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Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I and Part II: Hearing Before the H. Comm. on Science and Technology, 110th Cong., Feb. 13, 2007 (Statement of Professor David C. Vladeck, Geo. U. L. Center)

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Hearing: OMB and Guidance to Agencies

February 13, 2007

U.S. House Committee on Science; Subcommittee on Investigation and Oversight

Mr. Chairman and Members of the Science and Technology Committee, thank you for inviting me to be here today to share with you my views about the January 18, 2007 revisions to Executive Order 12,866, which are set forth in Executive Order 13,422, 72 Fed. Reg. 2763 (January 23, 2007). I am the Director of the Institute for Public Representation and an Associate Professor of Law at Georgetown University Law Center. Prior to joining Georgetown's law faculty, I spent nearly thirty years at Public Citizen Litigation Group, serving as its director from 1992 through 2002. I have practiced extensively in the area of administrative law, served as a Public Member of the Administrative Conference of the United States, the Chair of the D.C. Bar Association's Section on Administrative Law, on the Council of the American Bar Association's Section on Administrative Law and Agency Practice, testified on many occasions before congressional committees on administrative law issues including issues concerning the constitutionality and wisdom of centralized regulatory review and I write in the field of administrative law. I also serve as a Scholar with the Center for Progressive Reform.

My testimony today will explain why Executive Order 13,422 represents an important chapter in the Executive Branch's longstanding effort to wrest control over administrative agencies from Congress, and certainly the most important measure taken by President Bush. To put the new Order in context, I will begin by briefly describing the problems brought about by Executive Order 12,866 and its predecessor, Executive Order 12,291, and explain why centralized regulatory review has seriously impaired the ability of federal agencies to provide needed safeguards to the American people.

I will then turn to Executive Order 13,422 and address why it marks a further and substantial erosion of Congress' role in the administrative process and deals a body blow to the ability of our agencies to do their jobs. Here I make a number of points about Executive Order

--The Executive Order Usurps Congressional Authority By Directing Agencies to Justify

Regulatory Actions on the Basis of Market Failure. Under our system of separated powers, it is Congress, not the Executive, that sets the substantive standards that guide agencies in the performance of their delegated tasks. Executive Order 13,422 disrespects this structural limit in the Constitution. It requires agencies, as a precondition to taking any regulatory action at all, to justify their proposed action on the basis of "market failure." And "significant" agency guidance may not be issued until the agency obtains clearance from the Office of Regulatory Affairs (OIRA) of the Office of Management and Budget (OMB). The "market failure" supermandate appears nowhere in statute. It is not in keeping with the decisional criteria that Congress has established, and it cannot be reconciled with the dominant thrust of the health and safety statutes, which are designed to prevent deaths and injuries by avoiding market failure, rather than waiting until it is too late and market failure is evident.

--The Executive Order Unwisely Expands OIRA's Authority to Guidance Documents. Whatever the wisdom of centralized OIRA review of binding agency rules, the same arguments do not extend to centralized review of non-binding agency guidance. Hundreds of guidance documents are issued each year, often in response to emergencies or other timesensitive developments. Requiring agencies to stop dead in their tracks to justify the provision of guidance on "market failure" grounds cannot be defended on policy grounds; nor can giving OIRA the authority to meddle in the substance of significant agency guidance.

--The Executive Order Resurrects the Discredited Concept of a Regulatory Budget. Amended section 4(c)(1)(B) forbids any agency even the so-called "independent" agencies from commencing any rule-making unless the agency's regulatory plan sets forth, among other things, "the agency's best estimate of the combined aggregated costs and benefits of all its regulations planned for that calendar year." These estimates give OIRA the ability to effectively cap the amount of compliance costs an agency may impose in a calendar year, a power OIRA has long coveted. Nothing in the statutes Congress has enacted give OIRA the right to ration the protection to be provided to the American people through regulation.

--The Executive Order Further Politicizes the Regulatory Process. Executive Order 13,422 requires each agency "to designate one of the agency's Presidential Appointees" to serve as the agency's regulatory policy officer. At the same time, the Order greatly expands the duties of the policy officer, providing that, "[u]nless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the [agency's annual regulatory] Plan without the approval" of the policy officer. Nothing in the Order suggests that the political appointee must also be subject to Senate confirmation. This is a troubling, and no doubt deliberate, omission. The statutes Congress enacts to delegate power to agencies designate the agency head and not a subordinate as the decision-maker. Congress does this to ensure that decisions are made by an official accountable to Congress as well as the President. The amended Executive Order undermines Congress' designation of the agency head as the decision-maker by requiring that a

political employee accountable to the President but not necessarily to Congress be given control over an agency's regulatory output. That, to me, is quite a disturbing development and one that should not be accomplished by Executive fiat, but, if at all, by legislation.

