GEORGETOWN UNIVERSITY LAW CENTER

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March 31, 2009

Via Email & Fax

Mr. Kevin Neyland
Acting Administrator
Office of Management and Budget

Re: *Developing an Executive Order to Govern Review of Regulations by Executive Branch Agencies*

Dear Mr. Neyland:

Thank you for extending to members of the public an opportunity to comment on this important issue. No prior Administration has solicited public input in formulating its approach to centralized review of agency regulations, and this marks an important step forward in making government more transparent.

My comments are set forth in detail below. In a nutshell, I urge the Administration to undertake a substantial overhaul of process of reviewing regulations developed by Executive Branch agencies. The process used by Presidents since President Reagan has not served the public well. It results in weakened protections for workers and consumers; it further ossifies an administrative process already overladen with procedures; it provides a back-door channel that can used to influence the outcome of important regulatory decisions; and it sends the disturbing signal to the public that health and safety of Americans can easily be and often is sacrificed on the altar of cost-benefit analysis. The process of regulatory review has also taken a toll on our agencies — they spend time and money (both of which are in short supply) preparing extensive analytic documents, like cost benefit analyses, to meet the terms of the Executive Order, even where the agency is forbidden by law from using those documents to make regulatory decisions. It is time to bring rationality to this process.

I urge a number of reforms, which are set out below:

* The Executive Order should be revised to end mandatory review of agency rules simply because they might impose significant annual costs. The Office of Information and Regulatory Affairs (OIRA) should review, at most, a handful of regulations annually, and those regulations

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ought to be selected by OIRA, in consultation with the agencies, because of the clear-cut importance of the rule to our nation's economy or because the rule raises important policy considerations that cut across the jurisdiction of a number of Executive Branch agencies.

* The Executive Order should be revised to state explicitly that OIRA has no authority to displace decisional authority assigned to the agency by Congress and its role is to advise agencies on how to make regulation more effective and efficient.

* The Executive Order should be revised to make clear that agencies are not required (or even encouraged) to prepare cost benefit analysis where the rule subject to review seeks to implement a statute that does not permit cost benefit considerations to be used a decisional factor. Cost benefit analysis should similarly not be required where the rule subject to review seeks to implement a statute that does not direct the agency to consider costs in formulating its rule. OIRA should undertake a review of the current methodology for cost benefit analysis to determine why these analyses systematically overestimate the cost of regulation and underestimate (or omit altogether) the benefits of regulation. Additional consideration should also be given to ensure that there is due consideration of the distributional impacts of regulation. And finally, OIRA should cease or substantially revise its practice of heavily discounting the benefits in health rules to health and safety rules, especially where discounting is used to block needed protections that will benefit future generations.

* The Executive Order should be revised to accelerate, not further ossify, the regulatory process.

* The Executive Order should be revised to make explicit that OIRA shall not second-guess an agency on technical, scientific or engineering matters within the agency's expertise.

* The Executive Order should be revised to make the OIRA review process transparent and accountable. All communications between OIRA and an agency during the course of OIRA review should be documented and placed in the agency's rulemaking record no later that the publication of the final agency rule.

I. Background and Problems with Centralized Review Under Executive Order 12,866.

Although all Presidents since President Ford have employed some form of centralized review of agency regulations, systematic, wholesale review of regulations did not begin until the Reagan Administration. Just a month after his inauguration, President Reagan issued Executive Order 12,291, which required agencies to prepare detailed Regulatory Impact Analyses specifying the costs and benefits of all proposed "major" rules. The Order provided that, unless otherwise forbidden by law, an agency could not undertake rulemaking unless "the potential benefits to society . . . outweigh the costs," and the agency selected the regulatory option

"involving the least net cost to society."[1] The Order further required agencies to submit drafts of all proposed and final rules to OIRA before publication in the Federal Register, and publication could not proceed without OIRA's approval.

