

COMMENT

NOT GOOD ENOUGH FOR GOVERNMENT WORK: HOW OMB’S GOOD GUIDANCE PRACTICES MAY UNINTENTIONALLY COMPLICATE ADMINISTRATIVE LAW

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INTRODUCTION

After receiving comments on its Proposed Bulletin for Good Guidance Practices issued on November 30, 2005, the Office of Management and Budget (OMB) published its Final Bulletin for Good Guidance Practices (Final Bulletin) on January 25, 2007.¹ OMB issued its Final Bulletin in response to the proliferation of guidance documents promulgated by federal agencies, and due to OMB's concern with their impact on private parties, a concern OMB has expressed since 2002.² At the same time that OMB issued its Final Bulletin, President Bush issued Executive Order 13,422, which amended Executive Order 12,866 on Regulatory Planning and Review, placing guidance documents under greater scrutiny by the White House.³ Although the Final Bulletin and Executive Order 13,422 touch on some of the same issues, discussion of the Executive Order is beyond the scope of this Comment.

Some characterize agency use of guidance documents to bind private parties as a backdoor way of regulating without having to undertake the necessary procedures reserved for binding rules.⁴ Indeed, agency treatment of guidance documents, especially guidance that is later determined to be "practically binding" on regulated entities, is subject to much criticism,⁵ despite Congress—via the Administrative Procedure Act (APA)—

1. See Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007) [hereinafter Final Bulletin] (acknowledging that guidance documents may be "poorly designed or improperly implemented" and therefore clear and consistent agency practices are needed); see also Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 71,866 (Nov. 30, 2005) (indicating that the draft bulletin defines guidance, describes the legal effect of guidance documents, and establishes practices for developing guidance documents and receiving public input). Note that although a "bulletin" is a substantive rulemaking document, it is generally considered a "policy statement" in administrative law and should have no binding legal effect. 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, 1315 (1992).

2. See Final Bulletin, 72 Fed. Reg. at 3432 (stating that "[a]s the impact of guidance documents on the public has grown, so too, has the need for good guidance practices").

3. See Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007) (addressing the potential need for interagency review of certain significant guidance documents by providing the Office of Management and Budget (OMB) authority to have advance notice of, and to review, agency guidance documents).

4. See H.R. REP. NO. 106-1009, at 1 (2000) (finding that "some guidance documents were intended to bypass the rulemaking process" and that "[s]uch 'backdoor' regulation is an abuse of power").

5. See Leslie M. MacRae & Kenneth E. Nicely, *Break the Rules and Run an Industry: Guidance Manuals More Destructive of the Rule of Law Than Bad Accounting*, 11 U. BALT. J. ENVTL. L. 1, 2 (2003) (noting that many agencies argue their policies bind regulated parties, but that these policies are adopted without following the Administrative Procedure Act's (APA) procedures for rulemaking); Anthony, *supra* note 1, at 1315 (suggesting that "[w]hile these nonlegislative rules by definition cannot *legally* bind, agencies often inappropriately issue them with the intent or effect of imposing a *practical* binding norm upon the regulated or benefited public").

differentiating a binding rule from a nonbinding issuance.⁶ Though not defined in the APA, “guidance” is a broad term that could include an interpretive rule or a general policy statement.⁷

This Comment examines whether OMB’s Final Bulletin mitigates the confusion regarding the legal status of guidance documents, both for private parties who are asked to adhere to the guidance, and for courts that must discern the legal efficacy of the guidance. Part I discusses the importance of guidance documents in administrative law and the resulting criticism and confusion surrounding their proliferation and misuse. Part II examines OMB’s Final Bulletin in greater detail. Part III evaluates the Final Bulletin with regard to how it comports with pertinent case law and explores how the Final Bulletin may lead to unintended consequences, both with respect to the legal effect of guidance documents and the type of judicial deference afforded them. Finally, Part IV recognizes the need for certain good guidance practices, but recommends that OMB reconsider allowing notice and comment prior to the issuance of guidance documents to mitigate the potential for unintended consequences.

I. BACKGROUND

A. *What is Guidance?*

While the term “guidance” is not defined in the APA and generally is viewed as a legally insignificant term,⁸ a guidance is a “substantive rulemaking document”⁹ and can take the form of a wide-range of issuances from federal agencies—such as memoranda, manuals, and circulars—and

6. See Administrative Procedure Act, 5 U.S.C. § 553(b), (c) (2000) (mandating that for a rule to be binding, a general notice of proposed rulemaking must be published in the Federal Register and that after such notice the agency must give interested persons an opportunity to submit written comments for agency consideration); *id.* § 553(b) (2000) (providing exemptions from the notice and comment procedures in certain situations, such as when an agency merely issues an interpretive rule or policy statement).

7. See Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 159 (2000) (recognizing that “guidance,” as a distinct legal category, is a new concept in American administrative law); see also Anthony, *supra* note 1, at 1315 (distinguishing guidances as “policy statements” pursuant to APA terminology). While Professor Anthony is able to easily characterize guidance as a policy statement under the APA, agencies and courts have had a difficult time determining whether a guidance document constitutes an interpretive rule or a policy statement. See *Syncor Int’l Corp. v. Shalala*, 127 F.3d 90, 93-94 (D.C. Cir. 1997) (suggesting that courts and litigants are prone to group interpretive rules and policy statements together in contrast to their treatment of substantive rules); RICHARD J. PIERCE, JR., 1 ADMINISTRATIVE LAW TREATISE § 7.10 (4th ed. 2002) (noting that characterizing a rule as exempt from notice and comment procedure is challenging because it is difficult to determine whether it is a statement of policy, an interpretative rule, or a rule of procedure).

8. See PIERCE, *supra* note 7, § 6.1 (explaining that labels such as “guidances,” “compliance policies,” “handbooks,” and “manuals” have no legal significance).

