

Due Process and Management for Guidance Documents: Good Governance Long Overdue

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On January 18, 2007, President Bush signed amendments to clarify and strengthen Executive Order (E.O.) 12,866, which President Clinton had issued to update principles for inter-agency planning and review of regulations. The most important provisions of President Bush's E.O. 13,422 clearly extend inter-agency review to guidance documents. E.O. 13,422 was reinforced by a Bulletin for Agency Good Guidance Practices issued by the Office of Management and Budget (OMB).¹ Together, E.O. 13,422 and the OMB Bulletin establish the first government-wide "rules of the road" to manage the development and use of guidance documents.

OMB now has clear authority to review significant agency guidance documents, just as OMB reviews significant agency regulations. The agencies, in turn, are required to give OMB advance notice of their upcoming significant guidance documents. OMB will be responsible for ensuring that other interested agencies occasionally have notice and an opportunity to provide input into the most important guidance documents.

In the view of the authors, the outcry that followed the issuance of the Order and Bulletin was remarkable and unwarranted.² On one hand, the two most controversial provisions in E.O. 13,422 (which are irrelevant to guidance documents) were edits to authorities already provided by the Clinton Order—edits that were unnecessary and unlikely to practically affect regulatory policy de-

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¹ Under the OMB Bulletin, agencies first must implement procedures for the approval and use of significant guidance documents by appropriate senior officials. Second, significant guidance documents must have standard elements. Agencies are directed to avoid inappropriate mandatory language in guidance documents. Finally, the Bulletin establishes public access and feedback procedures. See Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007). For the Order, see Exec. Order No. 13,422, 72 Fed. Reg. 2763, 2765 (Jan. 23, 2007).

² See, e.g., Paul Krugman, *The Green-Zoning of America*, N.Y. TIMES, Feb. 5, 2007, at A21; Robert Pear, *Bush Directive Increases Sway on Regulation*, N.Y. TIMES, Jan. 30, 2007, at A1; Cindy Skryzcki, *Bush Order Limits Agencies' "Guidance,"* WASH. POST, Jan. 30, 2007, at D1.

velopment.³ On the other hand, extending the existing regulatory review process to significant guidance documents is a beneficial and essential change—the most important change to the regulatory review process since President Reagan formalized it in 1981. This Essay briefly reviews the evolution of E.O. 13,422 and the OMB Bulletin and argues that their good guidance provisions were firmly supported by precedent and long overdue.

I. Background

President Reagan's Executive Order 12,291, which firmly established OMB regulatory review, covered virtually all rules.⁴ E.O. 12,291 defined its scope by incorporating most of the definition of "rule" from the Administrative Procedure Act, which includes not only legally binding legislative rules ("regulations"), but also interpretive rules and policy statements ("guidance documents").⁵ In theory, OMB's authority under the Reagan Order was strikingly broad on two levels: First, it did not establish a "significance" threshold for OMB review. Second, the Order did not limit OMB review of guidance documents.

In practice, too, the breadth of OMB's authority was unwieldy. Each year, agencies issue on the order of 4000 regulations,⁶ and the number of guidance documents is orders of magnitude larger.⁷ With several dozen staff, OMB's Office of Information and Regulatory Affairs (OIRA) cannot hope to review more

3 The most-criticized features of E.O. 13,422, a provision on Regulatory Policy Officers and a provision on market failure analysis, were actually established by President Clinton's E.O. 12,866. E.O. 13,422 only made minor modifications to those provisions, and those modifications have little practical significance. See *Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I: Hearing Before the Subcomm. on Commerce & Admin. Law, of the H. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Paul R. Noe, Partner, C&M Capitolink LLC), available at <http://judiciary.house.gov/media/pdfs/Noe070213.pdf>. Others have staunchly disagreed, and some have gone so far as to claim that the provision on Regulatory Policy Officers is unconstitutional. *Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I: Hearing Before the Subcomm. on Commerce & Admin. Law of the H. Comm. on the Judiciary*, 110th Cong. (2007) (statement of Peter L. Strauss, Professor, Columbia University School of Law), available at <http://judiciary.house.gov/media/pdfs/Strauss070213.pdf>.