For the purpose of this Administration's reconsideration of the role centralized review should play in the development of regulations issued by Executive agencies, it is worth noting that the justification for the Executive Order, written by the Office of Legal Counsel in the Department of Justice, was based on what is now referred to as the "unitary executive" theory of Presidential power.[2] That theory claims that the Article II of the Constitution vests broad power in the President to supervise and guide the performance of his Executive Branch subordinates. This theory, it bears emphasis, argues that the President is free to play an active role in the formulation of agency policy, even where, as is generally true in the development and promulgation of regulations, Congress has vested decisional authority, not in the President, but in the heads of agencies who have been subject to Senate confirmation.[3] Without going into the details of the debate among constitutional scholars over the legitimacy of that position, it is fair to say that there are many scholars who believe that the unitary executive theory of Presidential power represents a significant and unwarranted arrogation of power to the presidency at the expense of Congress.

For that reason, from the outset, Congress was troubled by the dominant and often obstructionist role OIRA played in rulemakings. OIRA delayed and weakened rules, met in secret with industry representatives, overrode agency determinations on complex matters of science, and otherwise thwarted the ability of the regulatory agencies to do their jobs.[4] During 1982-83, the House held no fewer than seven hearings to examine health and safety rules

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[1] Exec. Order 12,291, §§ 1(b), 7(g)(2); 3 C.F.R. 127 (1981), *reprinted in* 5 U.S.C. § 601, at 431 (1982).

[2] See Memorandum of Acting Assistant Attorney General Larry L. Simms, *Proposed Executive Order Entitled "Federal Regulation,"* (Feb. 13, 1981).

[3] See generally Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 Mich. L. Rev. 193 (1981).

[4] See generally Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 Mich. L. Rev. 193 (1981); David C. Vladeck, *Unreasonable Delay, Unreasonable Intervention: The Battle to Force Regulation of Ethylene Oxide*, in Peter L. Strauss, ed., ADMINISTRATIVE LAW STORIES (Foundation Press 2006).

seriously delayed or weakened by OIRA.[5] And when the first challenge to the constitutionality of OIRA's meddling in agency rulemaking came before an appellate court, the Chairmen of the five House Committees having jurisdiction over regulatory agencies filed a brief setting forth a blistering critique of OIRA review. Here is just a brief sampling of what the five Chairmen said:

> The amici Congressmen object to the systematic usurpation of legislative power by OMB pursuant to Executive Order 12,291 * * * Executive Order 12,291 is the cornerstone of a steadily growing Presidential apparatus, the effect of which is to contravene explicit Congressional delegations of authority, to subvert meaningful public participation in and judicial review of federal regulations, and to impose substantive standards on decisionmakers foreign to the statutes they administer. Unless it is checked, the program embodied in Executive Order 12,291 will fundamentally damage the administrative process by which our laws are implemented, the legislative system by which our laws are enacted and monitored, and the separation of powers upon which our system of government rests.[6]

In 1993, shortly after taking office, President Clinton issued Executive Order 12,866 to make a number of significant modifications to the Reagan Executive Order. In my view, the most important was to inject transparency into the OIRA review process.[7] The Clinton Order cut back on the number of "significant" agency rules reviewed by OIRA. It also required OIRA, as a general rule, to complete its review of proposed and final rules within ninety calendar days. And it required all agencies, including the so-called independents, to prepare an annual regulatory plan outlining all important regulatory actions the agency intended to take during that fiscal year.

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[5] See, e.g., *OMB Control of OSHA Rulemaking,* Hearings before the Subcomm. on Manpower of the House Comm. on Gov't Operations, 97th Cong., 2d Sess. (1982); *Infant Formula: The Present Danger*, Hearings before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 97th Cong., 2d Sess. (1982); *EPA: Investigations of Superfund and Agency Abuses (Part 3)*, Hearings before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce, 97th Cong., 1st Sess. (1981).

[6] Brief of John Dingell, Chair, House Energy and Commerce Committee, Peter Rodino, Chair, House Judiciary Committee, Jack Brooks, House Government Operations Committee, Augustus Hawkins, Chair, House Education and Labor Committee, and William D. Ford, Chair, House Post Office and Civil Service Committee, in *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479 (D.C. Cir. 1986).

[7] See Executive Order 12,866, §§ 6(b) & (c); 58 Fed. Reg. 51,735 (1993).

