed to protect "health, safety, and environmental risks." This phrase, which at its core is an apt description of a category of well-defined regulatory programs, would -- as used here -- apply a series of requirements to a large number of regulatory activities that do not warrant, and could not conceivably profit from, a full-blown risk assessment.

For example, do you really want the Department of Commerce to have to go through the risk assessment and peer review process before issuing a rule opening a fishing season at a particular set of fisheries? The Department of Interior before it authorizes the seasonal hunting of certain migratory birds otherwise illegal to shoot? The Internal Revenue Service before it revises its income tax regulations concerning the electric vehicle or the alternative fuel tax credit? The Bureau of Alcohol, Tobacco, and Firearms before it restricts the sale of a type of explosive? The Department of Transportation before it issues mirror requirements to help school bus drivers see children near the bus? The Federal Aviation Administration before it prohibits runways from being used for both takeoffs and landings at the same time? The Occupational Safety and Health Administration before it can protect forklift drivers, scores of whom are, each year, crushed in roll over accidents because of inadequate training? The Food and Drug Administration before it can prohibit the importation of cans containing lead?

Section 635(b)(4) states that a risk assessment "shall be prepared at the level of detail appropriate and practicable for reasoned decisionmaking on the matter involved, taking into

consideration the significance and complexity of the decision and any need for expedition." This provision makes sense; it permits agencies to spend resources on risk analysis that are commensurate with the significance of the regulatory decision to be made.

Unfortunately, however, other provisions of this section and the one that follows it effectively negate that sensible language. Read literally, as a statute should be, Subchapter III requires an agency to perform a full-blown risk assessment (including a discussion of comparative physiology, routes of exposure, bioavailability, and pharmacokinetics; a presentation of plausible and alternative assumptions, a full description of the model used in the risk assessment and the assumptions incorporated therein, and an indication of the extent to which this model has been validated by empirical data; a statement of the reasonable range of scientific uncertainties; a best estimate of risk; an explanation of the exposure scenarios employed by the risk analysis; comparisons to other health risks; and an analysis of any substitution risks) <u>every</u> time it makes <u>any</u> characterization about <u>any</u> risk that it wishes to communicate to the public or to Congress or that it wishes to rely on in pursuing virtually any regulatory activity.[9]

Congress has in some cases specified the factors that agencies are to consider in issuing health, safety, and environmental regulations, and it has on occasion explicitly or implicitly precluded the consideration of risk in decisionmaking. Technology-based standards are one example. In those instances, what purpose is served by requiring an agency to perform a rigorous risk assessment, let alone undertake each and every one

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[9] There are very limited exceptions in Section 632 for use of risk assessments for screening analyses that do not result in positive findings of risk and in emergencies.

of the specified steps? And even in those circumstances where the underlying statute does not preclude consideration of risk, the requirements in the Subchapter III are overly broad and undifferentiated given the different missions of different agencies. For example, the focus of several of the provisions appear to be on cancer risks. That may be one of several factors relevant to EPA's regulation of toxic chemicals, but does it make sense when evaluating a Department of Agriculture proposal designed to reduce the instances of bacterial contamination of meat? What purpose would be served by requiring the FAA, in determining whether an airplane should be grounded because of icing problems, to "explain the exposure scenarios" used in its risk assessments, or the Department of Commerce, in regulating against overfishing of fisheries, to compare the risk of fish depletion to six other risks?

There is general agreement that agencies should use objectively verifiable scientific methods, provide sufficient information so that their scientific analysis could be replicated, explain and make transparent their assumptions (including who or what is being protected and why), and provide meaningful explanations of risks (including comparisons that are meaningful to the public and relevant to the decision being made). Subchapter III, however, is quintessential command and control. Rather than specifying what is to be achieved (or, in regulatory parlance, the performance standard that is to be met), it tells agencies not only what to do, but also how to do it and when to do it.

Section 630 -- Peer Review. Like the risk assessment/risk characterization requirements in Subchapter III, its peer review requirements reflect a "one-size-fits-all" approach. Section 630 requires the Director of the Office of Science and Technology to develop "a systematic program for the peer review," which is to be "used uniformly across the agencies." Yet different agencies

have very different missions, and not surprisingly their peer review needs and requirements vary accordingly. Thus, for example, the Department of Transportation, which possesses very concrete data concerning automobile and airplane accidents, is less likely to require the same type or scope of peer review as the Environmental Protection Agency's program office that is working on global climate change issues.

The peer review requirements are troubling for two additional reasons. First, Section 638(1) requires that each agency head certify that its risk assessments are "supported by the best available scientific data, as determined by a peer review panel. . . ." This provision would take ultimate authority away from the agencies and vest it in individuals who do not work for, and are not responsible to, the Federal government. Such a delegation of ultimate power is, to my knowledge, unprecedented since the days of President Roosevelt's National Recovery Administration. Second, Section 639 carries micromanagement so far that it explicitly makes an exception to customary standards of ethical conduct by prohibiting agencies from restricting those with an interest in the outcome from participating on the panel.

Would it not be more productive for the legislation simply to require agencies to have a peer review plan, tailored to the types of risks they address and the relevant sciences that are involved? The plan could indicate which types of risk assessments would be subject to peer review, whether external or internal, and these plans could be made available to the public -- indeed, there could be public comment on the plan. Here, as above, we urge that whatever legislation is passed set forth the objective and not seek to specify each and every detail along the way.

Section 801 -- Comprehensive Report and Wait. Section 801 provides that, subject to certain limited exemptions, any major rule is to lay over in Congress for 45 days awaiting, under expedited procedures, a potential legislative override. While Section 801 purports to restore power to the Congress to stabilize the balance of power, it could in fact shift that balance in undesirable ways.

I need not belabor the Constitutionally established separation of powers: Congress -- the Legislative branch -- authorizes the Executive branch to carry out designated responsibilities. The Executive branch is responsible for the day-to-day decisionmaking -- the conduct and fulfillment of these Federal responsibilities. To oversee these day-to-day activities, Congress -- its Committees, its leadership, its individual Members -- retains well-established mechanisms of formal and informal oversight.

But in Section 801, the Congress may be putting itself into the position -- for 45 days -- to have individual Members, their staff, and any private constituents whose help they request scrutinize the agencies' work product. Will some suggest "modest changes" if the agency wants its rule to go forward? Will others suggest the addition (or deletion) of one "small piece" of the proposed package? This is a potentially significant lever to give an individual Member -- or his or her staff -- and it will permit the lobbying on particular regulations (which can be quite intense) to move from the agency -- where the often competing claims are to be reconciled -- to the Hill, where there may not be the time nor the resources to verify information, hear the "other side of the story," or resolve the conflict. And this intervention would take place at the end of the administrative rulemaking process and without any of the disclosure and record requirements set forth in the Administrative Procedure Act, which stresses openness, accountability, and due process for all.

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If the layering of the regulatory process with complicated requirements were costless, we would not object so much to S. 343 and its inflexibility. But we must be clear about what is at stake. The effect of these requirements is not to bring sound science and solid economics to bear on regulation, but to create more bureaucracy, more paperwork, and less efficiency in government -- to the point that the regulatory system could not move forward and our ability to take sensible steps to protect human health and safety and the environment would be substantially retarded.

I regret that I have spent so much time speaking to matters on which we disagree rather than on the areas where we do agree. As President Clinton said, "We all want the benefits of regulation. We all want clean air and clean water and safe food and toys that our children can play with. But let's face it, we all know the regulatory system needs repair. Too often the rule writers here in Washington have such detailed lists of dos and don'ts that the dos and don'ts undermine the very objectives they seek to achieve, when clear goals and operation for cooperation would work better. Too often, especially small businesses, face a profusion of overlapping and sometimes conflicting rules. . . . We need to change this system."

Working together, I am confident that we will be able to help bring the American people a rational regulatory system that works for them, not against them, and that improves our quality of life, promotes our health and safety, and protects the environment, without imposing undue costs or burdens.

Thank you, Mr. Chairman. I am happy to answer your questions.

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THE FIRST YEAR OF EXECUTIVE ORDER NO. 12866

I. INTRODUCTION AND SUMMARY

Just over one year ago, on September 30, 1993, President Clinton issued Executive Order No. 12866, "Regulatory Planning and Review." The Order was designed to restore integrity and accountability to centralized regulatory review, qualities notably absent during the previous administration. The Order also articulated this Administration's philosophy and principles regarding regulation. These are best summarized in the Order's opening lines:

> The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable.

The President directed the OIRA Administrator to report on the implementation of the Executive Order after its first six months. A written report covering the period October 1, 1993, through March 31, 1994, was delivered to the President and Vice President on May 1, 1994, as requested, and was published in the Federal Register on May 10, 1994.

In the Report, we described in some detail the progress we have made, including improved coordination both between OMB and the agencies and among agencies themselves; more timely OMB review of significant rules; more openness and early

participation by the public in rulemaking; and extensive outreach to State, local, and tribal governments and to small businesses. We also noted that the startup time had been longer than we had anticipated, and that to some extent it was simply too early to judge the success of the Order. In particular, while we had extensive information on the process, we had little information on the substantive compliance with the Order.

We now have data on the period April 1 through September 30, 1994, giving us an opportunity to evaluate the full first year of implementation. Overall, we continue to be pleased with the progress that has been made in achieving the objectives of the Executive Order, but at the same time we are acutely conscious of the work that remains to be done to realize the full benefits that we had hoped to achieve.

As will be discussed below, the processes established by the Order are now for the most part in place, and in general they are operating well. We also have more experience with, and a better feel for, the implementation of the philosophy and principles set out in the Order, particularly as they are reflected in the rules that OIRA reviews. While insufficient time and/or data have resulted in some regulations that may not be the most cost-effective means of achieving their objectives, there are many examples where agencies, by adhering to the philosophy and principles of the Order, have in fact produced "smarter" regulations. In these cases -- whether through increased outreach to the public, greater inter-agency cooperation, improved analysis, or all of the above -- agencies have been better able to balance the complex variety of factors that make up regulatory benefits and costs.

It is important to keep in mind the constraints under which the agencies are operating. The regulatory pipeline is a long one, and it is not uncommon for rules to be issued years after

the authorizing statute or the regulatory initiative first began; indeed, many of the rules promulgated by the agencies this past year were conceived and to a large extent developed before this Administration took office, and thus before the Executive Order was signed. More importantly, some of the rules that have been issued were required by statutes that contain highly prescriptive regulatory requirements, complete with time lines that drive much of the rulemaking process, particularly in the areas of health, safety, and the environment. In addition, rulemaking is often driven by other factors beyond the direct control of the Executive Branch, such as court decisions and dramatic public events that require immediate action.

Moreover, agencies today face unusual pressures to regulate. With budgetary constraints so tight, and with the difficulty of enacting new legislation in the highly partisan atmosphere that characterized the last Congress, the only means left for the agencies to implement their initiatives is through regulation. This puts inordinate pressure on any attempt to hold steady or reduce the amount of regulation in which they are engaged.

Measuring the success of the Order is complicated by other factors as well. While some of its processes can be measured with precision (for example, the number of rules reviewed by OIRA), it is not so easy to judge the success of the philosophy and principles of the Order in producing "smarter" regulations. It is tempting to argue that if all the affected stakeholders are equally irritated, then the correct balance has been struck. Whatever the truth in this, it is a uniquely gloomy definition of success to which we do not subscribe. We believe it is possible for parties to be satisfied, if not jubilant, with the outcome of a rulemaking, recognizing it for what it is, or should be -- a good faith effort in an imperfect world to further the public good.

One of the reasons it is difficult to easily measure the success of the Order is that neither the philosophy nor any of the basic principles -- development of alternatives, setting regulatory priorities, obtaining the best reasonably available information, assessing benefits and costs, considering Federal, State, local, and tribal needs, coordinating with other agencies -- lends itself to facile, mechanical application. Stated another way, the principles of the Order are not a simple check list of tasks. Instead, they are a complex and interactive body of standards that require reasoned judgment, difficult decisions, and balances of competing priorities.

Moreover, though the principles appear simple and straightforward, they are not always easy to apply in particular situations, and the agencies are often faced with imperfect information and limited personnel and financial resources to devote to analysis. And they ultimately face what must be acknowledged as a daunting task: In a society composed of complex and changing webs of institutional and individual behavior, they must predict the future, attempting to control behavior harmful to the common good, without impeding or unwittingly restraining acceptable and beneficial activities.

