PRESIDENTIAL MANAGEMENT OF REGULATORY POLICY: A STRONGER ROLE FOR SCIENCE, ENGINEERING, AND ECONOMICS

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The Office of Management and Budget is well known as the center of budgetary policy in the executive branch, but OMB's role as a force for sound regulatory policy is not well understood. Today I would like to discuss some of OMB's recent initiatives to strengthen the roles of science, engineering and economics in federal regulation. Before doing so, I believe I need to provide some basic background about the responsibilities of my Office at OMB: the Office of Information and Regulatory Affairs (OIRA).

The best way to proceed may be by posing the following question: "Why would any clear-thinking President ask a senior OMB official with a modest staff of 40 analysts to oversee the entire federal regulatory state?" Let me suggest, at the outset, that any such effort might justly be considered ambitious.

There are over 100 federal agencies and subagencies with regulatory mandates from Congress. They churn out 4,500 new rules each year. The 40 OMB professionals in my office are obviously outnumbered by the thousands of regulatory specialists in the agencies.

All significant rulemakings must be submitted to OMB for review and clearance before they are published in the Federal Register. Yet once a regulatory proposal is formally submitted to OMB, there is already powerful organizational momentum behind the proposal. Not only have agency staff devoted potentially years of work to data collection and analysis; policy officials at agencies may have managed delicate relationships among stakeholders. At this stage, any changes suggested during OMB review are destined to make waves and bruise egos, which means that they will be resisted, sometimes fiercely and effectively.

Despite these realities, I do not share the view that Presidential management of the regulatory state is hopeless. Rather, I share the vision of Supreme Court Justice Stephen Breyer who described in his book, BREAKING THE VICIOUS CIRCLE, an experienced cadre of civil servants in the Executive Office of the President who have broad expertise in the craft of regulatory policy. More importantly, these analysts are empowered to look beyond the "tunnel visions" that plague individual agencies, thereby fostering a more holistic approach to regulatory policy.

I think the following empirical fact is instructive: Every President since Richard Nixon, Democrat and Republican, has insisted on some type of centralized management of regulatory policy. The common theme has been professional analysis of regulations to make sure they are sensible. Given this history, it is informative to consider why leaders are so determined to manage the regulatory state.

For starters, Presidents have recognized that, regardless of whether we like rules, the federal regulatory state is here to stay. While economic regulation has seen much privatization over the last 30 years, the public and Congress have revealed a growing commitment to public health, safety and environmental protection. In fact, science-based regulation is on the rise in areas ranging from bioengineered foods and pesticides to motor vehicle fuel economy and diesel exhaust control.

Capitalism is at the heart of American society and is the engine of America's record of prosperity but citizens also recognize the limitations of capitalism. For example, recent revelations about the Enron fiasco have stimulated discussion of the need for appropriate public disclosure requirements and other regulations. As we advocate more worldwide appreciation of the form of democratic capitalism that America cherishes, we must continue to improve the regulatory policies that are designed to compensate for the limitations of capitalism.

The policy debate continues as to what level of government should possess the most regulatory power. There is surely an urgent need for federal regulators to consult with state and local officials and to respect the role of federalism in our national system of government. Indeed, my boss, OMB Director Mitch Daniels, has instructed me that I should return to agencies any proposed rule that does not have adequate consultation with our intergovernmental partners. This principle is particularly important when Washington seeks to impose unfunded mandates on state and local officials. But we should also respect the views of Alexander Hamilton, an important framer of our Constitution. Hamilton recognized the weaknesses in the original Articles of Confederation and the need for a strong centralized government to promote the welfare of the republic. Indeed, there is growing consensus that in certain fields of regulatory policy it is important for the federal government to preempt the regulatory powers of state and local governments. In other words, a thoughtful approach to regulatory policy envisions a substantial role for the federal government. And this role will only become more important as our nation engages in more international deliberations to harmonize regulations with our trading partners.

While we need federal regulators, let's face it: they are expensive. Now the total budgets of federal regulators are not much greater than $8 billion per year. But for every dollar that taxpayers provide to federal regulators, another 100 dollars in cost is imposed outside the federal sector on State and local agencies and the private sector. According to one recent estimate prepared for the Small Business Administration, federal rules cost American households $800 billion per year. Note that this figure is larger than the entire discretionary federal budget, amounting to an average annual cost of almost $8,000 per household. These regulatory costs are

like an invisible tax on the consumer who typically does not realize that regulation is causing higher prices for goods and services.

It is certainly true that many federal rules have significant, even lifesaving, benefits for households and future generations. OMB's recent Annual Report to Congress describes numerous cost-effective federal regulations. Yet there is real concern that regulatory costs are not always imposed wisely, suggesting that we could save more lives and do more for the consumer and taxpayer through a simple reallocation of the regulatory dollar.