The plans had to be personally approved by agency heads.[8]

The major change by President George W. Bush was to expand the role of OIRA to include the review of "guidance documents" — a measure that I strongly opposed.[9] Fortunately, one of the first acts of the Obama Administration was to rescind the Order.

Even with the adjustments made by President Clinton, and the Obama Administration's rescission of the guidance document order, centralized review of the regulatory output of administrative agencies has never accomplished its objective of making our regulatory agencies better serve the public. Indeed, the ultimate irony is that if OIRA's review process was subjected to cost-benefit analysis, OIRA review would not pass muster. The amount of time, energy, money and, at times, political capital that goes into satisfying OIRA that a rule is worthy of publication dwarfs any conceivable benefits that flow from the process. We have now had a twenty-five year experiment with centralized review. Judged by any legitimate measure, it is time to declare the experiment a failure and overhaul it completely. I hope that the Obama Administration does that just.

There are at least four significant flaws in the current Executive Order which should not be carried forward in any modifications made by the Obama Administration:

1. To begin with, centralized review has always been — in both Republican and Democratic Administrations — a one-way ratchet. OIRA presses agencies to do less to protect the public health, not more. Agencies do not complain that OIRA is forcing them to do more; they complain that OIRA is forcing them to weaken protections the agencies have determined are required by their statutes. OIRA's insistence that agencies do less stems from its singular focus on minimizing the burden on society — or, in other words, minimizing regulatory compliance costs. And the Executive Order does so by injecting a wide range of considerations into the regulatory process that are not specified in agency's organic statute.

There are several problems with this approach. For one thing, it encourages under-regulation. The Executive Order requires agencies to perform cost benefit analysis even when

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[8] The Solicitor General of the United States, and formerly Dean of Harvard Law School, Elena Kagan has traced the development of the Clinton Executive Order in *Presidential Administration*, 114 Harv. L. Rev. 2245 (2001).

[9] Executive Order 13,422, 72 Fed. Reg. 2763 (January 23, 2007); Testimony of David C. Vladeck, *Hearings on OMB and Guidance to Agencies*, House Science Committee, Subcommittee on Investigations and Oversight, 2007 WL 45833 (February 13, 2007).

the agency is not permitted by law to use cost benefit analysis for decisional purposes.[10] Many critics argue that cost benefit analysis — and especially the analysis mandated by OIRA — is inherently anti-regulatory.[11] My own litigation experience bears this out. I have represented workers and labor unions in litigation to force OSHA to protect workers from exposure to many highly toxic and carcinogenic chemicals, including ethylene oxide, cadmium, hexavalent chromium, formaldehyde and benzene.[12] In each case, OIRA was an obstacle to the agency's action. Part of OIRA's objection was its unwillingness to place any value, or only minimal value, on important health benefits of regulation — including avoided cancers, miscarriages, genetic damage that might cause infertility or birth defects, and kidney failure that might require dialysis or transplant — because they were too difficult to quantify. While the anticipated *costs* of regulation are generally easier to estimate (and overestimate), the *benefits* of regulation are notoriously difficult to quantify and are often downplayed or ignored by OIRA. And when OIRA does place a value on a benefit or regulation, it discounts those values heavily. Indeed, lives that are going to be lost twenty or thirty years down the road are devalued to the point of insignificance. This Administration ought to give serious thought to either scrapping the discounting of health and safety rules altogether, or reformulating its approach to discounting to ensure that important public health and safety measures are not defeated simply because their benefits accrue in the future.

2. There is also the problem of competence. Time and again, OIRA has intruded on OSHA's expertise in matters of worker health. For instance, OIRA sabotaged OSHA's regulation of ethylene oxide by insisting that the agency strip away worker protection from high-dose, short-duration exposures — even though exposures of that sort had been linked to serious health problems, including spontaneous abortion. Fortunately, OSHA/OIRA's decision was set aside by the courts, but OIRA's improper substitution of its judgment for OSHA's resulted in

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[10] See Executive Order 12,866, § 1(b)(6).