Finally, under the Executive Order, OIRA reviews only "significant" rules, less than half the rules formerly reviewed by OIRA and an even smaller percentage of the rulemaking documents that are published in the Federal Register. Accordingly, we neither track nor evaluate the extent to which the more routine but numerous regulations that are being issued by the agencies meet the principles of the Order.

For all of these reasons, we cannot assert that the philosophy and principles espoused in the Order either have or have not always been met by the agencies in their regulatory programs. We can, however, provide information that clearly

indicates that agencies are applying the principles in many and diverse rulemakings. We urge those who wish to rush to judgement to remember that even modest changes take enormous effort and much time to accomplish. Based on our experiences this past year that are described below, we believe that the Executive Order sets in place the means to make those changes, and that we are moving in the right direction.

The May 1st Report on Executive Order No. 12866 contained both a short history of regulatory programs of the U.S. Government and a detailed description of the Order and its objectives. These will not be repeated here. Instead, we update the data about the various processes established in the Order, followed by descriptions of some of the substantive changes we are seeing.

II. IMPLEMENTATION OF THE PROCESSES SET FORTH IN THE ORDER

Regulatory Planning

In the May 1st Report, we noted that the regulatory planning process set forth in Section 4 of the Executive Order had just begun. On April 5, 1994, the Vice President convened the Agencies' Policy Meeting. Guidance to the agencies was issued by the OIRA Administrator at this meeting, with additional guidance provided on May 12, 1994.

Draft Regulatory Plans were due to OIRA on June 1st. We asked for Regulatory Plan submissions from over 30 agencies -- all Cabinet agencies except the Department of State; major non-Cabinet agencies, including the Environmental Protection Agency (EPA); and several independent agencies. Some of the agencies, including the Departments of Defense (DOD) and Housing and Urban Development (HUD), as well as the Consumer Product Safety Commission (CPSC), Equal Employment Opportunity Commission (EEOC), the National Archives and Records Administration (NARA), and the Nuclear Regulatory Commission (NRC), submitted Plans on June 1st. Most of the Plans were submitted within the first two weeks of June. However, it took longer than expected to receive Plans from all the major regulatory agencies; in fact, several were not submitted until the end of June and the last was not submitted until late July.

As required by the Order (Section 4(c)(3)), the draft Regulatory Plans were circulated by OIRA to other affected agencies, the regulatory Advisors, and the Vice President within 10 days of receipt. Agencies were reminded to comment to the OIRA Administrator on any planned regulatory action of another agency that might conflict with its own policies (Section 4(c)(5)). Very few substantive comments were received by OIRA.

OIRA and OVP staff reviewed the Plans for conformance to Section 4. In general, the draft Plans, though a good start, were uneven. Several were serious, thoughtful efforts; several others were perfunctory. The better efforts were those of the Departments of Commerce (DOC), Labor (DOL), and Transportation (DOT), and EPA. In several of these cases, agency overviews were well-written descriptions of departmental objectives and their relationship to Presidential priorities.

After consultations with the Vice President's Office (Section 4(c)(6)), many agencies reviewed their draft Plans and improved them. These were submitted to OIRA during late August and September. At present the task of preparing the Regulatory Plans for publication in the Federal Register with the Unified Regulatory Agenda (as required by Section (4)(c)(7)) is proceeding on schedule. The Plans and Agenda are to be published on or about October 31, 1994.

The draft Regulatory Plans alerted us to areas where more than one agency was engaged in regulation, and they helped raise these issues to agencies' upper level managers. However, the Plans did not provide very many common themes, and, taken as a whole, they did not produce a consistent or coherent statement of the regulatory priorities of this Administration. While this is disappointing, it is not surprising given the different statutory mandates and missions of the agencies.

Cooperation and Coordination

OIRA and the Agencies: The improved relationships between OIRA and among the agencies that were noted in the May 1st Report have continued, grown, and generally become the norm. There remain differences of view, which can be quite sharp. But for the most part, the differences are healthy, leading to better rules, rather than sources of friction that are unproductive and detract from joint efforts.

Staffs of both OIRA and the regulatory agencies are now quite familiar with what at the turn of the year was a new and untried review process. The procedures by which agencies and OIRA select rulemakings as "significant," and thus subject to OMB review, has matured -- conforming to the requirements of Section 6(a)(3)(a) of the Order, yet retaining a necessary flexibility. While a monthly or bi-monthly list remains a common norm, many variations have developed. Moreover, agencies and OIRA staff have worked out an arrangement to designate informally, often over the phone, non-significant rules that must be published quickly. Even the most orderly regulatory planning and tracking systems must be able to accommodate unexpected events.

Some of the agencies have developed the practice of consulting OIRA staff on whether particular rules are significant even before putting them on a monthly list. Some agencies voluntarily submit advanced drafts so that OIRA staff can make a more informed judgement regarding significance. Also, in some cases, agencies exempted from the centralized review requirements of the Order have voluntarily submitted rules for review. For example, the Advisory Council on Historic Preservation (ACHP), which is formally exempted from the Order, submitted a draft proposal for review, knowing that it needed further interagency coordination. Thus, though the Order formally requires agencies to provide OIRA with a list "indicating those [rules] which the agency believes are significant regulatory actions" (Section 6(a)(3(A)), and specifically states that "OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3(A)" (Section 6(b)(1)), a flexibility built on trust and collegiality has developed with many of the agencies that permits the system to work smoothly and efficiently. This was unheard of a short time ago. We hope the pattern that is developing will ultimately spread to the agencies where historically there has been the greatest resistance to such a cooperative relationship.

Another specific manifestation of the improved relationship between OIRA and the agencies, which is a very constructive development, is the practice of early briefings by agencies on the content of significant rules. For example, early in the process of developing its rules for drug and alcohol testing for various transportation officials and workers, DOT consulted with the OIRA Administrator and staff on the major issues on which it would have to decide in the rulemaking. It then held subsequent briefings to update OIRA on the decisions being made at DOT and to continue to search for feedback. By the time the rules were submitted for OIRA review, there had been sufficient discussion of the important provisions that the review was promptly concluded.

In another instance, HUD was developing rules related to public housing policy regarding the elderly and the disabled. HUD officials provided information to OIRA and to other OMB staff even as decisions were being presented to HUD officials. This enabled the issues of concern to be addressed on a real time basis, and resulted in review being completed much more quickly than would otherwise have occurred.

As a final example, in March 1994, the Department of Education (ED) identified seven final regulations pertaining to student financial assistance programs that had to be published by a May 1, 1994, statutory deadline. OIRA worked with the Department's teams, discussing issues and reviewing early drafts as they were developed. As a result of this cooperative effort, a thorough review under the Executive Order took place, while, at the same time, the formal time period for review averaged only one day and the statutory deadline was met.

Lastly in the area of improved relationships between the agencies and OIRA, the Regulatory Training and Exchange Program has grown and developed. As mentioned in the May 1st Report, the

program, which implements a recommendation of the National Performance Review, brings agency career staff to OIRA on training details, so that they can learn how regulatory review is conducted and to work on Regulatory Working Group (RWG) matters. The objective of the program is to provide expertise to agency career staff regarding regulatory review that can be incorporated into the working practices of the agency.

OIRA has now hosted seven detailees, from the Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and DOT. Two trainees are currently at OIRA. In addition, an OIRA analyst has undertaken a training detail at HHS. All of these details have been extremely successful and well received, both by the trainees and by OIRA. The agency detailees have been fully engaged in substantive regulatory review, and we understand they have gained a new appreciation for the perspective of the central reviewer. They have all been senior career officials, highly motivated and knowledgeable, and have not only fit in well at OIRA, but have offered valuable insights to OIRA staff regarding agency points of view. As the good news about the program travels, we hope that more agencies will take advantage of this excellent opportunity.

Interagency Coordination: Just as important as improved relationships between OIRA and the agencies are better working relationships among the agencies themselves and the consequent heightened awareness of the need for interagency coordination and cooperation in complex rulemaking endeavors. The Executive Branch is an extensive enterprise, and its programs are dispersed among hundreds of different agencies, subagencies, and offices. We obviously cannot claim that there are no glitches, but we believe agencies are making strong efforts to engage in much more extensive interagency coordination.

For example, in the ACHP example noted above, the agency met at length with the Department of Interior (DOI), DOT, USDA, HUD, and EPA in developing its proposed rule. Not all these agencies were satisfied with the proposal that was eventually drafted, but all agreed that they had been fully consulted. This process is not over, and will continue during and subsequent to the public comment period, as ACHP develops its final rule.

In another instance, DOC, DOI, and the Council of Economic Advisors (CEA) worked closely together on DOC and DOI rulemakings that seek, through a survey methodology called "contingent valuation," to quantify the non-use value of damages to natural resources. After substantial consultation among the primary participants, as well as with EPA and the Department of Energy (DOE), DOI and DOC issued coordinated proposed rules whose comment periods only recently closed. It is expected that there will be even more extensive interagency coordination before the final rules are issued.

It is worth noting that interagency coordination is often quite time- and resource-consuming and not without its frustrations. Agencies do after all have different perspectives on their overlapping jurisdictions and mandates, and the process of working out an accommodation is not necessarily a trivial task. In such instances, however, OIRA can often serve as a facilitator of debate, leading to resolution of issues.

For example, a USDA final rule on farmland protection was drafted to implement a statutory requirement that Federal agencies measure the adverse effects of their programs on the conversion of farmland to nonagricultural uses. During its review at OIRA, the draft rule was the subject of extensive coordination among USDA, DOT, HUD, the Department of Justice (DOJ), and Treasury. Although the 90-day review period had to be extended, eventually the agencies reached understandings and

resolved their disagreements. All agreed that the result was a rule that met the intent of the statute without unduly burdening or restricting other Federal programs.

Similarly, coordination among agencies was essential to the issuance of EPA's rule on General Conformity. The Clean Air Act Amendments of 1990 (CAA) require that Federal agencies insure that any actions they undertake or support are consistent with State air quality planning under the Clean Air Act -- i.e., Federal actions must be shown to be in "conformity" with State implementation plans and must not cause or contribute to air quality problems.

Through its rulemaking, EPA sought to delineate the steps Federal agencies were to take and when they were to take them. EPA had initially chosen to interpret the statutory language to require the complex conformity determinations and mitigation/offsetting measures for a vast range of Federal actions -- even those where the Federal agency might exert no continuing control, such as the sale of DOD property or the granting of a Corps of Engineers wetlands modification permit. Because other Federal agencies' activities were clearly affected by this rulemaking, there were a series of multi-lateral and bi-lateral discussions organized by OIRA. As a result of those discussions, certain definitions were refined and certain proposed procedures simplified -- again producing a rule that met the intent of the statute without unduly burdening or restricting other Federal programs.

An example involving HHS and the National Science Foundation (NSF) illustrates the importance of interagency coordination in resolving difficulties with stakeholders and developing a consistent Federal policy. In September 1989, HHS's Public Health Service (PHS) proposed guidelines to prevent financial conflicts of interest by federally funded scientists. The

proposal was severely criticized by the research community as being unreasonably harsh and burdensome, and it was soon withdrawn. NSF then began its own efforts to address this issue, publishing a proposed policy for comment. Over the past year, OIRA and the Office of Science and Technology Policy (OSTP) worked with NSF and HHS to develop a coordinated policy regarding how agencies should regulate financial holdings of scientists who receive Federal grants. After several interagency meetings and extensive discussions, NSF and HHS agreed to develop a common approach. Moreover, the rules are designed to provide maximum flexibility to universities in implementing policies on how to address potential conflicts of interest.

The success of this effort is shown in an article published in Science Magazine describing the rules as "being roundly applauded for their reasonableness." (Science, Vol 265, July 8, 1994, p. 179-80). Whereas the original proposals were considered prescriptive and would have required institutions to turn over researchers' financial disclosures to the government, the final NSF rule states general aims leaving implementation to the universities. The article quotes the associate vice chancellor for research at the University of Illinois as viewing the rule as "a positive example of the process working for both sides. Institutions made comments [on the 1989 proposal], and the agency responded in a thoughtful way."

The coordination and cooperation described above is the result of strong support by the President and Vice President and of trust and cooperation among agency regulatory policy officials. The mechanisms established by the Executive Order to stimulate and encourage such coordination are working well. The Regulatory Working Group (RWG) has continued its role of keeping high level agency regulatory policy officials in touch with each other and with the White House regulatory policy advisors.