To understand the significance of Executive Order 13,422, it is useful to quickly sketch the development of the Executive Order on regulatory review and what it requires.¹ 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."² 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.

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. During 1982-83, the House held no fewer than seven hearings to examine health and safety rules seriously delayed or weakened by OIRA.⁴ 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.

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.⁶ 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. The plans had to be personally approved by agency heads.

Even with the adjustments made by President Clinton, 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 flunk. 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 move on. There are several reasons for my conclusion.

To begin with, centralized review is 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 required protections. See generally Frank Ackerman & Lisa Heinzerling, *8 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).

OIRA's insistence that agencies do less, not more, stems from its singular focus on "least net cost options" or, in other words, minimizing regulatory compliance costs. The Executive Order requires agencies to perform cost-benefit analysis, which many experts claim is inherently anti-regulatory.⁸ 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. In each case, OIRA was an obstacle to the agency's action. Part of OIRA's objection was its unwillingness to place any 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.

There is also the problem of competence. The next car you buy is almost certain to have a gauge

on the dashboard to warn you 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.

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.¹¹ 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, and my friend and co-panelist Sally Katzen, some efforts were undertaken to address them. But Executive Order 13,422 makes a bad situation worse. Let me now address how Executive Order 13,422 is a significant step backwards, and an affront to the power of Congress.

PRINCIPAL DEFECTS IN EXECUTIVE ORDER 13,422

As noted above, although packaged as an innocuous and minor amendment to Executive Order 12,866, the new Executive Order takes a number of dramatic and important steps in the wrong direction. The principal ones are these:

1. The Amendments Impose a "Super-Mandate" That Supersedes Legislation and Needlessly Burdens Already Overburdened Agencies.

The amendments to the Executive Order give OIRA a powerful new tool to block agency action. Before moving forward with any regulatory action, an agency must determine in writing that the action the agency wants to take or guidance the agency wants to provide is warranted by "market failure." There are several problems with the imposition of this mandate.

First, it serves to undermine the criteria that Congress has established for agency action. Under

our system of separated powers, it is Congress, not the Executive, that sets the substantive standards that guide agencies in the performance of their delegated tasks. Executive Order 13,422 is at odds with this rule. No statute requires an agency to consider "market failure" as a precondition to taking action. Nor is the consideration of market failure in keeping with the decisional criteria that Congress has established which generally focus on health, safety, and the protection of our environment and natural resources. Indeed, the elevation of "market failure" as a key determinant for agency action cannot be reconciled with the fundamental goal of the health and safety statutes, which is to prevent deaths and injuries by avoiding market failure, rather than waiting until it is too late and market failure is evident.

Second, the mandate adds a burden that will sap the resources of already overburdened agencies. To take any regulatory action at all, agencies will have to consider "market failure" and write a justification of the action it seeks to take on that basis. And for "significant" agency action including "significant" non-binding agency guidance documents agencies will have to demonstrate to OIRA's satisfaction that the failure of market forces warrants the action the agency seeks to undertake. Giving OIRA another tool to block agency initiatives is unwise; Ms. Dudley's writings are explored in depth in a report by Public Citizen and OMB Watch entitled *The Cost is Too High: How Susan Dudley Threatens Public Health Protections* (Sept. 2006) (available at <http://www.citizen.org/publications/release.cfm?ID=7448&secID=2565&catID=126>).

There is a related problem as well. Where agencies propose to take regulatory action, the Executive Order already requires agencies to conduct a rigorous cost/benefit analysis as part of the Regulatory Impact Analysis it must provide to OIRA. Now the amended Executive Order requires a market failure analysis as well. The Executive Branch apparently takes the view that it can continue to pile on analytical requirements on overtaxed regulatory agencies without limit and without Congress' approval. Make no mistake; each of these analytical requirements consumes scarce resources that agencies could use to carry out the instructions given to them by Congress. At some point if indeed that point has not already been reached the requirements imposed by Executive Order will crowd out those imposed by statute.

Third, and perhaps most problematic, while there is a modest effort in the Executive Order to define "market failure" (e.g., "externalities, market power, lack of information"), market failure is in the eye of the beholder. There is no commonly-accepted definition of the term, and, as a result, much will then depend on the definition OIRA's staff gives to the term market failure. This concern takes on special force when one considers the views of Susan E. Dudley, President Bush's nominee to head OIRA. Ms. Dudley's writings suggest that she believes markets almost never fail, and that government intervention is therefore rarely if ever appropriate. For instance, Ms. Dudley was virtually alone in opposing NHTSA's recent advanced air-bag rule. She did so on the ground that, in her view, there was no evidence of market failure, and therefore NHTSA's

