VI. APPENDIX I: SUMMITTED PAPERS

The U.S. Approach to Regulatory Policy

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Remarks at the Fourth Workshop of the
APEC-OECD Co-operative Initiative on Regulatory Reform
Vancouver, Canada, October 8, 2003

Thank you for the invitation to participate in this workshop. It is a pleasure to be here.

The U.S. approach to regulatory policy is characterized by three central elements, all of which are relevant to the development of the Integrated Checklist on Regulatory Reform. First, for three decades, the Executive Office of the President has provided centralized management and leadership of Federal rulemaking. This has allowed the Office of Management and Budget (OMB) to emphasize the importance of and adherence to regulatory principles and procedures. Second, OMB has stressed the need for high quality regulatory impact analysis. Strong analysis contributes to more informed policy decisions and promotes economic efficiency. Third, the U.S. program provides for a transparent rulemaking process that makes government officials accountable to the public. Transparency and accountability help address concerns about undue influence and allows all interested parties to be heard.

The Bush Administration's "Smarter Regulation" agenda is based on these key components of U.S. regulatory policy. More than a slogan, "Smarter Regulation" encourages the adoption of good rules, the modification existing rules to make them more effective and less costly, and the elimination of outmoded rules whose benefits do not justify their costs.

Centralized Management and Leadership

Since the Nixon Administration, six succeeding Presidents from both political parties sought oversight of their administrations' regulations by increasing transparency and analytical rigor.

- President Ford established the first regulatory impact analysis (RIA) requirement for major regulations (over USD 100 million in impact) by an Executive Order in 1975. The White House office that required RIAs, however, had no authority to stop rules, other than the effect that publicizing criticism of the RIAs generated.

- President Carter established the Regulatory Analysis Review Group. It made recommendations to improve regulations by filing statements in the issuing agency's public record but had no independent authority to enforce them.

- President Reagan firmly established regulatory oversight in the White House. Executive Order 11291, issued one month after he took office, required that agencies send their regulations to OMB for review and approval before publication in the *Federal Register*, as required by the Administrative Procedure Act (APA). This Executive Order was considered revolutionary at the time, in that it shifted power toward the president away from the so-called "iron triangle" of agencies, congressional committees, and special interest groups.

- President Clinton continued the basic Reagan-Bush oversight program at OMB by issuing Executive Order 12866, which refocused OMB oversight on "significant" rules and increased the disclosure procedures for contacts with outside parties. These changes addressed concerns that White House reviews of rules were too secretive.

- President George W. Bush maintained the Clinton Executive Order that requires the agencies to do RIAs and send their significant regulations to OMB for review.

Within the Executive Office of the President, the Office of Information and Regulatory Affairs (OIRA) has lead responsibility for overseeing Federal rulemaking. OIRA was established by the Paperwork Reduction Act of 1980, partially in response to the explosion in regulation that occurred in the 1970s and earlier in the U.S. The idea was to set limits on regulatory expenditures, similar to the constraints imposed through fiscal policy.

As part of the Office of Management and Budget—which develops the President's budget and is part of the Executive Office of the President—OIRA is a central body that has special standing with the agencies. This helps OIRA manage and coordinate Federal rulemaking. OIRA does this by providing guidance to agencies on complying with applicable executive orders and laws, and in our day-to-day review of draft regulations.

I would like to describe briefly OIRA's centralized regulatory review function. Agencies submit draft "significant" regulations—both proposed and final—to OIRA for an up-to-90-day review before publishing them in the *Federal Register*. By "significant," we mean rules that raise novel policy issues, require inter-agency coordination, and/or are "economically significant." Economically significant rules are those that are expected to impose over USD 100 million per year in economic effects, which can be costs, benefits, and/or transfers.

OIRA reviews about 500 regulations per year—those we determine to be significant—out of about 2 200 that are issued. About 70 of the 500 regulations are economically significant. For these rules, agencies must prepare an RIA.