The RWG followed up its initial meetings in November, January, and March, with meetings in April, May, June, and August. Implementation of the Executive Order was a frequent agenda item for these meetings, along with discussions of the Regulatory Plans, centralized review and the process by which rules are determined to be significant, public involvement and outreach in rulemaking, and the Section 5 review of existing regulations. Important legislative issues related to regulatory affairs were also discussed, including unfunded mandates, risk analysis, regulatory flexibility analysis, and takings. In addition, the RWG heard periodic reports by the four subgroups on cost-benefit analysis, risk analysis, streamlining, and the use of information technology in rulemaking. Finally, small business issues and issues related to the Paperwork Reduction Act were often subjects of discussion among the RWG members.

The Federal Partnership - Intergovernmental Cooperation: Executive Order No. 12866 places particular emphasis on improving the Federal Government's relationship with State, local, and tribal governments. (See Sections 1(b)(9), Section 4(e), Section 6(a)(1), and Section 6(a)(3)(B)(ii).) Executive Order No. 12875, "Enhancing the Intergovernmental Partnership," further addresses this issue, focusing on reduction of nonstatutory unfunded mandates largely through a process of formal consultation and coordination.

OIRA has continued its outreach to State, local, and tribal governments (Section 4(e)). In the May 1st Report, we noted that OIRA had held two conferences with representatives of these entities. We sponsored a third forum in July, at which representatives from the National Governors' Association, the League of Cities, the Conference of State Legislatures, the National Association of Counties, and the Advisory Commission on Intergovernmental Relations spoke about their regulatory concerns.

While we have no standard of measurement to gauge improvements, our sense is that agencies are generally taking seriously their obligations to work together with other governmental entities. For example, HHS Secretary Shalala writes to the governors on occasion summarizing major Departmental initiatives of interest to the States. This is part of an HHS effort to "strengthen the federal-state partnership that is crucial to the successful operation of so many of our Department's programs." It is our understanding that this effort to inform the States has been much appreciated.

Another example from HHS involves PHS. Over the next year, the agency has committed to extensive consultation with the States in developing guidelines for state mental health services planning. Such guidelines will assist States in establishing useful goals and objectives for monitoring the management of, and investments in, State mental health services.

EPA recently issued a proposal that would limit toxic air emissions from municipal waste combusters, many of which are either owned or operated by local governmental entities. In preparing its proposal, EPA consulted extensively with a wide variety of stakeholders, including the Conference of Mayors, the National League of Cities, the National Association of Counties, the Municipal Waste Management Association, and the Solid Waste Association of North America. In drafting its proposal, EPA considered the concerns expressed by these groups, and discussion with them will continue following the proposal.

A recent rulemaking by the Architectural and Transportation Barriers Compliance Board (ATBCB) concerning Americans with Disabilities Act (ADA) rules is another illustration of consultation with State and local officials, as well as of interagency coordination. ATBCB's rules set standards for State and local government implementation of the ADA through technical

specifications for the design of buildings, parks, roads, and the like to make them accessible to people with disabilities. (The ATBCB standards will ultimately be implemented through rules issued by DOJ and DOT.) In the course of Executive Order review, the ATBCB: requested comment about the scope of State and local accommodations in order to develop a better cost estimate to accompany the final rule; summarized prior consultations with States and localities, consistent with the provisions of Executive Order No. 12875; and, after meeting with DOJ, DOT, and OMB, developed a list of State and local organizations to receive copies of the rulemaking documents for comment.

ED also engaged in an extensive process of consultation with State and local entities during development of a regulatory proposal that would have required States to provide supplementary services, in excess of Federal funds for these services, to certain disadvantaged students receiving vocational education. ED held two public meetings with State and local education officials and student representatives, solicited written public comment on the issue, and worked with States to obtain additional information on the costs that the rule would impose on them. Unfortunately, this process did not result in agreement on certain issues, leading Congress to intervene to prevent the Notice of Proposed Rulemaking (NPRM) from being published. This highlights the fact that while consultation is essential to effective rulemaking, it may not be sufficient -- for all the consultation may not change the different participants' perspectives and does not necessarily ensure agreement.

It is also worth noting that some agencies are not only consulting with States, but actively seeking to enhance State flexibility and eliminate unnecessarily burdensome regulatory barriers. For example, HHS's Health Care Financing Agency (HCFA) is developing a Medicaid final rule which will simplify the process of obtaining Medicaid home and community-based services

waivers, thereby enabling States to offer a wide variety of cost-effective alternatives to institutional care. The rule will simplify the cost effectiveness test by eliminating the "bed capacity test," which had become burdensome and unproductive to maintain; it will also give States increased flexibility to assess their programs. Also in HHS, the Administration for Children and Families modified its Adoption and Foster Care Analysis and Reporting System to reduce burdens on States. Rather than require the submission of all reporting data, the agency allowed States to submit a sample of the data associated with the management and reporting of foster care and adoption cases.

Two final examples illustrate efforts by agencies to include tribal governments as partners. HUD consulted with tribal representatives in developing amendments to the Indian Housing Consolidated Program to simplify program processes, reduce the number of regulatory requirements, and provide more flexibility to local tribal and Indian housing authority officials. HUD held a session with the National American Indian Housing Council, regional Indian Housing Authority (IHA) associations, and tribal leaders. While HUD was fashioning the proposed rule, comments were solicited from the Native American housing community, and after publication of the proposed rule, the program offices continued to consult with the IHAs and tribes on the proposed changes.

The second example is the rulemaking on Indian Self-Determination, where DOI and HHS worked with tribal representatives to break a four-year logjam which had delayed publication of a proposed rule. The purpose of the rule is to implement a system whereby Indian programs currently administered by the Federal government may be contracted to, and administered by, American Indian tribes. There were extensive consultations with tribes, including three regional meetings and one national

meeting, to discuss their concerns with the proposed rule, which was published in January 1994. The Department is pursuing other ways to increase tribal participation in the development of the final rule, including forming a tribal committee under the Federal Advisory Committee Act.

Openness: Public Involvement

The trend toward increased public involvement in the rulemaking process has continued since the spring, and we believe it has become a common feature of rulemaking in the Clinton/Gore Administration. Although we have no statistics to measure increased public involvement, it is our sense that agencies increasingly are seeking ways to involve those affected by rulemaking, not only through formal means -- such as regulatory negotiations and longer comment periods after publication of proposed rules -- but also through more informal means earlier in the rulemaking process.

For example, HUD wanted to amend its existing regulations to simplify and expedite the Comprehensive Grant Program planning and funding process for certain housing agencies. In developing its proposal, the Department held a series of working sessions with various interest groups, housing authorities, and residents, soliciting their ideas and suggestions. HUD then published its proposed rule which incorporated many of their recommendations.

Agencies are also using electronic means to obtain early and more extensive public input. For example, last winter ED began developing a proposal to amend existing regulations governing the independent living programs. The Department sent out more than 400 letters inviting comments, along with computer diskettes that contained a draft of the proposed regulations, to State vocational rehabilitation agencies, statewide independent living councils, centers for independent living, constituent organizations, and other interested parties. The draft of the

proposed rules was also made available on the "DIMENET" AND "RSA BBS" electronic bulletin boards. A series of public meetings and teleconferences enabled a cross-section of individuals representing a wide variety of organizations and viewpoints to contribute their thoughts during the developmental process.

When the NPRM was published in the Federal Register, the Department made it available through these electronic bulletin boards, and a "CompareRite" copy of the proposal was provided that showed changes that were made as a result of the earlier public involvement. The public was also invited to submit comments on the NPRM electronically via the bulletin boards. This is an outstanding example of how outreach and technology can help the government to solicit the views of those most knowledgeable about a rulemaking. It also serves to increase the sense of partnership between the government and the public by making the rulemaking a joint enterprise rather than the imposition of commands by Federal authority.

Regulatory Negotiation: Another way this Administration has encouraged communication between the regulators and regulatory stakeholders beyond the barebones of the Administrative Procedure Act (APA) notice and comment procedures has been its encouragement of negotiated rulemaking or "reg neg."

A reg neg brings together the stakeholders in a potential regulatory situation to negotiate a proposed document that then goes through APA procedures. By involving interested parties directly in the drafting of the rule, and by having them negotiate out at least some areas of disagreement, it is expected that the rule will be more intelligently drafted and less contentious when it is proposed, and it will be more readily accepted and less likely to be litigated when it becomes final.

The Executive Order (Section 6(a)(1)) directed agencies to explore and use -- where appropriate -- regulatory negotiation as a consensual mechanism for developing rules. In addition, implementing a recommendation of the National Performance Review, the President by separate memorandum issued the same day as the Executive Order, directed each agency to identify to OIRA at least one rulemaking that it would develop through the use of reg neg during the upcoming year, or explain why the use of negotiated rulemaking would not be feasible.

The May 1st Report noted that agencies had provided reg neg candidates to OIRA by December 31, 1993, as the President had directed. Since then, many agencies have continued the substantial planning that is necessary for a successful reg neg, or have begun (or in some cases, concluded) reg negs.

DOT, which was the first agency to use reg neg over a decade ago and has much experience with this technique, has recently identified over a half-dozen possible candidates for negotiation during the next year; the Federal Railroad Administration (FRA) has already published a notice seeking public comment on its proposal to use reg neg for one of these -- a rulemaking addressing the hazards railroad workers face along rights-of-way from moving equipment. EPA is actively engaged in reg negs for disinfectant byproducts, enhanced surface water treatment, and small nonroad engines. DOI has formed a committee under the Federal Advisory Committee Act to deal with a Federal gas valuation rulemaking. OSHA has established a reg neg committee to examine its steel erection standard. And reg neg committees have also been approved for Federal Communications Commission (FCC) and Interstate Commerce Commission (ICC) projects.

Reg negs do not always work, though the experience so far with the technique is generally favorable. ED has been required by statute to use regulatory negotiation in many of its

rulemakings. One recent reg neg involving direct loans was a very prominent but not entirely successful negotiation. Although consensus was reached on a majority of the provisions in this rule, the negotiators did not agree on certain key provisions, including the mechanism by which borrowers would repay their loans. Nonetheless, a trade publication wrote that certain interests "who might otherwise have been the first to pounce on the proposed regulations said they were intimately familiar with -- and generally happy with -- the rules after spending the first half of this year negotiating with ED."

Another ED reg neg, involving guarantee agency reserves was less publicized but more successful in reaching agreement. The rule involved how to handle funds held in reserve by the agencies that "guarantee," or reinsure, student loans under the bank-based loan program. The negotiations took place two days a month from January to July 1994 and involved the Department, guarantee agency representatives, student representative, school associations, and State higher education officials. OMB observed the negotiations and concurred with the consensus NPRM that emerged, reviewing the formal submission from ED in one day. ED expects to publish the final rule by December of this year, with little or no problem in the process.

Small Business: Regulations often create a disproportionate burden on small businesses, since, for example, the same recordkeeping or reporting requirement may consume a much greater percentage of the managerial or administrative resources of a small business than of a large business. As a result, OIRA and the Small Business Administration (SBA) have taken steps to improve the participation of the small business community in the rulemaking process. We noted in our May 1st Report that OIRA and SBA sponsored a Small Business Forum in March 1994 for this purpose. This Forum brought together representatives of small business and six of the Federal agencies who most regulate them -

- the Internal Revenue Service (IRS), the Food and Drug Administration (FDA), DOT, EPA, DOL, and DOJ.

This Forum was followed by work sessions, which took place over a three-month period, that developed findings and recommendations centered around five industry sectors -- chemicals and metals; food processing; transportation and trucking; restaurants; and the environment, recycling, and waste disposal. These sessions were capped with a town-meeting-style forum held at the Chamber of Commerce in Washington and chaired by the Administrators of OIRA and SBA. An audience of about 75 small business owners, who had come to Washington to participate in SBA's Small Business Week and many of whom were winners of SBA small business awards, directed questions and comments to a panel of agency officials representing the six regulatory agencies listed above.

A second Small Business Forum was held on July 27, 1994, in which the recommendations and findings of these work groups were presented. The concerns expressed by small businesses and the recommendations drafted by agency staff to help alleviate these concerns parallel to a remarkable degree principal provisions of the Executive Order. These include:

- the need for better coordination among Federal agencies;
- the need for more small business involvement in the regulatory development process;
- the inability of small business owners to comprehend overly complex regulations and those that are overlapping, inconsistent and redundant;
- the burdens caused by cumulative, overlapping, and/or inconsistent Federal, State, and local regulatory and recordkeeping requirements;

- o the need for tangible evidence of paperwork reduction; and,
- o the perceived existence of an adversarial relationship between small business owners and federal agencies.