4 See Administrative Procedure Act, 5 U.S.C. § 551(4) (2000).

5 See Exec. Order No. 12,291, 3 C.F.R. 127, 127 (1981) ("Regulation" or 'rule' means an agency statement of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the procedure or practice requirements of an agency . . .").

6 See, e.g., Office of Mgmt. & Budget, Office of Info. & Regulatory Affairs, Report to Congress on the Costs and Benefits of Federal Regulations (1997), <http://www.whitehouse.gov/omb/inforeg/rocongess.html> (last visited Dec. 14, 2007).

7 See, e.g., Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1469 (1992) (noting that the formally adopted rules of the Federal Aviation Administration are two inches thick, but the corresponding guidance materials, over forty feet; Part 50 of the Nuclear Regulatory Commission's regulations on nuclear plant safety, in loose-leaf edition, is 3/16 of an inch, but the supplemental technical guidance is 9 3/4 inches; and the formally adopted regulations of the IRS occupy one foot of shelf space, but Revenue rulings and similar publications, about twenty feet); see also H. COMM. ON GOV'T. REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009 (2000) (noting that between March 1996 through 1999, NHTSA had issued 1225 guidance documents, EPA 2653, and OSHA 1641).

than a small fraction of these rules. Our understanding is that during the Reagan and G.H.W. Bush years, OMB rarely called in guidance documents for review and did not have an established practice for doing so. However, OIRA did routinely review large numbers of legislative rules in its early years.⁸

In 1993, President Clinton replaced the Reagan Order with E.O. 12,866, which limited OIRA review to “regulatory actions” that were “significant.” This was both wise and unwise. Given the vastness of federal regulatory activity and the limited resources of OIRA, it was eminently sensible to try to sort the significant agency activity from the insignificant. The problem is that while the Clinton Order applied to significant legally binding regulations, it neglected guidance documents. Indeed, while the Clinton Order is less than pellucid, it evidently curtailed the previous OMB authority over guidance documents.⁹ Former OIRA Administrator Sally Katzen has stated that “Executive Order 12,866 was written to apply *only* where agencies undertook regulatory actions that had the force and effect of law”¹⁰ and that she never reviewed a guidance document during her tenure in the Clinton administration. If that is the case, we believe that the Clinton Order was not only unclear but also fundamentally flawed.¹¹

II. The Foundation for Good Guidance Practices

There is a strong foundation for the good guidance practices reflected in the OMB Bulletin and E.O. 13,422. First and foremost, the Administrative

8 A cursory review of the record shows that OIRA reviewed a much greater number of rules under E.O. 12,291 during the Reagan and Bush-41 years than under E.O. 12,866 during the Clinton and Bush-43 years. For example, under E.O. 12,291, OIRA reviewed 2637 rules in 1982 (79 were economically significant) and in 1990 reviewed 2137 (82 were economically significant). By contrast, under E.O. 12,866, OIRA reviewed 831 rules in 1994 (134 were economically significant) and in 2002 reviewed 669 rules (100 were economically significant). See Office of Mgmt & Budget, Review Counts, <http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init> (last visited Dec. 14, 2007).

9 E.O. 12,866 applied to an “agency statement of general applicability and future effect, *which the agency intends to have the force and effect of law*, that is designed to implement, interpret or prescribe law or policy or to describe the procedure or practice requirements of an agency.” See Exec. Order No. 12,866, 3 C.F.R. 638, 641 (1993), *reprinted in* 5 U.S.C. § 601 (2000) (emphasis added).