"attempt[] to make all vehicles equally safe for occupants" was unwarranted.¹⁴ Ms. Dudley sees little room for government intervention in the market, even for protective health and safety regulation. Ms. Dudley's restrictive understanding of market failure raises serious questions. If Ms. Dudley saw no evidence of market failure with air bags where the evidence of continual market failure is overwhelming would she have insisted on clearer evidence of market failure before she let the EPA order the phase-out of lead in gasoline, the Consumer Product Safety Commission ban the use of flammable material for children's sleep-wear, or the FDA require that iron pills the single largest cause of poisoning children in the United States be sold in child-proof containers? We ought not wait for "market failure" to exact a toll on human health and safety before we permit our agencies to act. In the health and safety context, the only way market failure becomes apparent is when the body count gets too high. The point of regulation is to prevent market failure, not to try to remedy it once the damage is done. The Executive Order subverts that fundamental principle.

2. The Amendments Inappropriately Expand OMB's Authority and Entrench Gridlock.

Whatever the wisdom of centralized OIRA review of binding agency rules, the same arguments do not extend to centralized review of non-binding guidance. Agencies provide guidance constantly, in literally hundreds of guidance documents or interpretative missives each year. Consider just one agency. The most recent listing of the titles of guidance documents used by the Food and Drug Administration was published in January 2005. It runs nearly ninety pages 15 70 Fed. Reg. 824-913 (Jan. 5, 2005); see also FDA Center for Drug Evaluation and Research List of Guidance Documents (Feb. 1, 2007) (33-page document setting forth currently in force guidance documents) (available at <http://www.fda.gov/cder/guidance/CompList02_2007.pdf >). The CRS Report cited above, supra n.1, notes that the Occupational Safety and Health Administration reported in 2000 that it had issued 3,374 guidance documents since March 1996, thus averaging around 1,000 guidance documents a year. CRS Report at 10, n.22.

Agencies often use guidance documents to help industry meet regulatory obligations in time-sensitive or emergency situations. For example, OSHA's most recent guidance document provides employers with advice about how to address an influenza pandemic,¹⁶ one of the FDA's most recent guidance documents advises clinical laboratories on how to address public health problems that resulted from the failure of certain laboratories to properly conduct tests on human donors, and one of the EPA's most recent guidance documents provides advice to manufacturers of antimicrobial agents on how to properly test and register their products with the EPA.

Congress has long understood that, when it comes to the provision on guidance and advice, it is unwise to erect barriers between agencies and regulated entities and the public. Government must be accessible to those it regulates and to those who benefit from regulation.

For that reason, when Congress enacted the Administrative Procedure Act, it exempted guidance documents and interpretative pronouncements from all of the informal and formal rule-making requirements of the Act.

Executive Order 13,422 upsets Congress' judgment on that balance. Before issuing any guidance document, an agency must address in writing the question of "market failure" an analytic requirement that will delay the issuance of sorely needed guidance. The Executive Order is also highly prescriptive about the contents of guidance documents. Rather than permit agencies to retain flexibility and tailor guidance documents to their audiences, the Executive Order instructs agencies that every guidance document must (a) be based "on the best reasonably obtainable scientific, technical, economic, and other information;" (b) be compatible and not duplicative of guidance given by other agency; (c) be "simple and easy to understand;" and (e) be tailored "to impose the least burden on society, including individuals, businesses of different sizes, and other entities . . . taking into account, among other things, the costs of cumulative regulations."

Not only do "significant" guidance documents have to survive that gauntlet,²⁰ but also 2007). But aside from the indirect effects point, the definition is written in the disjunctive and it is easy to see how one could argue that virtually any guidance document that addresses broad public health questions, such as OSHA's guidance on pandemic influenza or the EPA's guidance on antimicrobial agents, might be said to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety." Thus, it is difficult to tell what guidance documents might be deemed "significant." It could be that hundreds or thousands of guidance documents each year would qualify under this potentially sweeping definition a concern heightened because OIRA, not the agency, will have the final say on what constitutes a "significant" guidance document.

3. Rationing of Health and Safety Protection.

Executive Order 13,422 also sets the stage for the resurrection of the discredited concept of a "regulatory budget." Under the new Order, "no rulemaking may be commenced" unless it appears on the agency's Regulatory Plan and the agency sets forth "the agency's best estimate of the combined aggregated costs and benefits of all its regulations planned for that calendar year." These estimates give OIRA the ability effectively to cap the amount of compliance costs an agency may impose in a calendar year or set a "regulatory budget" a power OIRA has long coveted.

The goal of this amendment is quite clearly to limit industries' exposure to regulatory costs. OIRA could wield this tool regardless of whether the compliance costs will be absorbed by different industries, regardless of the benefits that flow from regulation, and regardless of the

mandates Congress has set for the agencies. If Congress believes it is appropriate to experiment with regulatory budgeting, that is one thing. It is quite another for the Executive Branch to arrogate that power to itself.