Now, no one would suggest that agencies should be permitted to negotiate their "on-budget" resources from Congress, without any OMB review. Likewise, Presidents realize that regulatory expenditures, while off budget, require fiscal restraint for the same reasons that the size of public budgets need to be restrained. If the President restrains the federal budget without restraining regulation, regulatory advocates may simply respond by urging Congress to shift regulatory costs from the federal budget to states and the private sector. In other words, the President cannot manage the Nation's fiscal health without managing the regulatory state.

OMB also has a role in conflict resolution. When two or more agencies disagree about an issue, the President needs an experienced unit to forge a consensus so that governance can proceed. OMB often plays that role in the regulatory arena. For the last six months, the White House Council on Environmental Quality and OMB have been working with EPA and DOE to fashion a legislative strategy to promote cleaner power generation in America. This kind of consensus building is not easy. We are pleased that the President announced last week a strong market-based approach to environmental protection that will reduce pollution from the electric utility sector by 60-70% over the next 15 years.

Of course, Presidents use the powers of OMB regarding agency action to advance Administration priorities and policy objectives. President Reagan pursued an agenda of regulatory relief as one way to nurture a depressed economy riddled by the misery index: double-digit rates of inflation, unemployment, and interest. President Clinton used centralized review to promote a wide range of social objectives such as tobacco and firearms control and children's health. We should remember that OMB is an office within the Executive Office of the President and its actions necessarily and properly reflect Presidential priorities.

In this Administration, OMB's Office of Information and Regulatory Affairs is pursuing an agenda of quality regulation. What President Bush seeks is a smarter regulatory process rooted in sound science, engineering, and economics. A high-quality regulatory process is not uniformly pro-regulation or anti-regulation. Instead a smart process adopts new rules when market and local choices fail, modifies existing rules to make them more effective or less costly, and rescinds outmoded rules whose benefits no longer justify their costs.

We are pursuing the agenda of quality regulation under the terms of the Clinton-Gore executive order, which we believe – though not always enforced in the 1990s– is based on sound

principles and procedures. The changes we are making at OMB are not headline-grabbers: No far-reaching legislative initiatives, no rhetoric-laden executive orders, and no campaigns of regulatory relief. Yet we are making some modest changes that may have a long-lasting impact on the regulatory state by increasing the roles of science, formal analysis, peer review and public participation in regulation.

First, we have taken steps to enhance the openness of OMB's regulatory review process. Each day we post information on our web site about which rules are under review, who we are meeting with, and what we have decided. After rules are cleared, we also release information about how rules have changed due to OMB review. Through the Internet, it is now possible for the public to scrutinize how we use science, engineering, and economics to stop bad rules and help agencies craft better ones. We are also an active partner in a multi-year effort to link my office to the Administration's E-government initiative, which will allow electronic and interactive communication about OMB issues under review. Now, I certainly do not believe that the Executive Office of the President can operate in a fishbowl. There is a delicate balance to be drawn here but I do believe that more openness at OMB about regulatory review will enhance public appreciation of the value and legitimacy of a centralized, analytical approach to regulatory policy.

Second, we have reversed the 20-year decline in staffing at OIRA and have done so in a way that recognizes the increasing importance of science-based regulation in the federal agencies. We are now hiring the first scientists and engineers at OIRA to accompany a cadre of economists, statisticians, and information technology specialists. We believe this more diversified pool of expertise will enable us to ask better questions about agency proposals.

Third, we have sent clear signals to agencies that we care about regulatory analysis, QUALITY regulatory analysis. We are using both the carrot and the stick. The carrot we have offered is more deferential OMB review of proposals that agencies have voluntarily subjected to independent peer review. Administrator Whitman's recent decision on arsenic in drinking water was supported by just that type of review. The Bush Administration recognizes that we should consider and account for the consensus views of the leadership of the scientific community, regardless of whether it leads to a pro- or anti- regulation result. The stick has been a revival of the dreaded "return letter". In the last three years of the Clinton Administration, there were exactly zero return letters sent to agencies for poor quality analysis. I have signed 20 return letters in the last seven months and they are available for scrutiny on OMB's web site. A return letter does not necessarily kill a proposed rule. In five cases so far, we have ultimately cleared an improved version of a rule that we initially returned. Knowing that we care, agencies are beginning to invite OMB into the early stages of regulatory deliberations, where our analytical approach can be more effective.

Fourth, we have demonstrated that we are prepared to initiate new regulatory actions when they are needed. I am not simply talking about the series of new rules aimed at protecting homeland security, including airline safety, food safety, and immigration control. President Bush

himself recently announced new regulatory steps to protect the 401(k) and retirement plans of the American worker.