9. Anthony, *supra* note 1, at 1315.

most likely meets the definition of a policy statement under the APA.¹⁰ Guidance, therefore, plays an important role in federal administrative law.¹¹

A guidance has several possible uses. It may supply additional detail unreasonable to expect from senior agency officials,¹² or it may simply allow an agency to inform the public.¹³ Agency use of rulemaking is declining and, in its place, agencies increasingly are regulating through guidances and other nonlegislative rules.¹⁴ Numerous reasons for the extensive promulgation of guidance documents exist, including an agency desire to avoid “enhanced political accountability for policy decisions,”¹⁵ the “expensive and time-consuming procedures”¹⁶ Congress has imposed on the rulemaking process, and the desire to withstand judicial review that requires a “detailed” and “encyclopedic” statement of basis and purpose.¹⁷ Additionally, agencies often have little time to issue regulations.¹⁸ This reality is especially problematic given that issuing a rule pursuant to the APA’s notice and comment procedures consumes a great deal of an agency’s time and resources.¹⁹

10. *Id.*

11. *See* H.R. REP. NO. 106-1009, at 5 (2000) (discovering that the Occupational Health and Safety Administration (OSHA) issued 3,374 guidance documents between 1996 and 1999); RICHARD J. PIERCE, JR., 3 ADMINISTRATIVE LAW TREATISE § 17.3 (4th ed. 2002) (opining that a “quick inspection of the office of any senior agency employee or any private [regulatory] lawyer . . . will demonstrate that nonbinding agency instructions and policy statements dominate binding legislative rules” as sources of information for regulatory compliance); Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468-69 (1992) (offering that “publication rules” such as technical guidance and staff manuals are produced often and in far greater number than more formal rules).

12. *See* Strauss, *supra* note 11, at 1478 (noting that publication rules, including guidances, can be seen as “filling in the details”).

13. *See id.* at 1481 (stating that publication rulemaking has an informing character that allows important efficiencies to those who must deal with the government).

14. *See* PIERCE, *supra* note 7, § 7.11 (proffering that there is mounting evidence that agencies are using rulemaking less frequently).

15. *See id.* (explaining that the notice and comment requirement in advance of adoption gives Congress and the White House a good opportunity to deter an agency from adopting a policy that an agency prefers, but that the president or members of Congress oppose).

16. *See id.* (providing examples of bills that require an opportunity for limited oral testimony and cross-examination with respect to certain issues that are critical to the outcome of a rulemaking).

17. *See id.* (explaining that to avoid the risk of judicial reversal, an agency often must incorporate a statement of basis and purpose that is several hundred pages long); STEPHEN G. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY 544 (6th ed. 2006) (acknowledging that courts have changed notice and comment rulemaking into a “more formal and time-consuming” process); Final Bulletin, 72 Fed. Reg. at 3432 (suggesting that agencies have an incentive to issue guidance documents instead of regulations because they involve fewer procedures).

18. *See* MacRae & Nicely, *supra* note 5, at 2 (recognizing that agencies are under time and political pressures to efficiently and effectively regulate industries subject to the statute).

19. *See* PIERCE, *supra* note 11, § 17.3 (stating that amending or promulgating a major legislative rule often takes at least five years).

Nonetheless, “guidance is a good thing.”²⁰ Conceptually, the use of guidance allows agencies to better fulfill their responsibilities.²¹ However, federal agencies’ misuse of guidance documents has raised concern from Congress, corporations, and academics.²² Regulated parties may attempt to get out from underneath an agency’s thumb and contest agency guidance because the agency treats it as binding on private parties, even though it is not subjected to the APA’s notice and comment procedures. Three relatively recent decisions from the United States Court of Appeals for the District of Columbia Circuit illustrate this trend.²³

B. The Confusion

Legal scholars and federal courts struggle when attempting to determine whether an agency rule²⁴ should be subject to the APA’s notice and comment requirements or is simply an interpretive rule or policy statement, and therefore exempt from these requirements.²⁵ Determining whether a

20. Cindy Skrzycki, *Finding a Way to Better Guidance*, WASH. POST, Dec. 20, 2005, at D1 (quoting Professor Jeffrey Lubbers, who explains that guidance becomes problematic when agencies treat it as binding on the public without notice and comment).

21. See generally PIERCE, *supra* note 11, § 17.1 (indicating the necessity for agencies to have significant discretion to carry out their responsibilities effectively).

22. See *Is the Department of Labor Regulating the Public Through the Backdoor?: Hearing Before the Subcomm. on National Econ. Growth, Natural Res., and Regulatory Affairs of the H. Comm. on Govt. Reform*, 106th Cong. 342 (2000) (statement of LPA, Inc.) (highlighting the numerous abuses by the Department of Labor in issuing guidance documents); BREYER ET AL., *supra* note 17, at 544 (reporting that a review of the Federal Register for the first six months of 1987 shows that forty percent of rules published had been adopted without notice and comment by agencies invoking the exemptions in the APA); MacRae & Nicely, *supra* note 5, at 2 (noting that “arrogance is displayed towards the regulated and lawmakers by deliberately sidestepping rule making procedures”).

23. See *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 385 (D.C. Cir. 2002) (striking down polychlorinated biphenyls (PCB) risk assessment guidance as a legislative rule requiring notice and comment); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023-24 (D.C. Cir. 2000) (overturning emissions monitoring guidance as a legislative rule requiring notice and comment); *Chamber of Commerce v. Dep’t of Labor*, 174 F.3d 206, 213 (D.C. Cir. 1999) (declaring an OSHA Directive a legislative rule requiring notice and comment).

24. It is important to note that the term “rule” is defined broadly in the APA, and guidance documents issued by agencies likely fall under the APA definition. See 5 U.S.C. § 551(4) (2000) (defining a rule as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . .”); Att’y Gen.’s Manual on the APA (1947) at 13, available at http://www.oalj.dol.gov/PUBLIC/APA/REFERENCES/REFERENCE_WORKS/AG01.HTM (indicating that the definition of “rule” is not limited only to substantive rules, but embraces interpretive, organizational, and procedural rules as well, and that “rule” includes agency statements of general applicability and particular applicability). *But see* *Pac. Gas & Elec. Co. v. Fed. Power Comm’n*, 506 F.2d 33, 38 (D.C. Cir. 1974) (implying that a general statement of policy is not a rule under the APA, noting that it is not derived from either a rulemaking or an adjudication).