Officials from the participating agencies pledged to move ahead with various activities responsive to some of the recommendations and to examine ways to respond to the remaining recommendations. In addition, pilot projects with the governors' offices of New York and North Carolina were announced. These States will work with SBA and the regulatory agencies on means of improving Federal-State coordination regarding burdens on small businesses and State projects to improve their own ability to communicate better with, and involve small businesses in, State regulatory decisionmaking.

As a general matter, however, it is our experience that regulatory agencies still tend to draft one-size-fits-all rules, rather than tailoring them to particular regulated communities, including small businesses. It appears that it will take further effort before such tailoring becomes commonplace. We believe that more extensive early involvement by SBA in the rulemaking process could help move this process forward. Accordingly, we are currently developing with SBA a process to assure that SBA's Chief Counsel for Advocacy has full opportunity to review significant agency rulemakings where such tailoring would be most appropriate and to have agencies implement the Regulatory Flexibility Act more effectively and completely.

Integrity of OIRA Review

Prior to this Administration, the regulatory review process had been severely criticized for delay, uncertainty, favoritism, and secrecy. Restoring the integrity of centralized review was one of the primary tasks facing this Administration as it drafted Executive Order No. 12866.

Disclosure: Section 6(b)(4) of the Executive Order sets forth certain disclosure procedures "to ensure greater openness, accessibility, and accountability in the regulatory review process." OIRA's practices regarding these procedures were described in detail in our May 1st Report. It is a telling measure of the almost complete success of these procedures that there is little additional to say about them and, as far as we know, little interest in them anymore. OIRA adheres to these procedures, and they have long become routine.

We continue to make available a daily list of draft agency regulations under review. Starting in August 1994, this list was made available electronically as well on the Internet. Monthly statistics and data on rules for which review has been completed are also made public. Meetings and telephone calls with persons outside the Executive Branch on regulations under review continue to be logged, and an agency representative invited to such meetings. As of March 31st this log had 36 entries. It now contains an additional 35 entries for meetings that occurred between April 1st and September 30th. In all but 6 instances, these meetings were chaired by the OIRA Administrator; in these 6, the meetings were chaired by other OMB officials. An agency representative was invited to all meetings and attended in all but 5 instances. Materials sent to OIRA on pending regulations from anyone outside the Executive Branch are kept in a public file and a copy is forwarded to the appropriate agency. After a regulatory action that has undergone review is published, documents exchanged between OIRA and the agency during the review, including the draft rule submitted for review, are made available to anyone requesting them. As far as we know, this aspect of the Order is working as it was envisioned.

Regulatory Review Statistics: Executive Order No. 12866 changed the scope of centralized regulatory review by having OIRA review only "significant" rules. This was designed to return

responsibility for routine rulemaking to the agencies, to reduce delay, and to focus OIRA's limited resources on the most important rules. In the May 1st Report, we described in detail how this process was working. We noted that establishing the process for determining whether rules were "significant" or "not significant" had taken longer than anticipated to set up, but that after the first three months, the process of limiting the rules reviewed by OIRA seemed to be working. Based on another six months of experience, we can say that there continue to be some disagreements about whether or not a particular rule is significant, and not infrequently reaching a final decision can take longer than we would like. However, the significant problems we described in the May 1st Report that characterized the process during its first three months have for all practical purposes been resolved.

OIRA's regulatory review statistics show that in other respects as well, what was intended by the Executive Order has, in fact, taken place. Between April 1 and September 30, 1994, OIRA reviewed 388 rules (Table 1). By way of comparison, during the first six months of the Order, OIRA reviewed 755 rules (Table 2) [Note: see Tables 1 and 2 in the May 1 Report; the 755 figure includes rules submitted for review prior to Executive Order No. 12866.] Even though the first six months of the Order included review of rules received before the signing of the Executive Order and the continued submission of some non-significant rules, the total for the first year of the Order is 1143 reviews. This is half of the average reviews per year for the previous 10 years, slightly over 2,200. Between January 1 and September 30, 1994, when for the most part only significant rules were submitted to OIRA for review, OIRA reviewed 661 rules. At this rate, OIRA will review fewer than 900 rules in 1994, a 60% reduction from the annual average of the previous decade. Thus, the number of rules OIRA reviews has been reduced substantially.

The agencies with the greatest number of rules submitted for OIRA review between April 1 and September 30th were HHS 82, USDA 65, EPA 47, ED 35, HUD 34, and DOT 31. These six agencies account for 76% of the rules reviewed by OIRA. Table 1 also shows that of the 388 rules reviewed during the second six months of the Order, 66 (17%) were "economically significant," while 322 (83%) were significant for other reasons (Section 3(f)(2,3, and 4)). USDA and EPA had by far the most economically significant rules, 21 and 16, respectively.

Of the total of 388 rules, 149 or 38% were proposed rules; 179 or 46% were final rules; and the remaining 60 or 15% were notices (such as HHS, HUD, or ED funding notices, notices of selection criteria, or notices of procedures). OIRA concluded review without any changes being made on 58% of the rules reviewed; it concluded review with changes on 35%. The remaining 7% were withdrawn by the agency, were returned because they were sent improperly (5 USDA rules), or were cleared in order for an agency to meet a court or statutory deadline (8 of 9 were EPA rules). The percentage of rules cleared with changes varied widely by agency -- 18% for USDA, 26% for HHS, 26% for DOT, 47% for HUD, 60% for EPA, and 69% for ED.

The average review time for all rules reviewed was 30 days, compared to 38 days for those reviewed during the first six months of the Order. Reviews of economically significant rules were on average slightly longer (31 days) than those of other significant rules. Average review times for all rules varied by agency -- from below mean for USDA (22 days) and DOT (22 days); to about mean for HHS (29 days) and ED (30 days); to above the mean for HUD (37 days) and EPA (48 days).

In our May 1st Report, we indicated that once the review process was fully implemented and agencies submitted only significant rules to OIRA, the total number of rules reviewed was

likely to decrease. As noted above, this has certainly proven to be the case. We also predicted that the percentage of rules cleared with changes would increase. This has occurred to some degree; the average percentage of rules cleared with changes over the past decade averaged about 22% compared to 35% for the rules reviewed between April and September 1994.

We also predicted that average review time was likely to increase, particularly for economically significant rules. This has not proven to be the case. In fact, average review time is about what it has been over the past decade. More specifically, the review time for economically significant rules is only marginally greater than review time for other significant rules. There are several factors that may explain, in part, this phenomenon. We note, for example, that USDA had the greatest number of economically significant rules (21) and a very short average review time (14 days). This is because most of USDA's economically significant rules are crop price supports, regulations that essentially codify decisions already made through the appropriations process. It may also be that the average review time for economically significant rules is relatively low because agencies are consulting with OIRA earlier in the process, thereby obviating the need for lengthy reviews when the rule is formally submitted. Regarding the review time for significant rules in general, it appears that the Order's limitation of 90 days for review, as well as the OIRA Administrator's practice of having all rules under review longer than 60 days raised for her consideration, has resulted in an expedited review process.

OIRA's review is limited to 90 days except that extensions may be granted by the Director or requested by an agency head (Section 6(b)(2)(B and C)). Such extensions have been needed infrequently; for example, of the 388 rules reviewed between April and September, only 11 or 3% were extended beyond the 90-

day period. All of these extensions were made at the request of the agency.

The 90-day review period has generally proven adequate, and as has been noted, we are able to complete most reviews within that time period. However, in some instances 90 days is simply not enough to conduct an adequate review. Where interagency coordination is needed (such as USDA's Farmland Protection rule or EPA's General Conformity rule), issues may take more time to resolve, if only because of the logistics of getting all of the interested agencies together. In some other instances, we are rushed at the end of the review period, or rules must be extended beyond that period, because agencies are slow in responding to OMB questions or requests for analysis. Some of these may be the result of limited resources or otherwise beyond the control of the agency, but in some cases it may reflect a conscious decision by the agency that this rulemaking is of lesser importance than other pressing matters. We understand, and indeed sympathize, but it remains a concern for us because the agency's delay is on our clock and it is Executive Order review that is ultimately curtailed.

III. APPLICATION OF THE PHILOSOPHY AND PRINCIPLES SET FORTH IN THE EXECUTIVE ORDER

The processes described above -- regulatory planning, interagency and intergovernmental coordination, openness and encouraged public participation, restoring integrity to centralized review -- were all designed to lead to better, more focused, more effective, less burdensome -- i.e., smarter-- regulation. The many examples cited above demonstrate that the regulatory process has been improved. The question remains, are the philosophy and principles of the Order being applied to the fullest extent? Are we really getting smarter regulation? This is difficult to answer because, as noted in the Introduction, there is no direct measure of performance that we can use. We do have anecdotes, however, suggesting that the Administration is producing smarter regulations, as we now discuss.

One of the more important features of the Executive Order is its emphasis on good data and good analysis to inform (and not just justify) decisionmaking. One example of the application of this principle is DOT's National Highway Traffic Safety Administration (NHTSA) rulemaking on side-impact protection for light trucks. In the spring of 1994, NHTSA submitted to OIRA for review a proposed rule that would extend to light trucks many of the same side-impact protection requirements now applicable to passenger cars. The proposal was accompanied by a first-rate regulatory analysis prepared by NHTSA staff. The analysis revealed that while the added requirements were cost-effective when applied to the protection of front seat passengers, they were not cost-effective for protecting rear seat passengers. For this reason, NHTSA decided to delete the language proposing to prescribe requirements affecting rear seat passengers, instead seeking comment on the issue.

Another example is HUD's rulemaking on mobile home wind requirements. In the wake of Hurricane Andrew, HUD moved to upgrade the safety of mobile homes. However, increased safety standards means increased costs. The Wall Street Journal quotes HUD's Assistant Secretary for Housing as remarking that the issue requires "the classic balancing act. We could make these homes completely safe and solid - so much so that they'd be out of reach for lower-income consumers." To inform its policy choices and to stimulate discussion among the various stakeholders, HUD's draft regulatory impact analysis set forth the tradeoffs, and the data they are based on, for public scrutiny. Both the data and the analysis have been criticized, but this rulemaking demonstrates the value of analysis, even if it is flawed, in engaging stakeholders in the debate that leads to reasonable balances, as suggested by HUD's Assistant Secretary.

Another feature of the Executive Order is its preference for focused (or tailored) requirements and for performance-based (or flexible) provisions rather than across-the-board, mechanically applied, command-and-control approachs. An example of the application of these principles is the EPA proceeding on lead abatement. Congress directed EPA to create model inspection, worker training, and cleanup regulations for lead abatement of housing, commercial buildings, and various industrial structures. EPA plans to issue these regulations in phases throughout 1994. The first phase included primarily administrative matters, -- e.g., worker training, certification, and State program administration regulations. Initially, the proposal was heavily prescriptive (e.g., detailed diagrams for soil sampling), included extensive paperwork requirements (e.g., detailed documentation of each, identical sampling effort), and did not distinguish between potentially high-risk and low-risk lead hazards. EPA and OIRA staff, working together, substantially revised the draft proposal to reduce the prescriptive character of the rule, adopt more of a performance standard approach, and

re-focus the requirements on the more important sources of health risk (e.g., spending less resources on testing and studies, leaving more for cleanup itself). This revised proposal should also provide States and local governments with greater flexibility in establishing lead abatement programs than had originally been contemplated.

Also relevant here is the EPA combined sewer overflow policy. EPA developed a policy for controlling combined sewer overflows (CSOs) -- i.e., instances when, as a result of heavy rains, sewage and other waste overflow normal channels, bypassing treatment plants. The new policy ensures that an extensive planning effort is undertaken, so that cost-effective CSO controls can be developed that meet appropriate health and environmental objectives. It establishes clear control targets, but provides sufficient flexibility to municipalities so that they can tailor programs to their specific circumstances.

The DOT alcohol and drug testing rules were mentioned above as an example of improved agency/OIRA relations. They are also illustrative of a rulemaking where the Department approached a complex issue analytically and made significant improvements to its rule, reducing burden without reducing safety, by applying the principles of the Executive Order. For example, in its final rule, DOT adopted a performance-based approach for determining the rate of random drug and alcohol testing. Thus, based on already existing performance-based data, the random drug testing rate was reduced from 50% to 25% for the airline and rail industries; for alcohol testing, the testing rate will be 25% if the industry violation rate in any year is less than 1%, and it may decrease to 10% if the industry violation rate is less than 0.5% for two consecutive years. DOT also simplified and streamlined its requirements for reporting drug testing data, introducing sampling techniques and otherwise reducing the burden

and complexity of the information collection requirements from employers.