During our review, we examine the RIA and the regulation and make suggestions to improve both the RIA and the rule's cost-effectiveness and to make sure that it comports with the Executive Order's principles and the President's priorities. If the agency refuses to make changes or needs more time to make the changes, we can return the rule to the agency for reconsideration. Later, I will talk more about return letters.

Regulatory Impact Analysis

As I mentioned, OIRA's reviews of draft rules often address the RIAs that support them. This reflects the importance we place on sound analysis. By requiring RIAs, we hope to achieve two basic goals. First, RIAs can help ensure that we maximize net benefits to society, or at least know that the benefits of rules justify their costs. Second, RIAs promote economic efficiency by regulating only where markets fail and, when regulating, by using cost-effective and market-based approaches, as opposed to command and control remedies. The RIA is made up of three elements:

- a statement of need for the proposed action (*e.g.*, identification of the market failure);
- an examination of alternative approaches to addressing the problem; and
- an analysis of the benefits and costs of each alternative.

RIAs help ensure that analysis informs policy decisions. As an analyst in OIRA, one of my most important responsibilities is to provide my political management with the best possible information when a policy decision must be made.

Last month, OMB issue revised guidance to agencies on regulatory analysis.[9] Key features of the revised guidance include more emphasis on cost-effectiveness and more careful evaluation of qualitative and intangible values. OIRA Administrator John Graham, who came to OIRA from academia, was very interested in updating the guidance in light of these and other innovations now commonplace in the research community.

Dr. Graham has also expanded OIRA's professional staff to enhance our ability to work with agencies to improve regulatory analysis. Traditionally, OIRA's professional staff consisted mostly of economists, public policy analysts, and lawyers. OIRA recently hired four PhDs with expertise in epidemiology, toxicology, public health, and engineering. These specialists enable OIRA to better evaluate rules that rely on risk assessments and technical engineering data.

In stressing the importance of sound regulatory analysis, OMB is using both carrots and sticks. OMB, for example, is encouraging agencies to subject their RIAs and risk assessments to formal, independent, external peer review. We have told agencies that RIAs submitted to OMB that are peer reviewed will receive an extra measure of deference during our regulatory review.

OIRA has also resurrected the dreaded "return letter" to address analytic concerns. During the first year of the Bush Administration, OIRA returned more than 20 rules to agencies for reconsideration—more than the number of the returns in the entire eight years of the Clinton Administration. Agencies have learned that OIRA cares about good analysis. As a result, returns have become less frequent in recent months.

9. See Circular A-4, "Regulatory Analysis," published as part of OMB's 2003 Report to Congress on the Costs and Benefits of Federal Regulation. The report is available on OMB's website at: *www.whitehouse.gov/omb/inforeg/2003_cost-ben_final_rpt.pdf*

Transparency and Accountability

The third major element of U.S. regulatory policy concerns transparency and accountability. Each branch of the Federal government has a role. Within the Executive Branch, agencies must demonstrate to OMB, acting as an advisor to the President, that their regulatory analyses are of high quality and support findings that regulations are likely to maximize net benefits and are in compliance with the law.

After OMB concludes its review of a regulation and it is published in the *Federal Register*, Congress reviews it under the Congressional Review Act. Major regulations cannot go into effect until 60 calendar days after the later of publication in the *Federal Register* or its submission to Congress. Congress then has 60 legislative days under expedited rules to enact a law rescinding the regulation. The Regulatory Right-to-Know Act also requires OMB to issue a report to Congress each year estimating the costs and benefits of regulations in the aggregate, by agency and agency program, and by regulation.

The Judicial Branch also has a key role. After a rule goes into effect, affected parties can bring suit against the agency issuing the rule to have the courts reverse or mandate it back to the agency because it violated either the Administrative Procedure Act's process requirements, the statute that authorized the rules, or the U.S. Constitutions.