10 *Amending Executive Order 12866: Good Governance or Regulatory Usurpation? Part I. Hearing Before the Subcomm on Investigation & Oversight of the H. Comm. on Sci. & Tech.*, 110th Cong. 9 (2007) (statement of Sally Katzen, Adjunct Professor, University of Michigan Law School), available at <http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/katzentestimony.pdf>.

11 The growth in so-called “spurious rule” court cases in the 1990s may not be a coincidence. See, e.g., *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (striking down PCB risk assessment guidance as a spurious rule requiring notice and comment); *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000) (striking down emissions monitoring guidance as spurious rule requiring notice and comment); *U.S. Chamber of Commerce v. Dep’t of Labor*, 174 F.3d 206 (D.C. Cir. 1999) (striking down OSHA Directive as a spurious rule requiring notice and comment). An interesting research project would be to compare the growth in “spurious rule” court cases with the abstention of OMB review of guidance documents. See also Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3435 (Jan. 25, 2007); Office of Mgmt. & Budget, Key to Public Comments, <http://www.whitehouse.gov/omb/inforeg/keycomments.html> (last visited Dec. 14, 2007).

Conference of the United States (ACUS)¹² issued recommendations for the development and use of agency guidance documents.¹³ As far back as the mid-1970s, for example, ACUS recognized the importance of ensuring a notice and comment process for the most significant guidance documents.

ACUS Recommendation 76-5 states:

Before an agency issues, amends or repeals an interpretive rule of general applicability or statement of general policy which is likely to have a substantial impact on the public, the agency normally should utilize the procedures set forth in the Administrative Procedure Act subsections 553(b) and (c) Where there has been no prepromulgation notice and opportunity for comment, the publication of an interpretive rule of general applicability or a statement of general policy . . . should include . . . an invitation to interested persons to submit written comments.¹⁴

ACUS Recommendation 92-2 later added:

Agencies should not issue statements of general applicability that are intended to impose binding substantive standards or obligations upon affected persons without using legislative rulemaking procedures Policy statements of general applicability should make clear that they are not binding. . . . Agencies that issue policy statements should examine, and where necessary, change their . . . procedures . . . to allow as an additional subject requests for modification or reconsideration of such statements.¹⁵

In 1993, the American Bar Association (ABA) reaffirmed the ACUS recommendations on the use of informal notice and comment procedure for significant guidance documents.¹⁶ In 2001, the ABA further recommended that agencies “explore means to maximize the availability and searchability of existing law and policy on their websites” and include “their governing statutes, all

12 ACUS was a federal advisory agency charged with providing recommendations on administrative procedure issues. During its existence from 1986 to 1995, ACUS made over 300 recommendations on administrative procedure issues, and over 200 were adopted by agencies or by Congress. See Florida State University College of Law, ABA Administrative Procedure Database, www.law.fsu.edu/library/admin/acus/acustoc.html (last visited Dec. 14, 2007).

13 See Recommendations of the Administrative Conference of the United States, Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305922.html>; AM. BAR ASS'N, ANNUAL REPORT INCLUDING PROCEEDINGS OF THE FIFTY-EIGHTH ANNUAL MEETING 57 (1993) (“[T]he American Bar Association recommends that: Before an agency adopts a nonlegislative rule that is likely to have a significant impact on the public, the agency provide an opportunity for members of the public to comment on the proposed rule and to recommend alternative policies or interpretations, provided that it is practical to do so; when nonlegislative rules are adopted without prior public participation, immediately following adoption, the agency afford the public an opportunity for post-adoption comment and give notice of this opportunity.”).

14 Recommendations of the Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy, Rec. 76-5, 1 C.F.R. § 305.76-5 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305765.html>.

15 Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2.