25. See GARY LAWSON, *FEDERAL ADMINISTRATIVE LAW* 302 (3d ed. 2004) (stipulating that determining whether a rule is substantive as opposed to an interpretive rule or general policy statement is a question that has “proven to be one of the most troublesome in all of administrative law”).

rule is legislative, interpretive, or a policy statement is important because courts grant greater deference to a legislative rule than to an interpretive rule or policy statement.²⁶ As OMB noted, courts have not taken kindly to federal agencies attempting to bind regulated parties by way of guidance.²⁷ In *Community Nutrition Institute v. Young*,²⁸ the D.C. Circuit determined that Food and Drug Administration (FDA) “action levels,” which are the allowable levels of unavoidable contaminants in food,²⁹ while supposedly nonbinding, nonetheless practically bound third parties and should have gone through the APA’s notice and comment procedures required for legislative rules.³⁰ Subsequent cases before the D.C. Circuit indicate the court’s lack of patience with agencies that issue what the agency considers nonbinding documents exempt from notice and comment but treat these documents in a way that practically binds parties.³¹ Indeed, for years courts have considered whether an agency should issue a seemingly innocuous and nonbinding document in accordance with the APA’s notice and comment principles.³²

Recognizing that courts continue to find fault in agency use of guidance documents, OMB issued its Final Bulletin for Agency Good Guidance Practices as a way to provide greater clarity to the public with regard to such documents.³³ The foundation for the Final Bulletin is based on earlier recommendations and examples.³⁴

26. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) (ruling that “legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute,” or are reviewed for their reasonableness); see also *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (holding that courts do not treat rulings, interpretations, and opinions as controlling by reason of their authority, but that they are of value and may be relied upon by courts and litigants for guidance, and that their weight of authority is judged by their power to persuade).

27. See Final Bulletin, 72 Fed. Reg. at 3432 n.2 (indicating that courts are concerned with agency guidance practices).

28. 818 F.2d 943 (D.C. Cir. 1987).

29. *Id.* at 945.

30. *Id.* at 946 (finding that action levels are not policy statements).

31. See *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380 (D.C. Cir. 2002) (holding that the Environmental Protection Agency’s (EPA) guidance document is a legislative rule because it purports to bind both the agency and applicants with the force of law); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022-23 (D.C. Cir. 2000) (determining that whatever EPA may think of its guidance generally, the elements of the guidance strongly indicate a binding effect); *Chamber of Commerce v. Dep’t of Labor*, 174 F.3d 206, 211-12 (D.C. Cir. 1999) (finding that the Directive in question required more than adherence to existing law).

32. See *Airport Comm’n v. Civil Aeronautics Bd.*, 300 F.2d 185, 188 (4th Cir. 1962) (deciding that a press release issued by the Civil Aeronautics Board was not an exercise of rulemaking power and need not be published in the Federal Register pursuant to the APA).

33. See Final Bulletin, 72 Fed. Reg. at 3433 (stating that the purpose of the Good Guidance Practices is to inject transparency, quality, and accessibility into the formulation of guidance documents, and to ensure guidance documents are properly reviewed and issued and not improperly treated as binding).

34. See *id.* (noting that the Food and Drug Modernization Act of 1997, FDA’s Good Guidance Practices, and recommendations by the Administrative Conference of the United States (ACUS) informed the development of the Final Bulletin).

C. *The Genesis of Good Guidance Practices*

The idea of “good guidance practices,” a colloquial term with no legal definition, has existed since at least 1976 when the Administrative Conference of the United States (ACUS)³⁵ recommended ways to improve the manner in which agencies issue interpretive rules of general applicability³⁶ and statements of general policy.³⁷ At that time, the ACUS focused its attention on interpretive rules of general applicability or statements of general policy likely to have a “substantial impact” on the public, and recommended that the agency use the procedures for notice and comment set forth in the APA.³⁸ The ACUS also suggested ways for an agency to improve the use of interpretive rules of general applicability or statements of general policy, even if the agency could not seek public comment prior to issuing the documents.³⁹

In 1992, the ACUS made additional recommendations concerning agency policy statements.⁴⁰ Worried that regulated parties would not be able to effectively challenge binding agency policy statements, the ACUS recommended certain practices that allowed for interested parties to be heard.⁴¹ Specifically, the ACUS suggested that agencies afford affected

35. Congress formally established the ACUS in 1966 to, among other things, “promote more effective public participation and efficiency in the rulemaking process.” Administrative Conference Act, 5 U.S.C. § 591 (2000). The ACUS no longer exists. *See* Treasury, Postal Service, and General Government Appropriations Act of 1996, Pub. L. No. 104-52, 109 Stat. 480 (ceasing funding for the ACUS and terminating its operations by February 1, 1996). Congress recently reauthorized the ACUS, but because it has not appropriated money for its operations, the ACUS remains dormant. *See* Federal Regulatory Improvement Act of 2004, Pub. L. No. 108-401, 118 Stat. 2255 (authorizing appropriations for the ACUS for fiscal years 2005, 2006, and 2007).

36. *See* Administrative Conference of the United States, Rec. 76-5, 1 C.F.R. § 305.76-5 (1976), available at <http://www.law.fsu.edu/library/admin/acus/305765.html> (determining that an interpretive rule of general applicability is a means by which an agency explains its view of the meaning of a statute or rule).

37. *See id.* (noting that a statement of general policy is an issuance from an agency describing how it will exercise its discretion).

38. *See id.* (stating that an opportunity to comment is meant to ensure greater confidence in and broader acceptance of ultimate agency judgments, and that an agency should publish the proposed interpretive rule or policy statement in the Federal Register, provide a concise statement of its basis and purpose, and invite interested persons to submit written comments, with or without opportunity for oral presentation).

39. *See id.* (suggesting that even if such a document is issued without prior publication or invitation for public comment, the document nonetheless should be published and include a statement of its basis and purpose and invite comment for a period of not less than thirty days from the date of issuance).

40. *See* Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305922.html> (proposing that agency policy statements make clear that they do not bind parties).