[11] See generally Frank Ackerman & Lisa Heinzerling, PRICELESS: ON KNOWING THE PRICE OF EVERYTHING AND THE VALUE OF NOTHING (New Press 2004); Lisa Heinzerling, *Regulatory Costs of Mythic Proportion*, 107 Yale L. J. 1981 (1998).

[12] See, e.g., *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983); 796 F.2d 1479 (D.C. Cir. 1986); 823 F.2d 626 (D.C. Cir. 1987) (decisions requiring OSHA to regulate ethylene oxide, a potent carcinogen and teratogen); *International Chemical Workers Union v. Pendergrass*, 958 F.2d 1144 (D.C. Cir. 1992); 830 F.2d 369 (D.C. Cir. 1987) (decisions compelling OSHA to regulate cadmium, a potent lung carcinogen); *Public Citizen Health Research Group v. Chao*, 314 F.3d 143 (3d Cir. 2002); 145 F.3d 120 (3d Cir. 1998) (decisions forcing OSHA to regulate hexavalent chromium, a potent lung and liver carcinogen); *UAW v. Pendergrass*, 878 F.2d 389 (D.C. Cir. 1989) (decision requiring OSHA to regulate formaldehyde).

years of delay, which exacted a toll on exposed workers.[13]

Consider another example. The next car you buy is almost certain to have a gauge on the dashboard that will display a warning when the car's tires are under-inflated. Congress required this safety feature after a spate of deadly roll-over crashes caused, in part, by under-inflated tires. The National Highway Traffic Safety Administration (NHTSA) proposed to require automobile manufacturers to install devices that would detect under-inflated tires in virtually all cases. OIRA insisted that NHTSA permit the installation not only of the device NHTSA's engineers determined was best, but also a far less effective (and less expensive) device favored by the auto industry. Not surprisingly, NHTSA did what it was told. Empowering OIRA economists to second-guess highly technical judgments made by expert agencies is not good government. Ultimately, Public Citizen succeeded in getting a court to overturn the OIRA-dictated decision and direct NHTSA to require the installation of the more effective devices. But the introduction of this important, life-saving device was delayed because of OIRA's interference. This is hardly an isolated case.[14]

3. There is also enormous delay built into OIRA review which has resulted in the ossification of the regulatory process. The regulatory process is so overlain with procedural and regulatory requirements that agencies cannot get their work done in a reasonable time. It now takes OSHA a decade to promulgate a standard to protect workers from exposure to toxic substances.[15] While the rulemaking process grinds glacially ahead, workers are exposed to unreasonable risks to their health and well-being. Other agencies face comparable delays. And much of the delay can be traced back to all of the requirements imposed by the Executive Order. These problems are all well-known, and in fairness to the Clinton Administration, some efforts were undertaken to address them.

Apart from, and perhaps more significant than, the delay occasioned by OIRA review is the delay that results from layering on analytic requirements that agencies must satisfy to meet

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[13] *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983); 796 F.2d 1479 (D.C. Cir. 1986); 823 F.2d 626 (D.C. Cir. 1987) (decisions requiring OSHA to regulate ethylene oxide, a potent carcinogen and teratogen).

[14] OIRA's meddling in the tire pressure rule is recounted in *Public Citizen v. Mineta,* 340 F.3d 39 (2d Cir. 2003). For a more recent, but equally troubling, example of OIRA's improper meddling, see *Public Citizen v. FMCSA*, 374 F.3d 1209 (D.C. Cir. 2004) (setting aside on safety grounds a rule *extending* the hours truck drivers may drive after OIRA intervened on behalf of trucking companies to reverse the agency's proposed rule *reducing* the hours).

[15] See *Public Citizen Health Research Group v. Chao*, 314 F.3d 143 (3d Cir. 2002); 145 F.3d 120 (3d Cir. 1998)(describing pace of hexavalent chromium rulemaking).

the requirements of the Executive Order. Gathering the data for and then preparing the elaborate cost benefit and regulatory analyses the Order requires consumes extensive agency resources — both time and money — and both are in short supply. Steps must be taken to reduce this wasteful expenditure of scarce agency resources.