16 AM. BAR ASS'N, *supra* note 13.

agency rules and regulations, and all important policies, interpretations, and other like matters which members of the public are likely to request.”¹⁷

In 1997, the Food and Drug Administration (FDA) created a guidance document distilling its good guidance practices (GGP).¹⁸ Following the FDA’s publication of its original GGP, Congress then mandated by law certain aspects of the 1997 GGP document in the Food and Drug Administration Modernization Act of 1997 (FDAMA).¹⁹ In FDAMA, Congress detailed basic elements of good guidance practices and required the FDA to issue new GGP as regulations.²⁰

In the legislative history of FDAMA, Congress expressed particular concern about public knowledge of, and access to, FDA guidance documents; the lack of a systematic process for adopting guidance documents and for allowing public input; and inconsistency in the use of guidance documents.²¹ Recognizing that those same concerns apply to other agencies as well, OMB used the FDA regulations mandated by Congress as a model for its government-wide Good Guidance Practices.²²

Finally, though ACUS and the ABA do not have formal positions specifically addressing OMB review of guidance documents, they produced long-standing recommendations supporting presidential oversight of rulemaking as an essential element of good government.²³

In sum, the good guidance provisions of E.O. 13,422 and the OMB Bulletin are firmly rooted in the recommendations of leading authorities that have stood for decades. If anything, the Order and Bulletin modestly implement

17 AM. BAR ASS’N, RECOMMENDATION ON FEDERAL AGENCY WEB PAGES 1 (2001), <http://www.abanet.org/adminlaw/federal02.pdf>.

18 The Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997).

19 21 U.S.C. § 371(h) (2000).

20 *Id.* (establishing FDA good guidance practices as law). The FDAMA also directed the FDA to evaluate the effectiveness of the 1997 GGP document and then to develop and issue the regulations specifying the FDA’s policies and procedures for the development, issuance and use of guidance documents. The FDA conducted an internal evaluation soliciting FDA employees’ views on the effectiveness of GGP and asking whether FDA employees had received complaints regarding the agency’s development, issuance and use of guidance documents since the development of GGP. FDA found that its GGP had been beneficial and effective in standardizing the agency’s procedures for development, issuance and use of guidance documents, and that FDA employees had generally been following GGP. The FDA then made some changes to its existing procedures to clarify its GGP. *See Administrative Practices and Procedures: Good Guidance Practices*, 21 C.F.R. § 10.115 (2007).

21 FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997, S. REP. NO. 105-43, at 26 (1997).

22 *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432, 3432 (Jan. 25, 2007).

23 *See* Recommendations of the Administrative Conference of the United States, Presidential Review of Agency Rulemaking, Rec. 88-9, 1 C.F.R. § 305.88-9 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305889.html> (“Presidential review should apply generally to federal rulemaking.”); AM. BAR ASS’N, SECTION OF ADMIN. LAW & REGULATORY PRACTICE, REPORT TO THE HOUSE OF DELEGATES, RECOMMENDATION ON PRESIDENTIAL REVIEW OF RULEMAKING 1 (1990) (same); AM. BAR ASS’N, SECTION OF ADMIN. LAW, REPORT TO THE HOUSE OF DELEGATES, EXECUTIVE OVERSIGHT 1 (1986) (same).

those recommendations. For example, E.O. 13,422 established a more streamlined review process for guidance documents than used for regulations. Likewise, the OMB Bulletin requires pre-adoption notice and comment only for potentially “economically significant” guidance, whereas the FDA, as well as ACUS and the ABA, would do so for all significant guidance.²⁴

III. The Need for Good Guidance Practices

We support prioritizing regulatory review based on significance as President Clinton’s E.O. 12,866 did, but we have no doubt that guidance documents can be quite significant and have been neglected.

Although guidance documents may not properly carry the force of law, they are a key component of regulatory programs. As the breadth and complexity of regulatory programs has grown, agencies increasingly have relied on guidance documents to provide direction to their staff and to the public. That direction is essential to operating regulatory programs.