41. *See id.* (urging agencies to modify current informal and formal procedures to allow for an opportunity to challenge practically binding policy statements and that the particulars of such procedures should be left to an agency’s discretion).

persons a “fair” opportunity, either at or before issuance, “to challenge the legality or wisdom of the document and to suggest alternative choices in an agency forum that assures adequate consideration by responsible agency officials.”⁴²

The FDA incorporated the ACUS’s general recommendations into a document entitled “Good Guidance Practices” in 1997.⁴³ To ensure public awareness of guidance documents and thorough vetting of FDA-issued guidance documents, the FDA Good Guidance Practices categorizes guidance documents,⁴⁴ allows for public input in the development of certain guidance documents,⁴⁵ and allows the FDA to revise and reissue guidance,⁴⁶ among other things. While mirroring the ACUS recommendations, the FDA’s Good Guidance Practices, in reality, formalized its past practice of allowing notice and comment for interpretive rules and policy statements.⁴⁷ Congress codified the FDA’s Good Guidance Practices contemporaneously with the FDA’s implementation of them.⁴⁸

42. *Id.* ACUS also recommended other means of improving the use of policy statements, including suggestions that notice and opportunity for comment on such policy statements be afforded, and that a notice of the policy statement’s nonbinding nature be included with each document. *Id.*

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

44. *See* FDA Good Guidance Practices, 21 C.F.R. § 10.115(c)(1)-(2) (2005) (distinguishing between Level 1 and Level 2 guidance documents). Level 1 documents “(i) [s]et forth initial interpretations of statutory or regulatory requirements; (ii) [s]et forth changes in interpretation or policy that are of more than a minor nature; (iii) [i]nclude complex scientific issues; or (iv) [c]over highly controversial issues.” *Id.* Level 2 guidance documents “set forth existing practices or minor changes in interpretation or policy.” *Id.*

45. *See id.* § 10.115(g)(1)(i) (stipulating that the “FDA can seek or accept early input from individuals . . . outside the agency” in the preparation of a draft of a Level 1 guidance document “by participating in or holding public meetings or workshops”).

46. *See id.* § 10.115(g)(1)(v) (granting the FDA the option of issuing another draft of the guidance document after providing an opportunity for comment).

47. Lars Noah, *The FDA’s New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 138-39 (1997) (explaining that the agency announces availability of a draft guideline, invites public input, and occasionally issues a subsequent notice to extend the comment period).

48. *See* 21 U.S.C. § 371(h) (2004) (providing that the FDA develop guidance documents with public participation and that such documents be publicized).

II. OMB'S GOOD GUIDANCE PRACTICES

A. Overview

The Final Bulletin provides a broad definition of guidance documents.⁴⁹ It further distinguishes and defines a “significant guidance document”⁵⁰ and an “economically significant guidance document.”⁵¹ The Final Bulletin explicitly excludes certain documents from the definition of “significant guidance document,” including legal advisory opinions for internal executive branch use, editorials, press releases, and warning letters, among others.⁵² Additional elements of the Final Bulletin include setting forth approval procedures that agencies should implement when issuing significant guidance documents to ensure their endorsement by appropriate senior agency officials,⁵³ and standardizing each significant guidance document’s appearance, including a prohibition on the use of mandatory, binding language.⁵⁴

49. See Final Bulletin, 72 Fed. Reg. at 3439 (defining the term “guidance document” as “an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12,866, as further amended, § 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue”).

50. See *id.* (providing four possible definitions for a “significant guidance document”). These include documents that may:

reasonably be anticipated to (1) [l]ead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in Executive Order 12866, as further amended.

Id.

51. See *id.* (defining an “economically significant guidance document” as a document that may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include documents on Federal expenditures and receipts). While this definition closely resembles the definition of a “significant regulatory action” in Executive Order 12,866 regarding regulatory review, it differs in key respects. See Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,738 (Sept. 30, 1993). *But see* Final Bulletin, 72 Fed. Reg. at 3435 (noting that the Final Bulletin includes the words “may reasonably lead to” and “lead to” an economically significant effect, while Executive Order 12,866 defined significant regulatory actions as having such an effect).

52. Final Bulletin, 72 Fed. Reg. at 3439.

53. See *id.* at 3440 (requiring each agency to develop or maintain written procedures for the approval of significant guidance documents and prohibiting agencies from circumventing the requirements of public notice for such documents).

54. See *id.* (dictating that each significant guidance document must involve the following standard elements: (1) include the term “guidance,” (2) identify the agency issuing the document, (3) identify the activity to which and the people to whom the document

Ensuring public access and feedback, the Final Bulletin declares that each agency must provide access to all of its significant guidance documents via the Internet and publicize on its website the method that the public may use to comment on such documents.⁵⁵ Agencies are not required by law to formally respond to comments submitted with regard to significant guidance documents.⁵⁶ However, for most economically significant guidance documents, the Final Bulletin imposes an affirmative duty on agencies to invite public comment and respond to the comments submitted,⁵⁷ although the Final Bulletin exempts an agency from publicizing and seeking comment on certain economically significant guidance documents.⁵⁸

applies, (4) include the date of issuance, (5) note if it is amending a previous guidance document, (6) provide a title of the guidance, and (7) not include mandatory language such as “shall,” “must,” “required,” or “requirement” unless the agency uses these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties).

55. *See id.* (requiring each agency to post annually on its Web site a current list of its significant guidance documents in effect as well as to “clearly advertise on its website a means for the public to submit comments electronically on significant guidance documents, and to submit a request electronically for issuance, reconsideration, modification, or rescission of significant guidance documents”). It is important to note that the Final Bulletin does not require that significant guidance documents be published in the Federal Register. *See id.*

56. *See id.* (noting that public comments concerning significant guidance documents are solely for the agency’s benefit and that an agency is not required to respond formally to comments). However, OMB does encourage agencies to consider following notice and comment procedures for “interpretive significant guidance documents that effectively would extend the scope of the jurisdiction the agency will exercise, alter the obligations or liabilities of private parties, or modify terms under which the agency will grant entitlements.” *Id.* at 3437.

57. *See id.* at 3440 (mandating that when an agency prepares a draft of an economically significant guidance document, it publish a notice in the Federal Register, post it on the Internet in addition to making a hard copy available, invite public comment, and respond to such comments). The Federal Register notice is not required to include any specific information about the economically significant guidance document. Rather, such notice only announces that the draft guidance document is “available.” *Id.* This “notice” seemingly requires less detail than is needed under full notice and comment rulemaking under the APA. *See* 5 U.S.C. § 553(b) (requiring notice to include a statement of time, place, and nature of the proceeding, reference to the legal authority relied upon, and the terms or substance of the proposal). Nonetheless, the Final Bulletin does mirror certain provisions of the APA by providing that agencies can invite oral presentations on economically significant guidance documents and can incorporate suggestions into the economically significant guidance documents. *Compare* Final Bulletin, 72 Fed. Reg. at 3438, *with* 5 U.S.C. § 553(c) (requiring agencies to give persons an opportunity to participate in the rulemaking, including via oral presentation if possible, and to incorporate in the rules a statement of basis and purpose after consideration of the comments submitted). Thus, the Final Bulletin’s notice and comment requirements for economically significant guidance documents could be considered a hybrid of the APA’s notice and comment requirements for rulemaking. OMB seems to concur in this assessment. *See* Final Bulletin, 72 Fed. Reg. at 3438 (acknowledging that these procedures are “similar” to APA notice and comment requirements).