Another example from DOT involves the Coast Guard's rulemaking involving overfill devices. The Coast Guard was required by statute to promulgate rules involving the installation of signalling (overfill) devices to alert crew about the likelihood of a unanticipated spill. In its proposal, the Coast Guard added material concerning the use of lower cost signalling devices (i.e., stick gauges) rather than more costly and sophisticated alarm devices. The final rule, which will be published soon, will allow the lower cost devices on certain vessels (i.e., tank barges) thus significantly reducing the cost of the rule from about $90 million to about $40 million (npv) over 15 years. The Coast Guard does not believe that the use of the less costly signalling devices on these vessels will significantly increase the risk of small unanticipated spills.

An example from DOL's Occupational Safety and Heath Administration (OSHA) is that agency's rulemaking on asbestos. In preparing its final rule governing asbestos in the workplace, OSHA made substantial changes to its proposal to improve the clarity of the regulation and ensure that as much flexibility as possible was retained in process-specific standards. Thus, for example, while the proposal could be read to require extensive controls (e.g., glove bags, mini-enclosure, and respirators) for any maintenance work conducted around asbestos-containing materials, even if exposure was negligible (e.g., pulling wires above suspended ceilings), OSHA's final rule required such controls only when there is a physical disturbance of the materials. In addition, the final rule avoided inconsistencies with existing EPA standards by eliminating the use of terms to classify asbestos that differed from those used by EPA. Finally, OSHA raised in the preamble of the final rule the possibility of its adopting an action level to serve as a clear regulatory

threshold below which fewer protective measures would be needed if practical sampling devices become available.

HHS also has been attentive to the principles of the Order. For example, the Mammography Quality Standards Act of 1992 required FDA to establish Federal certification and inspection programs for mammography facilities; regulations for accrediting bodies for mammography facilities; and standards for mammography equipment, personnel, and practices. In designing these rules, FDA made the standards less burdensome on mammography facilities, which are nearly all small businesses, by incorporating existing standards to the maximum extent possible. It also provided for the issuance of Federal certificates to facilities already accredited by the American College of Radiology; required facilities to submit certification information only to an accrediting body and not to FDA; and permitted flexibility in meeting certain other standards.

As noted above, HHS has also been sensitive to minimizing the burden of Federal regulations on State, local, and tribal governments. For example, this past year, the Maternal and Child Health Bureau developed a streamlined, block grant application and annual report. The revisions resulted from an impressive consultation effort with State maternal and child health groups and the National Governor's Association. The burden imposed by the requirements has been cut in half, while the materials are easier to understand and will be more useful in local, State, and Federal planning.

HHS has also taken steps to streamline the burden on the private sector as well. In March 1994, HCFA published a rule that replaced the annual requirement for physicians to provide hospitals with a signed acknowledgement concerning penalties for misrepresenting certain information with a one-time signing requirement, fulfilled at the time a physician is initially

granted hospital admitting privileges. One major medical association characterized this change as one that will alleviate the "hassle factor" for physicians and one that is an important step toward restoring mutual trust between the Federal government and the medical profession.

Another example of burden reduction comes from DOT. The Federal Aviation Administration (FAA) realized that not all regulatory modifications are dramatic, but incremental efforts to reduce burden and unnecessary provisions can add up to significant improvements. Recently, in a broader rule that made other changes to the medical certification standards, FAA responded to an American Medical Association report suggesting that the burdens of the medical certification process for pilots could be significantly reduced by extending the two-year certification to a three-year duration for younger pilots. This simple change will cut the overall paperwork associated with the certification process by about 15% in total, and over 30% for those pilots under age 40.

In the same vein is a recent SBA action that eliminated a longstanding regulatory prohibition on making financial assistance available to businesses engaged in media-oriented activity. The so-called opinion molder rule had been based on a concern about Federal agency involvement in potential prior restraint of free speech; the result was a ban on SBA assistance to businesses involved in media activities. After first considering modest revisions to the rule, SBA concluded that the concern was no longer a valid one, and that the demand for assistance from small businesses in the media field far outweighed the need for caution in this area.

Several of the latter examples involve rethinking or redesigning existing regulation. Focusing on existing regulations has been an important feature of the Executive Order,

and, as we now discuss, we are beginning to see real progress in this area.

IV. IMPLEMENTATION OF THE LOOKBACK PROVISIONS OF THE EXECUTIVE ORDER

Individuals who must comply with Federal rules frequently comment, often with great frustration and anger, that it is the accumulated burden of rules in effect -- many of which appear unnecessary, redundant, outdated, or downright stupid -- that is so exasperating to them. In response to these concerns, the Executive Order provides that agencies are to review existing regulations to ensure that their rules are still timely, compatible, effective, and do not impose unnecessary burdens (Section 5).

In the May 1st Report we noted that this review of existing regulation, a "lookback" process, had begun, although it had proven more difficult to institute than we had anticipated. We observed that, understandably, agencies are focused on meeting obligations for new rules, often under statutory or court deadlines, at a time when staff and budgets are being reduced; under these circumstances, it is hard to muster resources for the generally thankless task of rethinking and rewriting current regulatory programs. Six months later, we are somewhat further along, although we continue to believe that any real progress will depend on the extent to which senior policy officials recognize and attend to this effort.

It is important to emphasize what the lookback effort is and is not. It is <u>not</u> directed at a simple elimination or expunging of specific regulations from the Code of Federal Regulations. Nor does it envision tinkering with regulatory provisions to consolidate or update provisions. Most of this type of change has already been accomplished, and the additional dividends to be realized are unlikely to be significant. Rather, the lookback provided for in the Executive Order speaks to a fundamental re-engineering of entire regulatory systems, many of which have

remained fundamentally unchanged for 30 to 50 years. To do this successfully requires a dedicated team in an agency with broad understanding of the program's objectives, expertise in the intricacies of the regulatory program, an intimate knowledge of the stakeholders, and resourcefulness, tenacity, resolve, and support.

Probably the best example of such a re-engineering of a regulatory system is the work currently being done by the DOC's Bureau of Export Administration (BXA) to rewrite the Export Administration Regulations (EAR). This comprehensive review is intended to simplify and clarify this lengthy and complex body of regulations that establishes licensing regimes for dual-use products -- i.e., those that may have both commercial and military applications -- and to make the regulations more user-friendly, which they currently are not. The rules were first promulgated in 1949 to implement the Export Control Act of 1949. There has not been a complete overhaul of the EAR since that time. This effort is important enough that DOC has chosen it as one of its four entries for the Regulatory Plan.

In its re-engineering of the EAR, BXA is following the recommendations of the Trade Promotion Coordinating Committee (TPCC), a Presidential committee mandated by the Export Enhancement Act of 1992. BXA has already published a notice in the Federal Register requesting comment on a simplification of the program. Meanwhile, a task force within the agency has been working on a complete overhaul and restructuring of the rules. In particular, the rules are being fundamentally redirected from the current negative presumption that all exports subject to the Act are prohibited unless authorized, to a positive approach that all exports are permitted unless a license is specifically required. The agency tentatively plans to have an NPRM published by the end of this year.

A good example of an institutionalized lookback program is the continual review of selected regulations by DOT's National Highway Traffic Safety Administration (NHTSA). NHTSA has been conducting these safety standard evaluations for over 15 years, and to our knowledge, it is the only program of its kind in the Executive Branch. NHTSA rules deal primarily with automobile and light truck safety. On a regular basis, the agency selects rules from its current programs to review, evaluating not only the effectiveness of the rule and whether there are any provisions that are unnecessary, unduly burdensome, or in need of change for other reasons, but also reviewing the initial analysis itself -- whether the predicted costs and benefits have been realized, and, if not, why not. This approach not only enables the agency to modify its current rules based on analysis, but also helps the staff continually improve the analytic techniques used in assessing the costs and benefits of new rules. Indeed, its recent standards for side-impact protection resulted directly from a review of its previous standard, which revealed that the rule was not providing benefits in multi-vehicle accidents. More recently, the agency completed reviews of front seat protection in passenger cars and its glass-plastic windshield standard No. 205. NHTSA also recently published a Federal Register notice describing its future evaluation plans and soliciting public comment on which additional assessments it should pursue.

DOT's Federal Highway Administration (FHWA), like BXA, has initiated a major, "zero-based" review of its Federal Motor Carrier Safety Regulations. These are the primary body of regulations that are designed to ensure the safety of commercial trucks and drivers. The regulations have not been extensively revised since the early 1970's. The goals and objectives of the zero-base review are (1) to focus on those areas of enforcement and compliance that are most effective in reducing motor carrier accidents; (2) to reduce compliance costs; (3) to encourage innovation; and (4) to clearly and succinctly describe what is

required by the regulations. Through the zero-base review, FHWA intends to develop a unified, performance-based regulatory system that will enhance safety on the nation's highways while minimizing the burdens placed on the motor carrier industry.

Other DOT lookback efforts include FRA's revision of its power brake regulations to reduce the frequency with which railroads must inspect their brake systems. Recently, the FRA proposed performance-based rules that would reduce inspection frequencies, as long as brake systems, when inspected, meet certain brake defect ratios. Also, FAA is reviewing its regulations to identify those rules that are inconsistent with state-of-the-art technology or current industry practice. To enhance its ability to perform its statutory role without undue economic burden on the aviation industry, FAA announced a comprehensive review in January of this year, asking interested parties to identify those regulations that are believed to be unwarranted or inappropriate. The comments provided in response to this notice are assisting the agency in establishing its priorities for future regulatory changes.

USDA is also conducting several lookbacks. The Food and Nutrition Service (FNS) has proposed to revise its school meal nutrition standards, the first major modification to these standards in nearly 50 years. To ensure that children have access to healthy meals at school, USDA has updated nutrition standards to meet the Dietary Guidelines for Americans and, at the same time, USDA has streamlined the administration of the rule so that local school food service staffs may concentrate on providing healthful food for their students rather than on bureaucratic red tape.

This effort was the result of extensive outreach and substantial analysis by USDA. Although commenters on the rule

have raised concerns, the initial press reaction to the proposal was overwhelmingly positive. The New York Times concluded:

> The Agriculture Department recognizes that these ironclad rules (current meal patterns) are irrelevant in a nation where most children get not only too much protein but too much fat, saturated fat, cholesterol and sodium . . . . School meals might finally catch up with late-20th-century nutrition science.

USDA and HHS are also working to re-engineer their food safety and inspection regulatory programs. Building upon their generally successful efforts to coordinate the nutrition labeling of foods, USDA and HHS are moving forward with ambitious plans to modernize the system of food safety regulation in the United States. Both Departments took steps in 1993 and 1994 to require Hazard Analysis Critical Control Point systems (HACCP) in the production of food.

The Food Safety and Inspection Service (FSIS) at the USDA has initiated a comprehensive review of the regulations that ensure the safety of all meat and poultry. The meat and poultry regulations are based upon the Federal Meat Inspection Act first passed in 1907. Although the meat and poultry statutes and regulations have been amended a number of times over the last 85 years, USDA has never undertaken a top-to-bottom review of the inspection system.

FSIS' review is intended to move the meat and poultry inspection system -- currently based upon "organoleptic" inspection, whereby an inspector uses the senses of touch, sight and smell to test the safety of the product -- towards more science-based procedures that address microbial contamination. For example, under a HACCP system, plants would identify the points along their processing line that are vulnerable to the

greatest hazards (risk of contamination), and devise plans to mitigate those hazards.

FDA, which has jurisdiction over all foods not regulated by FSIS, such as fish, fruits, and vegetables, has announced plans to greatly expand its use of HACCP systems. FDA sees HACCP as a revolutionary way to ensure that proper production processes and controls are being maintained, even when an inspector is not present. In January 1994, FDA issued a proposed rule that would require HACCP analysis and recordkeeping by all firms that process seafood in the United States. Also, after consultation with USDA, FDA published an Advance Notice of Proposed Rulemaking in August 1994 exploring the possibility of extending HACCP systems beyond the seafood industry to other food production within the next ten years.

Other agencies are also conducting lookbacks. In HHS, HCFA is looking at Medicare regulations that govern conditions of participation for home health agencies and hospitals, and conditions of coverage for the payment of end stage renal disease. HCFA believes that the existing rules are unnecessarily burdensome, outdated, and process oriented, and should be replaced with more universally applicable provisions that are patient/outcome oriented and driven by meaningful data to better ensure healthy outcomes for aged patients and those with disabilities. In redesigning these regulations, HCFA has met, and is continuing to meet, with a variety of provider and consumer representatives.