Nonetheless, concerns have persisted over the years about agency guidance practices. On one level, there are basic concerns about due process and fairness—the need for greater transparency, opportunity for comment, and accountability in issuing guidance. There also have been concerns about the need for coordination and management of guidance documents so they are coherent within and across agency programs and do not conflict with the priorities of the President. Finally, there is growing concern that guidance documents often are being used in lieu of regulations—without observing the procedural safeguards for regulations. As the D.C. Circuit observed:

The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in regulations. One guidance document may yield another and then another and so on. . . . Law is made, without

24 See FDA Good Guidance Practices, 21 C.F.R. § 10.115(g) (2007) (pre-adoption notice and comment for “Level 1” guidance documents); Recommendations of the Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy, Rec. 76-5, 1 C.F.R. § 305.76 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305765.html> (pre-adoption notice and comment for nonlegislative rules “likely to have a substantial impact”); AM. BAR ASS’N, ANNUAL REPORT INCLUDING PROCEEDINGS OF THE FIFTY-EIGHTH ANNUAL MEETING 57 (1993) (same). While the OMB did not go so far as to mandate pre-adoption notice and comment for all significant guidance, the OMB encouraged it. As it stated in the preamble to its Bulletin:

Although this Bulletin does not require agencies to provide notice and an opportunity for public comment on all significant guidance documents before they are adopted, it is often beneficial for an agency to do so when they determine that it is practical. Pre-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial.

72 Fed. Reg. at 3438. Perhaps in the future after the Bulletin has been successfully implemented, its scope could be expanded consistent with this precedent.

notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.²⁵

It should be noted that whether or not guidance documents are “spurious rules”²⁶ subject to legal challenge, as a practical matter guidance can have coercive effects or lead parties to alter their conduct. As OMB explained in the preamble to the Bulletin:

For example, under a statute or regulation that would allow a range of actions to be eligible for a permit or other desired agency action, a guidance document might specify fast track treatment for a particular narrow form of behavior but subject other behavior to a burdensome application process with an uncertain likelihood of success. Even if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact. Similarly, an agency might make a pronouncement about the conditions under which it believes a particular substance or product is unsafe. While not legally binding, such a statement could be reasonably anticipated to lead to changes in behavior by the private sector or governmental authorities such that it would lead to a significant economic effect.²⁷

Because such impacts—while perhaps more remote and attenuated—can be as significant as the impacts of regulations, it is reasonable that the Bulletin establishes a presumption of pre-adoption notice and comment for “economically significant” guidance and that E.O. 13,422 facilitates interagency review of significant guidance.

Prior to the issuance of E.O. 13,422 and the Bulletin on Good Guidance Practices, OMB had received scores of examples of problematic guidance and agency practices in response to its 2002 request for comments on problematic guidance,²⁸ other requests for regulatory reform nominations,²⁹ and the public comments on the proposed Bulletin.³⁰ The supporters of good guidance practices were as diverse as the Ornithological Council, homebuilders, funeral directors, the farming community, large and small business, educational organizations, and state and local government.

25 *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (striking down emissions monitoring guidance as requiring notice and comment through legislative rulemaking procedures).

26 *See supra* note 11.

27 *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. at 3435.

28 Office of Mgmt. & Budget, Key to Public Comments, http://www.whitehouse.gov/omb/inforeg/key_comments.html (last visited Dec. 14, 2007).

29 Office of Mgmt & Budget, Peer Review and Public Comments on the 2005 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, http://www.whitehouse.gov/omb/inforeg/2005_cb/toc.html (last visited Dec. 14, 2007); Office of Mgmt & Budget, Public Comments on 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, http://www.whitehouse.gov/omb/inforeg/2004cb/list_2004cb.html (last visited Dec. 14, 2007).

30 Office of Mgmt & Budget, Comments on Proposed Bulletin on Good Guidance Practices, http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html (last visited Dec. 14, 2007).