58. Final Bulletin, 72 Fed. Reg. at 3440 (stating that agencies may at their discretion, but in consultation with the Administrator of the Office of Information and Regulatory

B. Commentary on OMB's Proposed Good Guidance Practices

To better understand OMB's reasoning behind the Final Bulletin, it is helpful to review the Proposed Bulletin and the comments submitted to OMB during the development of its good guidance practices. OMB received numerous comments on its Proposed Bulletin.⁵⁹ Generally speaking, commenters supported OMB's proposals regarding public access to significant guidance documents.⁶⁰ The bulk of the attention and criticism focused on OMB's definitions of significant guidance documents and economically significant guidance documents; some commenters found OMB's definitions too broad,⁶¹ while others found them too narrow.⁶² The

Policy (OIRA), identify particular guidance documents or classes of guidance documents for which the notice and comment procedures are not feasible or appropriate).

59. Office of Mgmt. & Budget, Comments on Proposed Bulletin on Good Guidance Practices, available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html (last visited Feb. 1, 2007) (providing a complete listing of the comments OMB received).

60. See, e.g., Am. Bar Ass'n, Comments of the American Bar Association with Regard to OMB's Proposed Bulletin for Good Guidance Practices (2005), available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-aba.pdf [hereinafter ABA Comments] (noting that the ABA supports OMB's efforts to make guidance documents available over the Internet); Citizens for Sensible Safeguards, Comments of Citizens for Sensible Safeguards with Regard to OMB's Proposed Bulletin for Good Guidance Practices 2 (2006), available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-watch.pdf [hereinafter CSS Comments] (stating that while it believes that there could be better means to attain the goals of transparency and public participation, it has "no quarrel" with the substance of the public access portion of the Proposed Bulletin); Gen. Elec. Co., Comments of the General Electric Company with Regard to OMB's Proposed Bulletin for Good Guidance Practices 10 (2006), available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-ge.pdf [hereinafter GE Comments] (recognizing that OMB's provision mandating the posting of significant guidance documents on the Internet is an important provision that furthers the goal of transparency).

61. See ABA Comments, *supra* note 60 (expressing concern that OMB, by defining significant guidance documents to include "initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy," unnecessarily sweeps into the category of significant guidance documents all initial agency guidance no matter how routine or substantial). OMB seemed to agree with the ABA and did not include that particular definition in the Final Bulletin. See Final Bulletin, 72 Fed. Reg. at 3434 (recognizing that the "broad application" of the Final Bulletin and the "need for clarity" required changing the definition).

62. See GE Comments, *supra* note 60, at 6-7 (arguing that OMB should broaden the definition of "highly controversial issues" to include not just interagency concerns but all highly controversial issues that may arise, and should not limit "novel or complex issues" to include only those that are technical or scientific, but to include "precedent-setting" issues as well); see also U.S. Chamber of Commerce, Comments of the U.S. Chamber of Commerce with Regard to OMB's Proposed Bulletin for Good Guidance Practices 3-4 (2005), available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-chamber.pdf [hereinafter Chamber Comments] (urging that the definition for "guidance documents" be clarified to state that any agency policy that is not a rule is guidance if it is used by the agency to "manage the regulatory process"). Although OMB did not clarify the definition per the Chamber of Commerce's suggestion, it did redefine the term "guidance document" in the Final Bulletin to exclude a regulatory action that is "an interpretation of a *statutory* or regulatory issue." Final Bulletin, 72 Fed. Reg. at 3439 (emphasis added). The Proposed Bulletin merely excluded from the definition "an interpretation of or a policy on a regulatory or technical issue." OMB, Proposed Bulletin for Good Guidance Practices 1, 9 (2005), available at http://www.whitehouse.gov/omb/inforeg/good_guid/good_guidance_preamble.pdf

American Bar Association expressed additional concerns regarding the exclusion of memoranda of understanding and contractor instructions from the definition of guidance,⁶³ the failure of the Proposed Bulletin to distinguish between guidance that binds an agency and guidance that binds subordinate employees of an agency,⁶⁴ and the absence in the Proposed Bulletin of any reminders for agencies to follow APA procedures when issuing guidance documents.⁶⁵

Citizens for Sensible Safeguards (CSS) expressed the greatest criticism of the Proposed Bulletin, calling it “a solution in search of a problem.”⁶⁶ CSS contended that if OMB implemented the Proposed Bulletin, further production of guidance materials would be hindered because the notice and comment requirements and agency approval processes would create “heavy burdens” and lead to less guidance.⁶⁷ Despite suggesting that the Proposed Bulletin was unnecessary, CSS nonetheless offered improvements to the document, including eliminating the provision requiring notice and comment for economically significant guidance documents.⁶⁸ Other parties balanced CSS’s strong critique by arguing that the Proposed Bulletin would serve as a valuable and necessary tool for agencies to use when issuing guidance documents.⁶⁹

[hereinafter Proposed Bulletin].

63. See ABA Comments, *supra* note 60 (noting that some memoranda of understanding and contractor instructions have regulatory impacts, and suggesting that consideration be given to include them in the definition of significant guidance documents).

64. See *id.* (reminding OMB that an agency can appropriately bind its subordinate employees without having to resort to notice and comment rulemaking).

65. See *id.* (proposing that OMB advise agencies to follow APA procedures when issuing guidance documents, such as the publication requirements of § 552). A review of the Final Bulletin indicates that OMB did not take the ABA up on its suggestion.

66. CSS Comments, *supra* note 60, at 3 (characterizing the Proposed Bulletin as “blind to the role of government in meeting the public’s needs”).

67. *Id.* at 13 (suggesting that heavy burdens will discourage agencies to produce guidance); see also Rebecca Adams, *Graham Leaves OIRA with a Full Job Jar*, CQ WkLY., Jan. 23, 2006, at 227 (reporting that agency officials worry that the proposed good guidance practices will deter agency interactions with the regulated public or will lead to more “covert” interactions).