HUD has planned a review of its public housing development program rules. The current rules are outdated and contain unnecessary restrictions on the flexibility of public housing authorities (PHAs). HUD expects to revise the regulations to provide more flexibility for all participants, with even greater flexibility for the best performers. "High performer" PHAs will

have maximum latitude to develop public housing within very broad parameters, and with minimal HUD oversight; remaining PHAs will be given broadened responsibility commensurate with their abilities and areas of expertise. Streamlining the program will help to reduce a substantial pre-construction pipeline and expedite the provision of replacement housing for developments that should be fully or partially replaced.

The Office of the Comptroller of the Currency (OCC) has started a review of existing regulations on national bank lending limits to modernize, simplify, clarify, and eliminate unnecessary regulatory burden. In developing this review project, OCC designed a more efficient internal review process that involved senior agency officials earlier in the project to provide policy guidance. OCC published an NPRM in February 1994.

DOL's Pension and Welfare Benefit Administration (PWBA) has initiated a review of its rule concerning disclosure of plan information to participants. Since enactment of the Employee Retirement Income Security Act (ERISA) in 1974, there have been few modifications either to the law's reporting and disclosure provisions or to the underlying regulations. PWBA issued a Request for Information last December to solicit comments from the public concerning the adequacy and timeliness of the information provided pursuant to these rules. The agency is currently reviewing the many comments to assess the need for regulatory and/or statutory changes. Also at DOL, OSHA has started a review of its outdated walking and working surfaces standards with an eye to replacing them with performance-oriented standards to permit more flexibility in compliance.

Several Departments have used the Federal Register to gather information on those regulations that might be candidates for elimination, modification, or other improvement. DOE published a notice of inquiry in the Federal Register and has solicited

recommendations from over 200 stakeholder organizations and DOE field offices. Based on this input, DOE prepared a second notice of inquiry targeting particular areas of its regulations for review. Similarly, DOI published a notice in the Federal Register announcing its intent to review its significant existing regulations and requesting public comment on which regulations should be reviewed. After a 60-day comment period, DOI published a second notice, announcing which regulations will be reviewed, and requesting specific comments on how those regulations should be revised.

These examples of lookbacks vary from major projects well underway to initial, in some cases tentative and not fully formed, efforts. They are indicative of a serious effort by this Administration to look not only at rules that are being developed, but at the accumulation of regulatory programs that are already on the books. There is no apparent reason why every Department and agency cannot initiate at least one such project. We expect that lookbacks will become more prevalent and more productive over the coming months.

CONCLUSION

In our May 1st Report, we concluded that while it was too early to arrive at a final judgment regarding the success of the new system, the early indications were that there had been substantial improvement in the rulemaking process. With six months more experience and data, we are more confident that the Executive Order is making a difference, that the Administration is moving in the right direction, and that there is much to be proud of. As before, however, our optimism is guarded; we know full well that there is much to be done to obtain the benefits we are seeking to realize.

EXECUTIVE ORDER REVIEWS BY CODE
APRIL 1, 1994 - SEPTEMBER 30, 1994

TABLE 1

	NUMBER OF REVIEWS			ACTIONS TAKEN								AVERAGE REVIEW TIME		
AGENCY	ECON SIG	OTHER THAN ECON SIG	TOTAL	WITHOUT CHANGE	WITH CHANGE	WITHDRAWN BY AGENCY	SENT IMPROPERLY	RETURNED	SUSPENDED	EMERGENCY	STAT/JUD DEADLINE	ECON SIG	OTHER THAN ECON SIG	ALL
USDA	21	44	65	46	12	1	5	0	0	0	1	14	25	22
DOC	2	5	7	5	2	0	0	0	0	0	0	14	4	7
DOD	1	4	5	5	0	0	0	0	0	0	0	48	38	40
ED	1	34	35	9	24	2	0	0	0	0	0	68	29	30
DOE	1	1	2	0	2	0	0	0	0	0	0	37	73	55
HHS	5	77	82	60	21	0	1	0	0	0	0	20	29	29
HUD	0	34	34	14	16	4	0	0	0	0	0	NA	37	37
DOI	2	6	8	4	4	0	0	0	0	0	0	12	40	31
DOJ	1	5	6	5	0	0	0	0	0	1	0	2	8	7
DOL	2	2	4	1	3	0	0	0	0	0	0	47	61	54
STATE	0	5	5	5	0	0	0	0	0	0	0	NA	12	12
DOT	5	26	31	21	8	1	1	0	0	0	0	50	16	22
TREAS	0	1	1	1	0	0	0	0	0	0	0	NA	2	2
VA	0	9	9	5	4	0	0	0	0	0	0	NA	25	25
EPA	16	31	47	9	28	2	0	0	0	0	8	48	49	48
ACHP	0	1	1	1	0	0	0	0	0	0	0	NA	39	39
ACTION	0	1	1	1	0	0	0	0	0	0	0	NA	55	55
AID	0	1	1	1	0	0	0	0	0	0	0	NA	15	15
ATBCB	2	0	2	1	1	0	0	0	0	0	0	47	NA	47
CNCS	1	0	1	1	0	0	0	0	0	0	0	27	NA	27
FAR	4	3	7	5	1	1	0	0	0	0	0	40	39	40
FEMA	0	1	1	1	0	0	0	0	0	0	0	NA	14	14
GSA	0	5	5	5	0	0	0	0	0	0	0	NA	43	43
IMS	0	1	1	1	0	0	0	0	0	0	0	NA	47	47
[illegible]	0	1	1	1	0	0	0	0	0	0	0	NA	30	30
NASA	0	4	4	3	1	0	0	0	0	0	0	NA	18	18
NSF	0	1	1	0	1	0	0	0	0	0	0	NA	6	6
OGE	0	1	1	0	1	0	0	0	0	0	0	NA	71	71
OPM	0	12	12	7	3	2	0	0	0	0	0	NA	42	42
OTHINDAG	0	1	1	1	0	0	0	0	0	0	0	NA	14	14
SBA	2	4	6	4	2	0	0	0	0	0	0	13	7	9
USIA	0	1	1	1	0	0	0	0	0	0	0	NA	NA	NA
TOTALS:	66	322	388	224	134	13	7	0	0	1	9	31	30	30
% TOTAL:	17.0%	83.0%	100.0%	57.7%	34.5%	3.4%	1.8%	0.0%	0.0%	0.3%	2.3%			

TABLE 2

EXECUTIVE ORDER REVIEWS BY CODE
OCTOBER 1, 1993 - MARCH 31, 1994

	NUMBER OF REVIEWS			ACTIONS TAKEN								AVERAGE REVIEW TIME		
AGENCY	ECON SIG	OTHER THAN ECON SIG	TOTAL	WITHOUT CHANGE	WITH CHANGE	WITHDRAWN BY AGENCY	SENT IMPROPERLY	RETURNED	SUSPENDED	EMERGENCY	STAT/JUD DEADLINE	ECON SIG	OTHER THAN ECON SIG	ALL
USDA	13	109	122	85	26	7	2	0	0	0	2	37	28	29
DOC	1	55	56	38	15	3	0	0	0	0	0	128	23	25
DOD	0	10	10	1	5	4	0	0	0	0	0	NA	55	55
ED	2	33	35	3	26	6	0	0	0	0	0	7	46	44
DOE	1	9	10	5	5	0	0	0	0	0	0	78	82	82
HHS	8	158	166	118	30	11	5	2	0	0	0	46	38	39
HUD	4	31	35	19	12	4	0	0	0	0	0	52	45	46
DOI	1	40	41	29	11	1	0	0	0	0	0	4	33	33
DOJ	0	15	15	15	0	0	0	0	0	0	0	NA	17	17
DOL	1	1	2	0	2	0	0	0	0	0	0	9	20	15
STATE	0	6	6	5	1	0	0	0	0	0	0	NA	17	17
DOT	15	36	51	22	27	2	0	0	0	0	0	16	48	37
TREAS	2	4	6	2	4	0	0	0	0	0	0	1	70	47
VA	0	29	29	21	4	4	0	0	0	0	0	NA	62	62
EPA	16	53	69	15	38	0	0	0	0	0	16	40	53	50
AID	0	1	1	0	1	0	0	0	0	0	0	NA	36	36
CNCS	1	3	4	0	4	0	0	0	0	0	0	22	23	23
EEOC	0	2	2	1	0	1	0	0	0	0	0	NA	116	116
FAR	3	3	6	3	1	2	0	0	0	0	0	39	23	31
FEMA	0	4	4	0	4	0	0	0	0	0	0	NA	38	38
FFIEC	0	1	1	0	1	0	0	0	0	0	0	NA	70	70
GSA	0	18	18	11	7	0	0	0	0	0	0	NA	36	36
IMS	0	1	1	1	0	0	0	0	0	0	0	NA	10	10
NARA	0	2	2	1	1	0	0	0	0	0	0	NA	116	116
NASA	0	8	8	6	1	1	0	0	0	0	0	NA	31	31
NSF	0	5	5	3	1	1	0	0	0	0	0	NA	73	73
OGE	0	1	1	1	0	0	0	0	0	0	0	NA	2	2
OMB	0	1	1	0	1	0	0	0	0	0	0	NA	108	108
OPM	0	23	23	17	3	3	0	0	0	0	0	NA	22	22
OTHINDAG	0	1	1	0	1	0	0	0	0	0	0	NA	74	74
RRB	0	5	5	0	0	0	5	0	0	0	0	NA	39	39
SBA	3	13	16	9	6	1	0	0	0	0	0	15	42	36
USIA	0	3	3	3	0	0	0	0	0	0	0	NA	6	6
TOTALS:	71	684	755	434	238	51	12	2	0	0	18	33	38	38
% TOTAL:	9.4%	90.6%	100.0%	57.5%	31.5%	6.8%	1.6%	0.3%	0.0%	0.0%	2.4%			

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The Business Roundtable:
Toward Smarter Regulation

65pgs

The Business Roundtable

file
Regulatory
reform

Toward Smarter Regulation

FW file
Reg. Advisors

OFFICE OF THE VICE PRESIDENT
WASHINGTON

94 NOV 18 P1 : 03

November 17, 1994

MEMORANDUM FOR THE REGULATORY POLICY ADVISORS TO THE PRESIDENT

FROM: THE VICE PRESIDENT

SUBJECT: REGULATORY REFORM

In the months since the President charged us with implementing his Executive Order on regulatory planning and review, we have made great progress in bringing a new sense of accountability and order to the regulatory review process. It is now time to take the next steps and develop for the President options for further reforms in the regulatory area.

Set forth below is a process by which I suggest we undertake to develop these various options. The process will focus on a series of "regulatory policy reviews" in which we can explore innovative approaches to achieve regulatory objectives in cost-effective and reasonable manners. These reviews will examine -- with the help of innovative and interesting thinkers and experts -- a variety of sectoral and cross-cutting issues so to enable us to make well-considered recommendations to the President early next year.

In addition, there are several issues closely related to the regulatory issues noted below which, as you know, have already been the object of excellent work by several White House offices. I refer to risk, takings and unfunded mandates. These issues should be considered in a coordinated, but expedited, manner by the same group that will look at the broader regulatory agenda. To that end, I propose that the Regulatory Policy Advisors also coordinate (through an inter-office process) the development of options to address these issues. Specifically, I propose that, over the next three weeks, the DPC and OEP lead a review of the takings issue, OIRA and OSTP take the lead on risk, and the DPC coordinate the development of a proposed response to the unfunded mandates issue. Ideally, these offices would prepare recommendations to be considered by the Regulatory Advisors on or before December 12, 1994. We would then forward a decision memorandum to the President.

For the remaining regulatory-related issues, I suggest the following schedule:

November - December 1994

During this period, we will discuss with affected agency heads and each other the format and process for regulatory policy reviews. We will also finalize a schedule for the policy review sessions.

December 1994 - February 1995

During this period, we will conduct the review sessions. Each review session will be organized by the relevant White House office. I will co-chair the sessions with the head of the office that organizes the session. My office will coordinate the overall schedule of the sessions and provide additional assistance as necessary.

Subject to our further discussion, suggested topics and leaders for the review sessions would include:

- General regulatory and cross-cutting regulatory issues -- OIRA
- Environment, energy and other natural resources -- OEP
- Financial institutions -- NEC and CEA
- Small business regulation -- CEA
- Information technology -- OSTP
- Customer service in the regulatory environment -- OVP
- Food and drug -- DPC
- Health industry regulation -- DPC
- Transportation -- NEC
- Equal opportunity -- White House Counsel
- Workplace safety and labor issues -- DPC
- Agriculture -- NEC

February - March 1995

At the end of the review process, the Regulatory Advisors will hold a series of meetings to determine (after appropriate consultation with affected agency heads) which of the options developed during the first phase should be presented to the President. The proposals chosen will then be drafted by the relevant policy office. These drafts will form the basis of the options memorandum to the President.