As OMB detailed in the preamble to the Bulletin, such concerns have been raised for years by many authorities, including Congress,³¹ the courts,³² the Executive Branch,³³ the ABA,³⁴ scholars,³⁵ and the regulated community.³⁶

In July 2007, after a rider to block funding for implementation of E.O. 13,422 was attached to a House appropriations bill, the regulated community swiftly reacted to oppose a similar Senate provision. Sixty-four trade associations representing most of the American economy opposed the rider, including big and small business, agriculture, education and other interests.³⁷ The primary motivation evidently was to preserve the good guidance practices reflected in the Order and Bulletin.³⁸ In addition, the Director of OMB sent a let-

31 See, e.g., Congressional Review Act of 1996, 5 U.S.C. §§ 801-808 (2000) (providing fast-track procedures for Congressional resolutions of disapproval of rules and incorporating the APA definition of "rule"); Food and Drug Administration Modernization Act of 1997, 21 U.S.C. § 371(h) (2000) (establishing FDA good guidance practices as law); Congressional Accountability for Regulatory Information Act, H.R. 3521, 106th Cong. § 4 (2000) (proposing to require agencies to notify the public of the non-binding effect of guidance documents), H. COMM. ON GOVERNMENT REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009 (2000) (criticizing "backdoor" regulation); FOOD AND DRUG ADMINISTRATION MODERNIZATION AND ACCOUNTABILITY ACT OF 1997, S. REP. NO. 105-43, at 26 (1997) (raising concerns about the lack of transparency and consistency in the use of guidance documents).

32 See *supra* note 11.

33 Recommendations of the Administrative Conference of the United States, Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305922.html> (stating that agencies should afford the public a fair opportunity to challenge the legality or wisdom of policy statements and to suggest alternative choices); Recommendations of the Administrative Conference of the United States, Interpretive Rules of General Applicability and Statements of General Policy, Rec. 76-5, 1 C.F.R. § 305.76 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305765.html> (stating that agencies should utilize APA notice and comment procedures for interpretive rules of general applicability or statements of general policy likely to have a substantial impact on the public); The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997) (notice) (establishing FDA's original good guidance practices); Draft Report to Congress on the Costs and Benefits of Federal Regulations, 67 Fed. Reg. 15,014, 15,034-35 (Office of Mgmt. & Budget Mar. 28, 2002) (detailing concerns over soliciting public comments on problematic agency guidance practices and specific examples of guidance documents in need of reform).

34 AM. BAR ASS'N, ANNUAL REPORT INCLUDING PROCEEDINGS OF THE FIFTY-EIGHTH ANNUAL MEETING 57 (1993) (recommending notice and comment for guidance documents likely to have a significant impact on the public); AM. BAR ASS'N, *supra* note 17 (recommending that agencies post on their Websites, *inter alia*, all important policies and interpretations).

35 See, e.g., Robert A. Anthony, "Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: *Lifting the Smog*, 8 ADMIN. L.J. 1 (1994); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals and the Like—Should Federal Agencies Use Them to Bind the Public?* 41 DUKE L.J. 1311 (1992).

36 One of the more notorious examples of problematic agency guidance during the Clinton administration was an OSHA advisory letter instructing a company stating that employers were liable for ensuring that the home offices of their employees were in compliance with OSHA workplace regulations. See *OSHA Policy Concerning Employees Working at Home: Hearing Before the Subcomm. on Oversight & Investigations of the H Comm. on Educ. & the Workforce*, 106th Cong. (2000), available at <http://commdocs.house.gov/committees/edu/hedo&i6-81.000/hedo&i6-81.htm>.

37 Letter from sixty-four trade associations to The Honorable Robert C. Byrd, Chairman, Comm. on Appropriations, and The Honorable Thad Cochran, Ranking Member, Comm. on Appropriations (July 12, 2007) (on file with the author).