68. CSS Comments, *supra* note 60, at 19 (criticizing the term “economically significant guidance” as misleading and incomprehensible, and arguing that making agencies subject such guidance to notice and comment would be “onerous and draining”).

69. GE Comments, *supra* note 60, at 4 (noting that the Proposed Bulletin is modeled largely after the FDA’s Good Guidance Practices and that the FDA has not been burdened in promulgating guidance since the inception of those practices); see also McKenna, Long & Aldridge LLP, Comments of McKenna, Long & Aldridge LLP with Regard to OMB’s Proposed Bulletin for Good Guidance Practices 3 (2006), available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-mckenna.pdf [hereinafter McKenna Comments] (suggesting that the Proposed Bulletin will lead to less judicial review of guidance documents and affords “administrative due process”).

III. ANALYSIS

A. The "Practically Binding" Effect

Courts often must decide whether an agency-issued guidance document binds private parties, the agency, or both. In so doing, courts also must determine whether such a document constitutes a legislative rule that should have been subject to notice and comment.⁷⁰ Whether a rule is legislative, interpretive, or a general statement of policy continues to challenge courts and scholars.⁷¹ OMB seemingly issued its Final Bulletin in an attempt to mitigate the confusion regarding the legal effect of guidance, as evidenced by OMB's concentration on the D.C. Circuit's opinions on the matter.⁷²

In assessing whether OMB's good guidance practices will alleviate the confusion regarding the legal effect of guidance documents, it is important to review the reasoning of the D.C. Circuit in *Community Nutrition Institute v. Young*⁷³ and its offspring.⁷⁴ In *Community Nutrition*, the court examined whether the FDA's action level for aflatoxins in corn violated the APA because it constituted a legislative rule issued without the requisite notice and comment procedures.⁷⁵ The FDA represented the action levels as a "nonbinding statement of agency enforcement policy."⁷⁶ The court looked at two criteria to distinguish between legislative and interpretive rules. First, the court analyzed whether the pronouncement acted prospectively because a statement of policy "may not have a present

70. See *supra* note 31 and accompanying text (discussing the holdings of the U.S. Court of Appeals for the District of Columbia Circuit with regard to legislative rules masquerading as nonbinding guidance documents).

71. See *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 93 (D.C. Cir. 1997) (acknowledging that the court has long recognized "that it is quite difficult to distinguish between substantive and interpretive rules"); LAWSON, *supra* note 25, at 302 (noting the "troublesome" nature of the distinction between substantive and interpretive rules); Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 383-84 (recognizing that although the theoretical difference between the legal effect of legislative and nonlegislative rules is clear, the practical difference is far less clear); ABA Comments, *supra* note 60 (stating that "the law concerning interpretive rules and policy statements may be among the most complex in administrative law").

72. See Final Bulletin, 72 Fed. Reg. at 3432 (quoting the D.C. Circuit's opinion in *Appalachian Power* extensively as justification for why the good guidance practices are necessary); Skrzycki, *supra* note 20, at D1 (quoting then-Administrator of the Office of Information and Regulatory Affairs (OIRA), John D. Graham, as stating that groups worried about good guidance practices burdening agencies should balance that concern against the time spent on court cases addressing "confusion about what is a rule and what is guidance").

73. 818 F.2d 943 (D.C. Cir. 1987).

74. See generally *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002); *Appalachian Power v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000); *Chamber of Commerce v. Dep't of Labor*, 174 F.3d 206 (D.C. Cir. 1999).

75. *Cnty. Nutrition Inst.*, 818 F.2d at 945.

76. *Id.* at 945-46.

effect.”⁷⁷ Next, the court asked whether the purported policy statement allowed the agency any discretion in enforcement.⁷⁸ In applying those two criteria, the court held that the action level pronouncement was practically binding and therefore subject to notice and comment.⁷⁹ The court specifically attacked the action level statement’s prominent use of the word “will” instead of the conditional “may,” in requiring food producers to secure exceptions to the action levels.⁸⁰ In addition, the court objected to the FDA’s statements indicating that the agency had no wiggle room to exercise discretion in determining whether the action levels could be breached without penalty.⁸¹

The court continued to use the criteria relied upon in *Community Nutrition* in subsequent cases, including the cases OMB references in its Final Bulletin.⁸² Of particular note is the court’s strident language in *Appalachian Power v. EPA*,⁸³ in which the court rejected a legal disclaimer at the end of an EPA guidance document expressing the agency’s intention that the document not bind parties.⁸⁴ According to the court, the document resembled an authoritative decree.⁸⁵ The court also took no solace in the fact that a guidance document may provide private parties a safe harbor in which to act, and even considered that to be a factor evidencing the practical binding effect of the guidance document.⁸⁶

77. *Id.* at 946.

78. *Id.*

79. *Id.* at 947 (stating that the use of mandatory and definitive language was a dispositive factor suggesting that action levels are substantive rules).

80. *Id.* at 946-47.

81. *Id.* at 947-49.

82. *See* Gen. Elec. Co. v. EPA, 290 F.3d 377, 382 (D.C. Cir. 2002) (citing the two criteria expressed in *Community Nutrition* regarding how a court draws a line between a legislative rule and statements of policy); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (recognizing that an agency’s pronouncements can, as a practical matter, have a binding effect); *Chamber of Commerce v. Dep’t of Labor*, 174 F.3d 206, 212 (D.C. Cir. 1999) (citing *Am. Bus. Assoc. v. United States*, 627 F.2d 525, 529-30 (1980)) (stating that the court determines if a rule is a policy statement by whether it has only a prospective effect and leaves the agency decisionmakers free to exercise informed discretion).

83. 208 F.3d 1015 (D.C. Cir. 2000).

84. *See id.* at 1022-23 (calling the EPA disclaimer “boilerplate”); *see also* Strauss, *supra* note 11, at 1485 (stating that the “best face one can put on such a notice is that it is a charade”).

85. *See Appalachian Power*, 208 F.3d at 1023 (opining that the guidance document “reads like a ukase,” an order with absolute authority).