The Administrative Procedure Act provides the foundation for regulatory transparency and accountability in the United States. Most importantly, the Act requires that agencies go through a notice and comment process open to all members of the affected public, both U.S. and foreign. This means that, before agencies can issue a final regulation, they must publish a proposed rule in the *Federal Register*, consider the public comments, and publish the final rule in the *Federal Register*, making sure that the final regulation is a logical out-growth of the proposal and the public record, and is not arbitrary or capricious. The information in the public record, and agencies' use of this information, is used by the courts in settling any challenges to regulations brought by the affected public.

The Bush Administration has taken steps to increase and make more accessible the information that OMB discloses to the public. For example, the public can consult OMB's website and learn each day which rules are under formal review at OMB and which have been cleared. OMB's website notes which outside groups have recently lobbied OIRA on rules under review: providing their names, organizations, date of the meeting, and the topic of the discussion. All written information and comments given to us while a rule is under review is sent to the agency, placed in our public docket reading room, and posted on our website. In addition, return letters sent to the agencies outlining our concerns with rules we send back to them are posted on our website. OMB views this increased openness as good government, because it has helped shift the public debate on regulation from process toward substance. Now, the question is not "who met with whom?" It is, "is this option more cost-effective than that option?"

Smarter Regulation

The Bush Administration's agenda of Smarter Regulation is building on the basic elements of U.S. regulatory policy. Administrator Graham, for example, has established a proactive program to bring to the attention of agency heads a regulatory matter with public "prompt letters." I will give you three examples:

- OIRA prompted the Food and Drug Administration to finalize a regulation to add a mandatory label for the trans fat content of foods in order to reduce an established risk factor for coronary artery disease.

- OIRA prompted the Occupational Safety and Health Administration to take actions promoting the availability and proper use of automated external defibrillators, a technology that can save lives among people suffering from sudden cardiac arrest.

- OIRA prompted the National Highway Traffic Safety Administration to initiate a new rulemaking that would require vehicle manufacturers to test cars and light trucks for occupant protection in what are called Aoffset@ frontal collisions, a crash mode responsible for a significant number of lower extremity injuries to occupants.

OIRA suggested these and other regulatory reforms because of information indicating that they are likely to generate significant net benefits.

Smarter regulation also promotes accountability by improving the quality of regulatory information. Pursuant to the Information Quality Law, OMB has issued guidelines to enhance the quality of information that agencies use and disseminate, and agencies must establish minimum quality standards for information that they disseminate to the public. These standards are intended to ensure and maximize the quality, objectivity, utility, and integrity of disseminated information. “Influential” data—such as data used to support regulations—must meet an even higher standard, in that it must be reproducible by qualified third parties. Under the Information Quality Law, any affected member of the public may challenge agency information and request a technical correction.

The Bush Administration, pursuant to the Regulatory Right-to-Know Act, is also in the process of implementing regulatory reforms. Most notably, in 2002 OMB sought public comment on two regulatory reform initiatives. First, the public nominated specific rules and regulatory programs in need of reform. Second, OMB asked that the pubic comment on agencies’ use of guidance documents. In response to this public solicitation, OMB received recommendations on 316 distinct rules, guidance documents, and paperwork requirements from over 1 700 commenters. In our review of the 316 nominations, we found that 109 of the reform ideas were already being addressed by agencies, and another 51 ideas were referred to independent agencies for their consideration. Of the 156 reform nominations that OMB determined were ripe for consideration by Cabinet-level agencies and the Environmental Protection Agency, agencies have decided to pursue 34 rules and 11 guidance documents for reform, are undecided about 26 rules and 4 guidance documents, and have decided not to pursue reform of 62 rules and 19 guidance documents at this time.

Conclusions

To sum up, I would like to offer a number of conclusions that should help inform the development of the integrated checklist. First, the U.S. experience indicates that a firm and enduring commitment from the center of government is a necessary condition for a successful regulatory program. This is particularly true when regulatory reform imposes short term costs before greater long term benefits materialize. Second, an affective regulatory program should ensure that economic analysis is conducted to promote economic efficiency. Economic efficiency implies market-based and pro-competition reforms that are non-discriminatory. Third, accountability is required because special interests are especially powerful in regulatory matters. Finally, transparency and openness are required to maintain long term support for the program.