38 See Cindy Skryzcki, *Congress Balks at White House Rulemaking Order*, WASH. POST, July 17, 2007, at D2.

ter to the appropriators threatening a veto recommendation for any provision that would prohibit funding or restrict implementation of E.O. 13,422.³⁹

The rider was dropped before the Senate appropriations committee markup, but the rider still had strong support.⁴⁰ Following a debate on the Order and Bulletin at the annual meeting of the ABA Section of Administrative Law and Regulatory Practice, the Section sent letters to Congress opposing defunding of the Bulletin and the good guidance provisions of the Order.⁴¹ Ultimately, the House rider was chopped from the final consolidated appropriations act.⁴²

In the day-to-day operations of the Executive Branch, there is a need for ground rules to address ignorance and confusion about what agencies are doing on important guidance documents. Likewise, there is a need to demarcate the authority and responsibilities of OMB and the agencies. E.O. 13,422 clarifies while streamlining the traditional review process. For guidance documents, the agencies need only provide OMB with an advance list of upcoming significant guidance (not the guidance itself, nor an economic analysis). OMB can call in for review only the small share of guidance documents that merit consideration by its limited staff and the other interested agencies. This avoids needless burdens on the agencies and OMB.

Finally, clear OMB authority over guidance documents is necessary to preserve OMB's authority over regulations. Otherwise, the dysfunction diagnosed by the D.C. Circuit in *Appalachian Power* could occur in the regulatory review process. An agency could issue "regulations containing broad language, open-ended phrases, ambiguous standards and the like."⁴³ Such skeletal regulation might pass through interagency review without raising concerns. However, the agency could then follow with guidance "expanding the commands in the regulations"⁴⁴ and so forth to a degree that would have raised concerns in the interagency review process—or in Congress—had the details appeared in the regulations from the start. Indeed, the dearth of clear OMB authority could explain how *Appalachian Power* occurred.

From that perspective, E.O. 13,422 can be viewed as part of a larger movement by the three constitutional branches of government—the Legisla-

39 Letter from Rob Portman, Director, Office of Mgmt. & Budget, to the Honorable Robert C. Byrd, Chairman, Comm. on Appropriations (July 12, 2007) (on file with the author).

40 See *Durbin Vows to Block Funds for White House Regulatory Review Order*, INSIDE EPA, Aug. 22, 2007 (on file with the Yale Journal on Regulation).

41 See Letter from Michael Asimow, Chair of the ABA Section of Administrative Law and Regulatory Practice, to Senators Richard Durbin and Sam Brownback (Nov. 8, 2007) (on file with the author). The letter does not take a position with respect to the controversial provisions of E.O. 13,422. See also *supra* note 3.

42 JOINT EXPLANATORY STATEMENT TO ACCOMPANY CONSOLIDATED APPROPRIATIONS AMENDMENT, FINANCIAL SERVICES AND GENERAL GOVERNMENT APPROPRIATIONS ACT, 2008, at 78, available at <http://www.rules.house.gov/110/text/omni/jes/jesdivd.pdf>.

43 *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1019 (D.C. Cir. 2000).

44 *Id.*

tive,⁴⁵ the Judicial,⁴⁶ and the Executive—to assert authority over the so-called “Fourth Branch of Government.”

IV. Conclusion

Controversy has been with us since the inception of centralized review of rules, and doubtless it will continue. Nonetheless, it is our hope that a close consideration of the relevant language and practical significance of E.O. 13,422 and the OMB Bulletin will mitigate those concerns. Formally extending the regulatory review process to guidance documents was much needed and long overdue.

45 Congress asserted direct supervisory power and “veto” authority over agency rules—both regulations and guidance documents—in the Congressional Review Act of 1996. *See* 5 U.S.C. § 804(3) (2000) (incorporating the APA’s definition of “rule”). As discussed above, in FDAMA Congress legislatively mandated FDA’s pre-existing good guidance practices. *See supra* notes 18-21 and accompanying text.

46 *See supra* notes 11 & 25 and accompanying text.