4. Further Politicization of the Regulatory Process.

Executive Order 13,422 breaks from past practice in another important respect: It requires each agency to designate a political appointee to head its regulatory policy office. In many agencies, the regulatory policy office has traditionally been headed by a career civil servant who is an expert in the arcane details of regulation.²⁴ But in all agencies, regulatory action is reviewed CRS Report raises serious constitutional questions that should be explored fully by Congress.

The amendments to the Executive Order, however, undermine the authority Congress has conferred on the agency head. This is a troubling development that Congress ought to care deeply about. The statutes Congress enacts to delegate decisional power to agencies explicitly designate the agency head and not a subordinate as the decision-maker. Congress is careful to designate the agency head to ensure that decisions are made by an official accountable to Congress as well as the President. To be sure, the President retains the power of appointment and removal, but Cabinet Secretaries and agency heads are presumed to have the power to decide questions independently, even at the risk of removal. Disputes between the White House and Cabinet officers and agency heads have emerged and, at times, the White House has relented. The amended Executive Order strips Congress' designation of much of its force by giving a different political appointee accountable to the President but not necessarily to Congress substantial control over the agency's regulatory output. This is not hyperbole. The Order expands the duties of the policy officer, providing that, "[u]nless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the [agency's annual regulatory] Plan without the approval" of the policy officer.²⁵ Under the new Order, the policy officer who has ties with and owes his allegiance to the White House will be the gatekeeper of the agency's regulatory output. As the New York Times put it, "[t]he White House will thus have a gatekeeper in each agency to analyze the costs and benefits of new rules and to ²⁶ Robert Pear, Bush Directive Increases Sway on Regulation, N.Y. Times, A1 (Jan. 30, 2007).

5. The Push to Formal Rulemaking.

Executive Order 13,422 amends section 6 of Executive Order 12,866 by adding the following: "In consultation with OIRA, each agency should also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations." To administrative law scholars, the suggestion that the White House is pushing agencies to undertake formal rulemaking under sections 556 and 557 of the Administrative Procedure Act is both stunning and stunningly ill- advised. To begin with, it betrays a

misunderstanding of administrative law to call sections 556 and 557 "rulemaking" provisions; they are not, they are "hearing" provisions. Rulemaking under the APA is generally governed by section 553, which calls for notice and comment rulemaking, not rulemaking based on a formal hearing. Sections 556 and 557 establish procedures for formal agency adjudicatory hearings (a) where adjudications are required under section 554 of the APA or (b) in those rare instances in which Congress has specified that an agency must hold a hearing as part of its rulemaking process. But agencies do not voluntarily hold hearings in rulemaking proceedings. Formal hearings are notoriously cumbersome, labor-intensive, and time-consuming and agencies have long sought to avoid them by any means possible a stratagem largely endorsed by the Courts.

Moreover, in the rare instances in which agencies engage in formal hearings under sections 556 and 557, the hearing is used to resolve matters of dispute between two parties, or among a small number of discrete parties such as a proceeding to confer a license on one of two or more competing parties. Unless mandated by Congress, formal hearings have not been used to establish regulatory policy or rules of general applicability for decades, and no one has advocated otherwise, until the issuance of Executive Order 13,422.

The inclusion of this provision in the Executive Order heightens concern about the purpose of the Order. As I have explained, one inevitable consequence of Executive Order 13,422 is that it will lead to the further ossification of an already overburdened administrative process. As an instrument of delay, formal rulemaking has no peer; it is the American version of Dickens' nightmarish *Jardynce v. Jardynce*. Empowering OIRA to push agencies to employ formal rulemaking to make complex determinations sends a disturbing signal, namely that delay and not resolution is the real goal.

CONCLUSION

Executive Order 13,422 constitutes an unprecedented consolidation of power over our regulatory agencies in the White House. It also constitutes an unprecedented assault on the ability of Congress to set the substantive standards that guide agencies in the performance of their delegated tasks. The consequences of this shift are far-reaching and tragic. Effective regulation is essential to our nation's well-being. For that reason, administrative agencies were created to bring expertise, independence, and transparency to the regulatory process. This Executive Order undermines those values. It gives a small group of generalists at OIRA the power to second-guess and undermine the expert and impartial judgments of the scientists, physicians, epidemiologists, engineers, and toxicologists who staff our health and safety agencies. It holds health and safety regulation hostage to economic considerations of market failure and cost/benefit analysis. It puts partisan politics at the center of our regulatory process by giving the White House substantial control over the day-to-day work of our agencies. And it undermines transparency by establishing an off-the-record process for OIRA review of significant guidance

documents.

Congress has acquiesced in this accretion of power to the President. I would urge that the time has come for Congress to consider reclaiming its authority. Thank you.