March 1995

Present options memorandum to the President.

* * *

Please review these proposed assignments (which I assume we will need to modify) and schedule and be prepared to discuss it at a meeting on the Regulatory Policy Advisors, which we will convene shortly.

Please feel free to contact Jack Quinn if you have any questions regarding the process outlined above or the meeting itself.

Distribution:
The Director of the Office of Management and Budget
The Chair of the Council of Economic Advisors
The Assistant to the President for Science and Technology
The Assistant to the President and Chief of Staff to the Vice President
The Assistant to the President and Counsel
The Assistant to the President for Domestic Policy
The Assistant to the President for Intergovernmental Affairs
The Assistant to the President for Economic Policy
The Assistant to the President for National Security
The Assistant to the President and Staff Secretary
The Deputy Assistant to the President and Director of the Office of Environmental Policy
The Administrator of the Office of Information and Regulatory Affairs

THE WHITE HOUSE

WASHINGTON

May 16, 1993

MEMORANDUM FOR JOHN PODESTA

FROM: PAUL RICHARD

SUBJECT: REGULATORY REFORM MEETING

The next meeting of the Regulatory Reform Group is scheduled for Monday, May 17 at 12 noon. You should probably check with Kumiki to find out where it will be located.

In general, the meeting was consumed with tinkering with the text and most of the planning issues on the attached agenda were not addressed. There was general agreement that the longer introduction was better, and Kumiki will be redrafting for the Monday meeting. There was some discussion of how to insulate the Order from tinkering by future administrations; the consensus was that that goal is impossible, but that clever drafting and solid political spadework would make it more difficult to undo the proposed changes.

Ellen Seidman thought that the draft contained an unwarranted presumption that the agencies will know what the President's priorities are. She thought that priorities needed to be identified, but not in the text of the EO.

Greg Simon asked how this version differs from 12291. The differences need to be highlighted. Weinstein thought that a mention of the private sector was necessary to get the new Democrats on board. Linda ? mentioned that the factors listed on pages 6 - 8 would cause a fairly high hurdle if all the requested analyses have to be done for all regs.

David Doniger had a general sense of foreboding (my characterization) that the planning process called for in the draft would simply start the regulatory process earlier. Jeff Lubbers noted that the relationship between the planning mechanism and 60-day report is unclear in the present draft.

Regarding your point about combining the constitutional references (on pages 16 and 17), the group wanted to maintain the distinction because of the requirement that the AG issue guidelines on takings within 90 days of the Executive Order.

I have attached the current draft with some markings from the meeting, along with the agenda, notes from Bob Knisely, and Ellen. There should be a new draft available at the Monday meeting.

May 14

May 13, 1993

CONFIDENTIAL

MEMORANDUM FOR THE REGULATORY REVIEW WORKING GROUP

FROM: JACK QUINN
COUNSEL TO THE VICE PRESIDENT

SUBJECT: DRAFT EXECUTIVE ORDER ON REGULATORY REVIEW

Attached please find the first draft of the Executive Order on regulatory review. Please treat this as highly confidential, and do not circulate it beyond those immediately working on this issue.

We will be meeting at 3:30 p.m. on Friday, May 14, 1993, in OEOB 248 to discuss the draft Order. This will be an important meeting, so please attend or send an appropriate designee from your office.

If you have any questions, please feel free to call Kumiki Gibson or me at ext. 7022.

Thank you.

Jack

Attachment

Distribution:
David Doniger
Andy Joskow
Sally Katzen
Bob Knisely
James Kohlenberger
Jeff Lubbers
Mark Middleton
John Podesta
Heather Ross
Ellen Seidman
Greg Simon
Joseph Stiglitz
Paul Weinstein

(MAY 12, 1993 DRAFT)

EXECUTIVE ORDER NO. _____

REGULATORY PLANNING AND REVIEW

The American people deserve a regulatory system that advances their health, safety, and well-being without imposing unacceptable or unreasonable costs on society. A regulatory system that demands ~~discipline~~, efficiency, reliability, and quality will improve not only the functioning of government, but also the American economy and, most importantly, the quality of life for the American people. We do not have such a regulatory system today.

With this Executive Order, the Federal government begins a program to reform the regulatory process. The objectives of this Order are to restore the integrity and legitimacy of centralized regulatory review and oversight for both new and existing regulations, by providing guidance to the federal agencies as to the principles applicable in the review process and by making the process more open and accessible to the public. The regulatory process, including the centralized review function, shall be conducted in a professional manner, so as to best serve the American people, and with due regard for applicable law and the discretion that has been entrusted to federal agency expertise.

Accordingly, by the authority vested in me as President of the United States, it is hereby ordered as follows:

Section 1. *Statement of Regulatory Philosophy and Objectives.*

[Federal agencies shall promulgate only such regulations as are required by law or made necessary by failures of the free market. In deciding whether to regulate, agencies shall assess all of the advantages and disadvantages of the proposed regulation. In choosing among alternative regulatory approaches, agencies shall choose only those approaches that maximize the net potential advantages to the American people. To these ends, federal regulatory agencies shall ensure that all regulations meet all applicable statutory requirements; reflect the regulatory priorities of the Administration; and maximize the economic, environmental, public health or other benefits and advantages of regulating without imposing unnecessary costs, burdens, or other disadvantages, and are otherwise justifiable and reasonable.]

OR

[Regulation, like other instruments of government policy, has enormous potential for both good and harm. Well-chosen and skillfully designed regulations can protect consumers from dangerous products, reduce the scope for fraud, reduce pollution, increase worker safety, discourage unfair business practices, and contribute in many other ways to a safer, healthier, more productive, and more equitable America. Excessive or poorly designed regulations, by contrast, can cause confusion and delay;

1. ¶ 1.
2. ¶

give rise to unreasonable compliance costs, capital investments, and on-going paperwork; retard innovation; reduce productivity; and adversely affect living standards. The challenge to regulatory policy-makers is not only to make sure that the benefits of regulation outweigh its costs, but also to ensure that the regulations are designed in the most cost-effective manner. Society, as a whole, should always win, not lose, as a result of regulatory activity.

A. *The Advantages of Regulation.*

Competition in the marketplace is the most effective regulator of economic activity. When markets are imperfect, however, society's resources may be inefficiently and ineffectively used. Regulation can sometimes be used to improve resource allocation or help obtain those societal objectives under a variety of circumstances.

- In an unregulated market, firms and individuals often impose costs on others, including future generations, that are not reflected in the prices of the products they sell. They may pollute streams, cause health hazards or endanger the safety of their workers or customers. Regulation can be used to reduce these harmful effects by prohibiting certain activities or imposing the societal costs of the activity in question on those causing the harm. One goal of regulation is to induce private parties to act as

they would if they had to bear the full costs that they impose on others.

- Similarly, in an unregulated market, firms and individuals may not have incentives to provide individuals with accurate or sufficient information needed to make intelligent choices. Firms may take advantage of consumer ignorance to market unsafe or risky products. Regulation may be needed to require disclosure of information, such as the possible side affects of a drug or the full cost of a home mortgage.
- Even when consumers have full information, the government may wish to protect individuals, especially children, from their own actions. Regulation, thus, is used to restrict such unacceptable practices, such as child labor and the sale of harmful substances.
- Certain markets may not be sufficiently competitive, thus potentially subjecting consumers to the harmful exercise of market power. Regulation can be used to promote competition and to make it less likely that firms engage in unfair trade practices.
- Regulation can also be beneficial in achieving goals reflected in national values, such as non-discrimination and universal education.

B. *The Disadvantages of Regulation.*

The major advantages of regulating must be considered in light of the potential disadvantages of regulating -- to the government, to those regulated and to society at large.

- The direct costs of administering, enforcing and complying with regulations may be substantial. It is important that regulations be as simple as possible and administered efficiently.
- Even when accomplished efficiently, the costs of regulation are paid for by firms and individuals, showing up in the form of higher prices, lower wages, and reduced output. [And, disadvantages of regulation are often difficult to measure. For example, less obvious disadvantages may include reduced flexibility and innovation. These must be fully considered when regulating.
- Unlike other government programs, disadvantages of regulation (except for government administrative costs) do not show up in the federal budget. Because the costs are imposed mainly on the private sector, they have not been examined as carefully as costs that appear in the budget and require increased taxes. This must change.
- The disadvantages of regulation can be cumulative. In assessing regulatory burden it is important to consider the total impact of all regulations -- not just those of a single federal agency, but all federal, state, and

local regulations -- on individuals, firms, industries, governments and the economy as a whole.

- Because many regulating authorities exist, even at the federal level alone, it is important to avoid inconsistent, incompatible, or duplicative regulations from these authorities.

C. *The Principles of Regulation.*

The decision to regulate should be based on the following considerations:

- There should be an ~~accurate~~ attempt to assessment ~~of~~ the problem the regulation is attempting to correct, including a ~~comparative~~ analysis of any risk sought to be reduced by the regulation relative to other risks to which the public is exposed;
- There should be an examination of whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is attempting to correct and whether those regulations (or other law) can be modified to achieve the regulatory goals more effectively;
- There should be an assessment of both the advantages of the regulation and the disadvantages of the regulation. ~~Based on obtainable information~~, reasonably a judgment should be made of whether the disadvantages of the regulation are justified by their disadvantages, recognizing that some

advantages and disadvantages are not as easily quantifiable as others;

- The regulatory objectives should be chosen to ~~maximize~~ enhance the net advantages to society -- for both consumers and producers combined;
- Regulations confer different advantages to different groups and impose different disadvantages on different groups. There should be an analysis of which groups bear the disadvantages and which groups reap the advantages.
- State and local governments often regulate the same activities. Federal regulations should consider the effects on and, as appropriate, be coordinated with State and local regulations.

The design of regulation should be based on the following principles:

- The most cost-effective approach should be used in achieving regulatory goals, subject to considerations of equity and fairness;
- Regulations should be simple and easy to understand, with the goal of reducing the costs of compliance and minimizing the potential for uncertainty and litigation;
- There are often trade-offs between administrative complexity and concerns about equity. Regulatory design must balance additional administrative complexity and gains in equity;

DD consistency predictability administrability

DD will redraft.

add. when feasible, support market incentives

1 cumulative impact from 6

Greg Simon delete

- ~~Regulations are costly to enforce, and compliance is seldom perfect.~~ Regulatory policies should consider enforcement costs and the possible consequences of non-compliance. [Monitoring compliance may be more efficiently accomplished through random sampling ~~with~~ stiffer penalties than a universal audit of all regulated activities. [Increased government expenditures on enforcement ~~compliance~~ must be balanced against the benefits that accrue from more uniform compliance.]

too much

- Information about the costs and benefits of a new regulation is often imperfect. Because of this inherent uncertainty, regulations should be flexible, and, more specifically, performance standards are preferable to design specifications because they encourage innovation and minimize interference by the government.

Gen. agreement that performance is preferable.

Dave D to redraft.

- Considerations should be given to whether there are preferable alternatives to direct regulation, such as establishing and assigning [property rights] to encourage individuals to internalize the costs of their actions; using marketable permits; providing information upon which choices can be made by the public; or using taxes to ensure desired behavior.]

Linda 2 Andy J. >

Section 2. *Organization.* An efficient regulatory planning and review process is critical to ensuring that the Federal government produces the best regulations for the American people.

A. *The Agencies.* Agencies are the repositories of substantive expertise and experience, and ~~they are the entities authorized by Congress to issue regulations~~. The agencies, therefore, are responsible, ~~in the first instance~~, for developing regulations and assuring that they are consistent with applicable law and the principles outlined in this Executive Order.

B. *Office of Management and Budget.* Centralized review is appropriate and necessary to ensure that regulations are consistent with the Administration's priorities within an applicable law and that decisions made by one agency do not conflict with the policy or action taken or planned by another agency. The Office of Management and Budget ("OMB") is best suited to carry out that function and shall therefore assist the President in implementing regulatory planning and reviewing individual regulations, as provided by this Executive Order.

C. *The Vice President.* The need for policy guidance and the resolution of inter-agency disputes is inevitable. The Vice President is best suited to assist the President in carrying out those functions and shall therefore oversee the development and presentation of regulatory policy recommendations to the President and otherwise ensure that the objectives of this Executive Order are realized. In fulfilling his responsibilities under this Executive Order, the Vice President shall be assisted by such

regulatory policy advisors within the Executive Office of the President and agency officials and personnel as he may, from time to time, consult.