4. There is also the problem of transparency. I recognize that the Clinton Executive Order made significant strides in open the OIRA review process to public scrutiny. But the procedures set forth in the Clinton Order can still be evaded by OIRA-agency discussions at the preliminary stages of the regulatory process. And the Executive Order explicitly keeps out of public view materials exchanged by the agency and OIRA, leaving a gaping hole in the public record. To be sure, the President has a right to engage in confidential conversations with Executive Branch officials. But that right is limited by the obligation, in the course of a rulemaking governed by the Administrative Procedure Act, to engage in off-the-record communications that often lead the agency to alter its position on matters of public importance. It is time to make the OIRA review process fully transparent.

2. Recommended Reforms:

As noted above, the Executive Order should be revised in the following ways:

A. To end mandatory review of agency rules simply because they might impose significant annual costs. OIRA should review, at most, a handful of regulations annually, and those regulations ought to be selected by OIRA, in consultation with the agencies, because of the clear-cut importance of the rule to our nation's economy or because the rule raises important policy considerations that cut across many Executive Branch agencies. At a minimum, the longstanding $100 million in annual cost yardstick should be scrapped. Apart from the fact that it has always been an artificial metric, there is often no correlation between the costs imposed by a rule and the novelty or complexity of the issues posed by the rule. Moreover, the $100 million figure is objectionable for purely symbolic reasons that should be repudiated by this Administration: It underscores the Executive Order's single-minded focus on *costs* rather than benefits. It may be that a rule is significant if it yields *benefits* in excess of that amount. Given that the avowed purpose of the Executive Order is to ensure rationality in the administrative process, the use of a wholly arbitrary metric based solely on costs to select rules to review undermines that notion.

B. To state explicitly that OIRA has no authority to displace decisional authority assigned to the agency by Congress and its role is to advise agencies on how to make regulation more effective and efficient. This reform is needed in order to distance the Obama Administration from the unitary executive theory that underlies the justification for the Executive Order articulated in the Reagan Administration and never renounced by following Administrations.

C. (i) To make clear that where an agency is seeking to promulgate a rule under a statute that forbids using cost benefit analysis as a decisional criteria — as does, for instance, the health standards provision of the OSH Act — the agency will not be required to (or even "encouraged" to) prepare a cost benefit analysis. Time and again, health and safety rules have been weakened for impermissible cost benefit reasons, largely at OIRA's insistence. It is time for this practice to come to an end;

(ii) To make clear that where the agency is seeking to promulgate a rule under a statute that places preeminent value on health or safety, and does not expressly contemplate the consideration of costs, the agency will not be required by OIRA to prepare a cost benefit analysis. It may be that some variant on cost effectiveness analysis — such as that employed in response to the D.C. Circuit's decision in the lockout/tagout case — may be encouraged, so long as there is some reasonable limit on the lengths an agency may be forced to go to demonstrate that the regulatory choices it has made is, in fact, cost effective;

(iii) To make clear that cost benefit analysis may be required only in instances where the agency is developing a rule under a statute that explicitly obligates the agency to consider costs as a decisional criteria;.

(iv) To direct OIRA to undertake a review of the current methodology for cost benefit analysis to determine why these analyses systematically overestimate the cost of regulation and underestimate (or omit altogether) the benefits of regulation. OIRA should also be directed to revise its practice of heavily discounting the benefits in health rules to health and safety rules, especially where discounting is used to block needed protections that will benefit future generations.

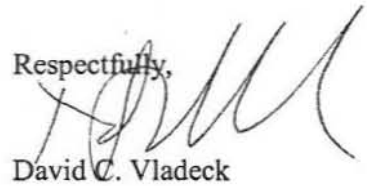
D. To accelerate, not further ossify, the regulatory process.

E. To make explicit that OIRA shall not second-guess an agency on technical, scientific or engineering matters within the agency's expertise.

F. To make the OIRA review process transparent and accountable by requiring that all communications between OIRA and an agency during the course of OIRA review of an agency rule should be documented and placed in the agency's rulemaking record no later that the publication of the final agency rule.

Please let me know if you have questions. I can be reached at

Respectfully,



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