86. *See id.* at 1021 (declaring that if an agency bases its enforcement decisions on the policies or interpretations proffered in the guidance document, then this demonstrates the practical “binding” nature of the document); *see also* Anthony, *supra* note 1, at 1329 (stating that if language in a document is such that private parties can rely on it as a safe harbor, it can be binding as a practical matter).

The practical binding effect test and criteria used by the court is not without criticism.⁸⁷ Nonetheless, the test must be juxtaposed with OMB's good guidance practices and the comments submitted in support of it to determine if, in fact, the Final Bulletin will ensure guidance documents are upheld as nonbinding. OMB prohibits guidance documents from using mandatory language such as "shall" and "must."⁸⁸ And while commenters agreed with that policy,⁸⁹ courts do not hold mandatory language determinative in assessing a document's practical binding effect.⁹⁰ Additionally, if private parties rely on the guidance issued via OMB's good guidance practices as a safe harbor, as some commenters suggested,⁹¹ a court could find that the guidance document is binding.⁹² This seemingly runs counter to OMB's intentions.⁹³ Finally, requests for a clear disclaimer indicating that the guidance document is not binding,⁹⁴ while possibly helpful in educating the public, likely will carry little weight with a court.⁹⁵

In light of the case law, it seems that OMB's good guidance practices may serve the public well by allowing notice and comment.⁹⁶ However, they may not necessarily serve the agencies well. The Final Bulletin's procedures could lead to courts deeming more guidance documents

87. See, e.g., PIERCE, *supra* note 11, § 17.3 (opining that the holding in *Community Nutrition* and its progeny has the potential "to create an administrative state with characteristics that resemble Dante's Inferno").

88. Final Bulletin, 72 Fed. Reg. at 3440.

89. See, e.g., GE Comments, *supra* note 60, at 8 (applauding OMB for "correctly" recognizing that guidance documents should not include mandatory language).

90. See *supra* notes 74-81 and accompanying text (discussing the various factors that courts analyze in assessing whether a guidance document is binding or not).

91. See McKenna Comments, *supra* note 69, at 10 (suggesting that it may be appropriate for agencies to create a safe harbor and that OMB should direct agencies to identify guidance documents that, if followed, would create a rebuttable presumption that the regulated entity complied with the regulatory requirements); see also GE Comments, *supra* note 60, at 9 (recommending that OMB direct agencies to refrain from alleging that activities consistent with the guidance violated the regulatory requirements that are the subject of the guidance).

92. See *supra* note 86 and accompanying text (discussing the ramifications of safe harbor provisions in assessing whether a document is binding). While OMB does not suggest in its Final Bulletin that guidance documents issued through the good guidance practices afford regulated entities a rebuttable presumption of compliance, it will be interesting to see how parties treat guidance issued by way of these OMB-mandated procedures, especially as agencies use the good guidance practices over time.

93. See *supra* note 72 and accompanying text (noting that OMB hopes that its Final Bulletin will end the confusion courts have with regard to guidance documents versus legislative rules).

94. See GE Comments, *supra* note 60, at 8-9 (stating that it is very important that agency guidance unequivocally state that the document is not legally binding).

95. See *supra* note 81 and accompanying text (recognizing that a court gives little deference to a boilerplate disclaimer in assessing the binding effect of a guidance document).

96. See Anthony, *supra* note 1, at 1373-75 (declaring that agencies, when issuing policy statements, ought to engage in an open-minded policy and allow for public participation in the development of the policy statements, which is consistent with APA principles of accountability and openness).

practically binding and susceptible to judicial challenge, or may have little effect on a court when it determines the legal efficacy of the guidance document.⁹⁷

B. Judicial Deference

In addition to possibly exposing guidance documents to more legal challenges—contrary to one of OMB’s primary motivations in issuing its Final Bulletin⁹⁸—OMB’s good guidance practices also may lead courts to afford greater deference to guidance documents than is otherwise justified.⁹⁹ A review of Supreme Court case law concerning judicial deference to administrative agency pronouncements indicates that courts apply varied levels of deference to agency issuances according to numerous factors. Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, certain agency issuances are granted substantial deference,¹⁰⁰ while under *Skidmore v. Swift & Co.*, others are entitled only to “respect” and are judged by their “power to persuade.”¹⁰¹ Various criteria influence whether a court should respect such issuances.¹⁰² Additionally, the Court stated in *United States v. Mead Corp.*¹⁰³ that the measure of deference varied with

97. See Strauss, *supra* note 11, at 1488-89 (reasoning that while public consultation in the promulgation of publication rules is desirable, cases undoubtedly will remain in which courts will conclude that legislative rule making is required for work that an agency characterizes as exempt).

98. See Final Bulletin, 72 Fed. Reg. at 3432 (highlighting the Final Bulletin’s focus on D.C. Circuit case law).

99. See Professor William S. Jordan, III, Comments of Professor William S. Jordan, III, with Regard to OMB’s Proposed Bulletin for Good Guidance Practices 3-4 (Feb. 23, 2006), available at http://www.whitehouse.gov/omb/inforeg/good_guid/c-wjordan.pdf [hereinafter Jordan Comments] (suggesting that various requirements of the Proposed Bulletin may have an unintended effect on judicial review because the procedural provisions and notice and comment requirement in the Proposed Bulletin may be enough to warrant *Chevron* deference). OMB, in its Final Bulletin, responded to this potential problem by suggesting that the good guidance practices “are not intended to, and should not, alter the deference that agency interpretations of laws and regulations should appropriately be given.” Final Bulletin, 72 Fed. Reg. at 3439 n.31. OMB’s opinion notwithstanding, whether guidance documents issued pursuant to the good guidance practices will receive greater judicial deference remains an open question.

100. See 467 U.S. 837, 843-45 (1984) (holding that a court reviews an agency construction of a statute that the court deems ambiguous, whether issued pursuant to an explicit delegation of Congress or an implicit delegation, based on whether it is a “permissible construction of the statute,” that statutory constructions borne from an explicit congressional delegation of authority are upheld unless they are “arbitrary, capricious, or manifestly contrary to the statute,” and statutory constructions evolving from an implicit congressional delegation of authority are upheld so long as they are a “reasonable interpretation”).

101. 323 U.S. 134, 140 (1944).

102. See *id.* (indicating that the thoroughness of the agency’s consideration of the issuance, the validity of the agency’s reasoning, the agency’s consistency with earlier and later pronouncements, and other persuasive factors will determine whether a court will respect an agency’s decision, even though the decision does not have the power to control).