Section 3. *Definitions.* For purposes of this Executive Order:

A. "Advisors" refers to the regulatory policy advisors to the President, who include: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Director of the National Economic Council; (4) the Domestic Policy Advisor; (5) the National Security Advisor; (6) the Director of the Office of Science & Technology Policy; (7) the Director of the Office of Environmental Policy; (8) the Chief of Staff; (9) the Administrator of the Office of Information and Regulatory Affairs ("OIRA"), who shall coordinate communications relating to this Executive Order among the agencies, OMB, and the other Advisors; and (10) the Vice President's counsel, who shall serve as counsellor to the Advisors in connection with the activities relating to this Executive Order.

B. "Agency" means any authority of the United States that is an "agency" under 44 U.S.C. § 3502(1).

C. "Director" means the Director of OMB.

D. "Regulation," "regulatory action," or "rule" means an agency statement of general applicability and future effect

designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

1. Regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. §§ 556, 557;

2. Regulations that pertain to a military or foreign affairs function of the United States, other than procurement regulations, and regulations involving the import or export of goods;

3. Regulations that are limited to agency organization, management, or personnel matters; or

4. Any other category of regulations designated by OIRA.

E. "Significant regulatory action" means any regulatory action that is likely to result in a rule that may --

1. Have an important effect on the economy; a sector of the economy; State, local, or tribal governments; a large number of individuals or entities; or the natural environment or depletion of natural resources, within or without the United States;

2. Be inconsistent or interfere with another action taken or planned by another agency;

3. Contravene or compromise the policy priorities of the Administration or raise questions as to the legality or constitutionality of the regulatory action.

Section 4. *Planning Mechanism.* In order to ensure that new or revised regulations promote the goals of the Administration and are consistent with existing regulations and to maximize consultation and coordination at an early stage, so to avoid serious conflicts or disagreements between agencies or between OMB and an issuing agency after a great deal of effort has been expended, these procedures shall be followed:

A. Each agency shall create an Annual Regulatory Plan ("Plan") of significant regulatory actions that the agency expects to issue in proposed or final form in the upcoming fiscal year, including any review of existing significant regulations. The Plan must be approved by the agency head and must contain at a minimum:

1. A statement of the agency's regulatory objectives and priorities;

2. A summary of each planned regulatory action;

3. A summary of the need and legal basis for each planned regulatory action;

4. A statement as to how the action fulfills the agency's statutory responsibilities or otherwise promotes the Administration's priorities, including, where appropriate, the health, safety, and environmental effects it will have;

5. A summary of the various possible means of achieving the agency's objectives, including reasonably viable non-regulatory actions, if any exist, and the relative advantages of the alternatives;

6. The agency's schedule for action;

7. An explanation of any plans by the agency to achieve, through adjudicatory or other means, policy that would ordinarily be accomplished through rulemaking; and

8. The name, address, and telephone number of a person the public may contact for additional information about the proposed regulatory action.

B. The agency shall forward its Plan to OIRA by May 1st of each year.

C. OIRA shall, by May 10th of each year, forward all agency Plans to other affected agencies and Advisors and to the Vice President.

D. An agency that perceives that a planned regulatory action in the Plan of another agency will impede its ability to fulfill its own statutory mission or the Administration's priorities shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the proposing agency, affected Advisors, and the Vice President.

E. The Vice President and [such of] the Advisors as he shall designate may consult with the heads of agencies with respect to their Plans and, in appropriate instances, render recommendations to the President as to the need for further review or inter-agency coordination at that time. ~~And~~ Greg Simon

F. OIRA shall publish all Plans by June 30th of each year. In this publication, the public shall be invited to comment on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing

regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public. All such comments shall be sent to the proposing agency. Where the comment raises issues of conflicts or inconsistencies with other planned or existing regulations, the comments shall be sent to the proposing agency, with a copy to OIRA.

Section 5. *Existing Regulations.* In order to reduce the regulatory burden on the American people, their families, their communities, and industries; to verify that regulations promulgated by the Executive Branch are compatible with one another; and to ensure that all regulations are consistent with the Administration's priorities within applicable law:

A. Each agency shall review its current regulations and determine whether, and to what extent, any of them are inconsistent with the objectives and standards set forth in this Executive Order. For all such regulations, each agency shall initiate the appropriate processes for reassessment and modification or elimination of the regulation; and

B. The Vice President, in consultation with the Advisors, may identify other existing regulations that are appropriate for review and reconsideration under this Executive Order. When such regulations are identified, the Vice President shall instruct the pertinent agencies to reconsider the regulations so identified and to undertake the appropriate processes to modify or eliminate the regulations or to justify their reason for inaction.

?

G Simon

- EOP
- Presidential

Section 6. *Centralized Review of Individual Regulations.* The following guidelines shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those considered to be independent:

A. *Agency Responsibilities.* Each agency (unless its own rules and regulations provide otherwise) shall provide the public with meaningful participation in the regulatory process. When feasible, each agency shall discuss the issues they confront with affected individuals and entities, including those who are intended to benefit from and those expected to be burdened by the regulation. [Each agency shall consult with elected State or local officials before proposing any regulatory action that may affect State or local governmental entities.] Each agency should afford the public a meaningful opportunity to comment, which in most cases should be at least a sixty-day comment period. Each agency is also encouraged to explore mechanisms for dispute resolution, such as negotiated rulemaking and other consensual processes. Finally, in addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act or other applicable legislation, each agency shall adhere to the following procedures:

1. On the first day of each month, each agency shall send OIRA a list of all regulatory actions that it seeks to promulgate [publicly announce] in the upcoming sixty days. The agency shall identify, with an asterisk, all those actions that constitute significant regulatory actions, as set forth in Section 3(E).

(iii) constitutional
(iv) takings > Shd these be combined?

answer not

leave in OIRA review # 1070 M

2. If OIRA does not notify the agency within ten working days after submission, the agency need not provide OIRA with any additional information regarding those actions not identified as significant regulatory actions.

3. For each matter identified as, or deemed by OIRA to be, a significant regulatory action, the proposing agency shall --

a. Provide to OIRA the text of draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

b. Assess the potential impact of the regulatory action and shall specifically explain its conclusions that --

(i) The regulatory action is consistent with a statutory mandate or otherwise promote the Administration's priorities;

[The regulatory action has been tailored to impose the least burden on individuals and small entities, including governmental burdens;]

(ii) The regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions;

(iii) The regulatory action does not violate any constitutional rights, including the freedom of expression and the right to privacy; and

(iv) The regulatory action will not effect an unintended taking of private property, as described in the pertinent guidelines established by the Attorney General, who shall, within 90 calendar days of this Order, and as necessary thereafter, issue such guidelines.

4. For those matters identified as, or deemed by OIRA to be, a significant economic regulatory action, as set forth in Section 3(E)(1), the agency shall also provide the following additional information to OIRA:

a. A statement of advantages anticipated from the regulatory action, such as the enhancement of general health and safety, the preservation of the natural environment, and the promotion of the efficient functioning of the economy and free markets; and where feasible, a quantification of the benefits

Joe suggests

b. A statement of the disadvantages of the regulatory action, including, any adverse impact on general health and safety, on the natural environment, and on the efficient functioning of the economy and free markets; and where feasible, a quantification of the benefits.

c. An identification of potentially effective alternatives to the planned regulation, including reasonably viable non-regulatory action, and an explanation as to why the particular alternative was selected.

5. For those regulatory actions that are governed by a statutory or court imposed deadline, the agency shall schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as outlined in Section 6(B).

[In emergency situations, when an agency wants to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and comply with Section 6(A)(3) to the extent practicable.]

to be discussed

[The agency shall not publicly announce any regulatory action until all applicable review is completed, subject to statutory or court imposed deadlines or emergencies.]

6. The agency shall identify the substantive changes between a proposed or final rule and the draft submitted for review in a clear and simple manner, by, for example, underscoring or italicizing the changes prompted by the review process.

7. All information provided to the public by the agency shall be in plain, understandable English.

B. *OIRA Responsibilities.* In order to provide meaningful guidance and oversight so as to ensure that each agency's actions are consistent with the applicable law and the objectives and standards set forth in this Executive Order, OIRA shall adhere to the following guidelines:

1. OIRA shall review only certain regulatory actions. Specifically, OIRA shall review any regulatory actions included by an agency in its Plan and any other regulatory action OIRA determines is appropriate for review based on the following considerations:

a. Whether the proposed regulatory action constitutes significant regulatory action;

Shd this be
30 rather than 60

30 vs. 90

for the $100 million

A Jaslow

[b. Whether the regulatory action may have an annual effect on the economy of $100 million dollars or more;]

c. Whether the planned regulatory action affects another agency's existing or planned regulations;

d. Whether the planned regulatory action relates to entitlements; and

e. The extent to which the proposed regulatory action raises important policy or legal issues.

2. OIRA shall complete its review or seek Presidential consideration within the following time period:

a. For regulations that do not include complex technical, scientific, or economic issues, OIRA shall complete its review within sixty calendar days after the date of submission; or

stet.

b. For regulations that involve complex technical, scientific, or economic issues, OIRA shall complete its review within ninety calendar days after the date of submission.

3. The review process may be extended by no more than thirty calendar days upon the written approval of the Director.

[4. In order to provide a periodic assessment of the status of proposed regulations throughout the Executive Branch, OIRA shall maintain and make available to the public a periodic Calendar, which shall include, at a minimum, the titles of all proposed rules that each agency has included in its Plan.]

In favor of
public record –

stupid
staff of OIRA should be able to talk
to outsiders

5. In order to ensure openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure guidelines:

a. Only the Administrator of OIRA and her deputy (or designated subordinate) shall communicate with persons not employed by the Federal [or State] government[s] regarding the substance of a pending regulatory action;

b. All substantive communications between OIRA and persons not employed by the Federal [or State] government[s] regarding a pending regulatory action shall be governed by the following guidelines:

(i) A representative from the issuing agency shall be invited to all meetings between OIRA and such person(s);

(ii) OIRA shall forward to the issuing agency, within ten calendar days of receipt of the communication(s), all written communications, regardless of format, between the reviewing entity and any person who is not employed by the Federal [and State] government[s], and the dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA and any such persons; and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in Section 6(B)(5)(c).

c. OIRA shall maintain a publicly available log which shall contain, at a minimum, the following information:

(i) The status of all pending regulatory actions [including if, and if so, when, Presidential review was sought];

(ii) All written communications, regardless of format, between OIRA and any person who is not employed by the Federal [or State] government[s]; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA and any person not employed by the Federal [or State] government[s].

d. OIRA shall send a letter to each issuing agency explaining its reasons for returning a regulatory action [without approval].

e. OIRA shall make the following available to the public after publication:

(i) Copies of draft Plans, Advanced Notices of Proposed Rulemaking, Notices of Proposed Rulemaking, and final Rules; and

(ii) Documents exchanged between OIRA and agency heads concerning each draft regulation submitted for review.

6. All information provided to the public by OIRA shall be in plain, understandable English.

Jack Quinn
concerned whether records
end up being UPI/P/ Fed records.
Newirth/JP to think there.
does this blur the scheme and difference.

Section 7. *Resolution of Conflicts and Inconsistencies.* Disagreements or conflicts among agency heads or between OMB and any agency that may arise during the regulatory process may be resolved by the President. Such resolution shall be based on recommendations provided by the Vice President in consultation with ~~such~~ the Advisors ~~of~~ and other Executive Branch officials or personnel as he deems appropriate.

Advisors given right to appeal?

Vice Presidential and Presidential consideration of such disagreements shall be available only to the Director, the issuing agency, or any other interested agency. [The Vice President and the President will not reconsider regulatory matters at the request of private parties.] [The Vice President or the President shall resolve all disagreements within ten/thirty days after submission.]

Section 8. *Judicial Review.* This Executive Order is intended only to improve the internal management of the Federal government and is not intended to create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, or any person.

Section 9. *Revocations.* Executive Orders 12291, 12498, 12606, 12612, 12630, and 12778; all amendments to those Orders; and any exemptions from those Orders heretofore granted for any category of rule are revoked.

Suggested language for "completing" reg-review.

Substitute for second bracketted para on p.18:

"Except in emergency situations, an agency may not publicly announce a regulatory action which is subject to review under this section until --

a. OIRA notifies the agency that it has completed or waived its review of the action;

b. the applicable time period in sec. 6(B)(2) expires, unless before the expiration of such period a request has been made for Presidential resolution [consideration] under sec. 7, or

c. an applicable statutory or judicial deadline expires;

whichever occurs first."