At OIRA we have devised a modest tool called the "prompt letter" that OMB uses to identify areas where agencies might improve regulatory policies. Our first four prompt letters, available on OMB's web site, address potential opportunities to save lives and improve health through cost-effective regulation. One OMB letter has accelerated FDA's deliberations on a rule that would require labeling of foods for their trans-fatty acid content, an important risk factor for coronary heart disease. Another OMB letter to OSHA has stimulated a national information program to promote workplace use of automatic defibrillators, a technology that saves lives from sudden cardiac arrest and is already found in airports and federal buildings. A recent letter to NHTSA suggests that priority be given to a new rulemaking that would test cars and light trucks in offset crash tests, as well as frontal crash tests, an approach that may reduce injuries in vehicle crashes. And our most recent letter to EPA, we encouraged targeted research to better understand the health benefits of reducing different types of particle pollution from power plants, industry, and motor vehicles. Unlike the more definitive Presidential directive, the prompt letter is a public request that is intended to stimulate agency and public deliberation. Final decisions about priorities remain with the agencies.

In the search for promising new regulations, we should not forget the urgent need to streamline existing federal regulations. Our goal is to modernize or remove outdated regulations. OMB does not believe that across-the-board reviews of all existing rules are a cost-effective use of agency resources; yet OMB does support selective reviews of existing rules based on public participation. We recently sought public comment in this area and learned of 71 specific suggestions to modify or rescind existing rules to increase benefits or reduce costs. We have rated these ideas in our recent annual report to Congress and are now in discussions with agencies about whether these suggested reviews should be an agency priority. We are also encouraging interested parties to prepare additional nominations for the public comment process on next year's annual report on the costs and benefits of regulation, which should be released in the next month or so.

Finally, and perhaps most importantly, OMB has developed government-wide guidelines to promote better quality in both the formal analyses and original data that agencies use and disseminate to the public. The OMB guidelines were mandated by Congress and we have developed them pursuant to an extensive public comment process. When agency information is so influential that it forms the basis of major public policies, we go beyond the standard of journal peer review and require that such information be reproducible, or is at least highly transparent about research design, data sources, and analytic methods.

When people are harmed or otherwise affected by poor quality information that agencies disseminate, the OMB guidelines provide new avenues for citizen complaints, agency corrections, and formal appeals processes to resolve disputes. Over the next year each agency, including the independent agencies, will be preparing information-quality guidelines that OMB

will review. The agencies will be reaching out to the scientific communities and the public to assist in this process and they will need your help. We urge you to participate in this process because we believe it has tremendous potential to enhance the competence and accountability of the federal regulatory state. As many of you know, dissemination of information by the government, with its broad consequences for citizens and firms in the USA and abroad, is often a more important act than the final adoption of a regulation.

I am aware that some science groups have argued that the government should accept the quality of any information that is published in a peer-reviewed academic journal. As an academic who practiced the "publish or perish" game for over 20 years before joining the Bush Administration, I must confess that some of my peer-reviewed papers are not ready for use in policy making. For example, my doctoral dissertation of 1983 projected that installing airbags in all new cars would save 9,000 lives per year. The error bars on my estimates were not large enough since the best studies, conducted after real-world experience, now estimate that the technology now in cars will save about 3,000 lives per year.

The point is: Even publications in the best academic journals have been shown to have serious problems, including some errors that could have been detected and prevented at the time of publication. I will conclude with two revealing examples of attempts at reproduction of peer-reviewed, published results. The first example involves a scientific report about a laboratory experiment about whether two or more chemicals can have a synergistic, damaging effect on the endocrine system of the body. The second example involves a scientific report indicating that long-term exposure to low levels of air pollution may cause a significant increase in human mortality.

After an intensive investigation of the first report, the Office of Research Integrity of the NIH concluded on October 12, 2001 that the author "committed scientific misconduct by intentionally falsifying the research results reported in Table 3 of a paper published in the journal Science. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the Science paper as a whole." Before this problem was exposed, this study was cited widely in environmental policy debates in the US and abroad.

The second report was subjected to an intensive re-analysis by the Health Effects Institute, an independent research organization in Cambridge, Massachusetts, and the result was more encouraging. HEI found no significant mathematical errors in the published report, although some of the reported associations between pollution and mortality were altered in size when plausible changes in the analytic approach were implemented. That was a paraphrase of HEI's findings, not a direct quotation.

I want to acknowledge that science is an evolving process where errors are made and then corrected. I am not asking scientists to be perfect. What I am suggesting is that regulators should be careful about using scientific, engineering, and economic information to support

important public policies when that information, the analysis and the original data, are not available for scrutiny by qualified third parties.

One of my objectives at OMB is to expose more of the critical regulatory information to the reproducibility test, regardless of whether the agency obtained the information from academics, in-house scientists, industry or other sources. The public has a right to expect that when agencies disseminate technical information to the public, that information satisfies minimum quality standards.

Thus, I hope that I have given you a better sense of the role that OMB is playing in this Administration, particularly our role in enhancing the place of science, engineering and economics in quality regulation. Thank you very much for the opportunity to speak today and I look forward to questions, comments and discussion.