103. See 533 U.S. 218, 226-27 (2001) (holding that *Chevron* deference can be applied only to agency interpretations of a statute when it is evident that Congress delegated

the circumstances and that courts analyze how careful the agency was in issuing the interpretation, the agency's consistency, the formality used to issue the interpretation, relative expertise of the agency, and the agency's overall persuasiveness.¹⁰⁴

Some scholars argue that the Court's decision in *Mead* has clouded when *Chevron* deference should be applied.¹⁰⁵ Soon after its ruling in *Mead*, the Court, in *Barnhart v. Walton*,¹⁰⁶ provided dicta that some scholars believe has created further "uncertainty" about the types of agency pronouncements that are due *Chevron* deference.¹⁰⁷ In particular, the Court noted that it may afford *Chevron* deference to an agency interpretation based on the interpretive method used.¹⁰⁸

OMB's Final Bulletin provides formalized procedures for agencies to follow when issuing certain guidance documents.¹⁰⁹ These procedures may constitute enough consideration to justify *Chevron* deference, especially in light of the decision in *Mead* and the dicta in *Barnhart*.¹¹⁰ Considering that the case law regarding judicial deference is a "mess,"¹¹¹ it is not

authority to the agency to promulgate interpretations with the "force of law").

104. *Id.* at 228. The Court indicated that while notice and comment rulemaking is "significant" in determining if *Chevron* deference is required, it is not necessary. *Id.* at 230-31. That being said, the Court does take into consideration whether the agency rule was issued pursuant to notice and comment and whether the ruling is treated as binding on third parties. *Id.* at 233.

105. See, e.g., Lisa Schultz Bressman, *How Mead Has Muddled Judicial Review of Agency Action*, 58 VAND. L. REV. 1443, 1447 (2005) (arguing that *Mead* has confused courts on whether *Chevron* deference applies to interpretations issued through informal procedures outside of full notice and comment rulemaking procedures). Of particular note is the Court's holding that *Chevron* deference can apply if the agency engages in activity evidencing a congressional delegation of authority, including notice and comment rulemaking, but also "some other indication of a comparable congressional intent." *Mead*, 533 U.S. at 226-27. Justice Scalia took particular umbrage with the holding. See *id.* at 239 (Scalia, J., dissenting) ("We will be sorting out the consequences of the *Mead* doctrine for years to come.").

106. 535 U.S. 212 (2002).

107. RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 3.5 (4th ed. Supp. 2006) (discussing the scope of *Chevron* and declaring that the "results to date are confusing and leave important questions unresolved").

108. See *Barnhart*, 535 U.S. at 222 (stating that the "interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that *Chevron* [deference may be appropriate]").

109. See Final Bulletin, 72 Fed. Reg. at 3440 (providing that each agency shall develop or have written procedures for the approval of significant guidance documents, including ensuring that such guidance documents are approved by senior agency officials, and that economically significant guidance documents be published in the Federal Register and be subject to notice and comment).

110. See Jordan Comments, *supra* note 99, at 4 (suggesting that the OMB-imposed notice and comment processes may constitute enough fairness and input to warrant *Chevron* deference).

111. Bressman, *supra* note 105, at 1444-46 (arguing that Justice Scalia understated the effect of *Mead*); see also PIERCE, *supra* note 107, § 3.5 (claiming that circuit courts are struggling to apply the Supreme Court's decisions on the scope of *Chevron* to a variety of

unreasonable to think that guidance issued via these procedures may be entitled to *Chevron* deference. Such procedures lend more gravitas to the guidance and demonstrate the “careful consideration” the Court seeks if *Chevron* deference is to be afforded,¹¹² notwithstanding the fact that guidance documents have been held to lack the force of law.¹¹³

Even if courts do not apply *Chevron* deference to guidance documents issued via OMB’s good guidance practices, the most likely scenario is that courts will always find such guidance persuasive enough to uphold it under *Skidmore* review.¹¹⁴ Indeed, economically significant guidance documents issued via a notice and comment procedure pursuant to OMB’s good guidance practices could more easily satisfy a court reviewing the issuance under the ever-present arbitrary and capricious test.¹¹⁵

CONCLUSION

OMB’s Final Bulletin for Agency Good Guidance Practices offers some positive requirements for agencies to follow when issuing guidance. Notice of and access to guidance documents, especially with the growth of the Internet, is consistent with the principles of the APA and open government. However, OMB’s decision to subject guidance documents to formal procedures, especially notice and comment procedures for economically significant guidance documents, is unwise and should be reconsidered. Based on the case law that OMB highlighted, it is not unreasonable to think that, at worst, courts could consider economically significant guidance documents as “practically binding” on third parties precisely because of the formalized procedures they must go through prior to issuance. At a minimum, OMB’s good guidance practices will achieve little in clarifying for courts the differences in legal efficacy between guidance documents and legislative rules.

agency pronouncements).

112. *Barnhart*, 535 U.S. at 222.

113. *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (holding that interpretations contained in opinion letters, agency manuals, policy statements, and enforcement guidelines all “lack the force of law” and “do not warrant *Chevron*-style deference”).

114. *See United States v. Mead*, 533 U.S. 218, 235 (recognizing that an agency ruling’s “power to persuade” can be determined by its writer’s “thoroughness, logic, and expertness, its fit with prior interpretations, and any other sources of weight”).

115. *See Motor Vehicle Mfrs.’ Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (requiring that the agency examine relevant information and articulate a satisfactory explanation for its action with a “rational connection” to the facts and the choice made); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416-17 (1971) (noting that under the arbitrary and capricious test, a court must consider whether the agency looked at the “relevant factors” and followed necessary procedural requirements).

Additionally, such good guidance practices may lead a court to apply *Chevron* deference to a guidance document, thereby giving it greater legal effect than either private parties or agencies need or desire. Alternatively, OMB's good guidance practices may buttress guidance documents subject to either a *Skidmore* review or judicial review under the arbitrary and capricious test—a result that regulated entities who challenge the legality of such documents would oppose. Thus, while imposing greater burdens on agencies when issuing certain guidance documents, OMB's good guidance practices could lead to the unintended consequence of making guidance documents more legally significant than they otherwise should be. In turn, this invites more litigation and further blurs the line between a binding rule and a nonbinding guidance document.