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Regulatory Beneficiaries and Informal Agency Policymaking

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REGULATORY BENEFICIARIES AND INFORMAL AGENCY POLICYMAKING

Nina A. Mendelson†

Administrative agencies frequently use guidance documents to set policy broadly and prospectively in areas ranging from Department of Education Title IX enforcement to Food and Drug Administration regulation of direct-to-consumer pharmaceutical advertising. In form, these guidances often closely resemble the policies agencies issue in ordinary notice-and-comment rulemaking. However, guidances are generally developed with little public participation and are often immune from judicial review. Nonetheless, guidances can prompt significant changes in behavior from those the agencies regulate.

A number of commentators have guardedly defended the current state of affairs. Though guidances lack some important procedural safeguards, they can help agencies supervise low-level employees and supply valuable information to regulated entities regarding how an agency will implement a program. Thus far, however, the debate has largely ignored the distinct and substantial interests of regulatory beneficiaries—those who expect to benefit from government regulation of others. Regulatory beneficiaries include, among others, pharmaceutical consumers, environmental users, and workers seeking safe workplaces. When agencies make policy informally, regulatory beneficiaries suffer distinctive losses to their ability to participate in the agency's decision and to invoke judicial review. This Article argues that considering the interests of regulatory beneficiaries strengthens the case for procedural reform. The Article then assesses some possible solutions.

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INTRODUCTION

In setting policy, federal regulatory agencies regularly bypass the requirements of the Administrative Procedure Act (APA) public notice-and-comment process for issuing legislative rules.¹ They instead use the statutory exception for general statements of policy and interpretative rules.² Compared with notice-and-comment rules, the volume of these materials, which I will collectively call "guidance documents," is massive.³ Examples range from the Forest Service's nonbinding Directive System regarding national forest management,⁴ to the Federal Aviation Administration (FAA) Advisory Circulars on air safety,⁵ to the Treasury Department's Examination Handbook on

¹ See 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, 1316 (1992) ("[I]t is manifest that nonobservance of APA rulemaking requirements is widespread.").

² 5 U.S.C. § 553(b)(3)(A) (2000).

³ See Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 159–60 (2000) (discussing the recent identification of "guidances" as a legal category in American administrative law). See generally Peter L. Strauss, Comment, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468–71 (1992) (presenting anecdotal evidence of the "extraordinary volume of [informal] standard-generating activity").

⁴ FOREST SERV., U.S. DEP'T OF AGRIC., OVERVIEW OF THE FOREST SERVICE DIRECTIVE SYSTEM, available at <http://www.fs.fed.us/im/directives/dughtml/overview.html> (last visited Feb. 3, 2007).

⁵ U.S. FED. AVIATION ADMIN., ADVISORY CIRCULARS, http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/MainFrame (last visited Feb. 3, 2007).

the operation of thrift institutions.⁶ In response to congressional requests, the Environmental Protection Agency (EPA) catalogued over two thousand guidance documents it had issued between 1996 and 1999, and the Occupational Safety and Health Administration of the Department of Labor (OSHA) catalogued over three thousand.⁷ During the same period, the EPA issued one hundred “significant” rules subject to Office of Management and Budget (OMB) review, and the entire Department of Labor, including OSHA, issued twenty such rules.⁸ A recent study of the Food and Drug Administration (FDA) suggests that on average it issues at least twice as many guidances as it does rules.⁹ According to another source, the FDA’s use of guidance documents continues to increase.¹⁰ This use of guidances dwarfs agencies’ production of notice-and-comment rules.

Guidance documents can closely resemble legislative rules, leading some to call them “nonlegislative rules.”¹¹ An agency may use

⁶ OFFICE OF THRIFT SUPERVISION, EXAMINATION HANDBOOK 010.1 (2004), available at <http://www.ots.treas.gov/docs/4/422001.pdf> (“The Handbook illustrates and describes, for examiners and the thrift industry, certain standards of conduct and prudent operation that [the Office of Thrift Supervision] views as important to the safe and sound operation of savings associations.”). See generally Nina A. Mendelson, *Agency Burrowing: Entrenching Policies and Personnel Before a New President Arrives*, 78 N.Y.U. L. REV. 557, 574, nn.69–70 (2003) (citing other examples of guidance documents).

⁷ See COMM. ON GOV’T REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009, at 5 (2000).

⁸ See Review Counts, <http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init> (search from “1/1/1996” to “12/31/1999” and display by “Stage of Rulemaking”). Only significant regulatory actions are subject to OMB review. See Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,740–41 (Sept. 30, 1993), reprinted as amended in 6 U.S.C. § 501 (2000). A “significant regulatory action” includes any action that materially alters rights and obligations under programs run by an agency. See *id.* at 51,738. The GSA library further identifies those with “economic significance,” probably referring to those with greater than a \$100 million impact upon the economy. See Memorandum from John D. Graham to President’s Management Council (Sept. 20, 2001), available at http://www.whitehouse.gov/omb/inforeg/oira_review-process.html. During this period, the EPA submitted sixty-seven proposed and final rules meeting this standard; the Department of Labor submitted fifteen. See Review Counts, <http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init> (search from “1/1/1996” to “12/31/1999” and display by “Number of Rules and Economically Significant Rules Reviewed and Average Review Times”).

⁹ See Erica Seiguer & John J. Smith, *Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances*, 60 FOOD & DRUG L.J. 17, 25 (2005). In some of the years studied, the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research issued ten times as many guidances as rules. See *id.* at 26 exhibit 5.

¹⁰ See Rakoff, *supra* note 3, at 168 (“If we compare the mid-1990s with the late 1970s or early 1980s, we find that the number of FDA regulations adopted each year in accordance with the APA’s rulemaking procedures declined by about fifty percent. By contrast, since the start of this decade there has been a striking increase in the number of FDA-issued documents intended to give guidance to the regulated industry but not adopted through public procedures. The rate per year for the 1990s is about four hundred percent greater than the rate for the 1980s.”).

¹¹ E.g., Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 381; John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 893 (2004).

such documents to indicate how it will implement a particular statutory or regulatory regime. For example, the EPA recently issued a major guidance document directed at drinking water treatment plants' handling of "filter backwash," the material released when water is run backwards through a drinking water filter to clean it.¹² The document implements a regulation that occupies less than one page of the Code of Federal Regulations.¹³ The guidance, however, contains over eighty pages of detailed information and instructions on what to do with filter backwash.¹⁴ The EPA explicitly states that the guidance may contain material that "go[es] beyond the minimum requirements" of the statute and regulations.¹⁵

This example shows how a guidance document differs critically from a legislative rule. Besides the lack of notice and opportunity for public comment, the EPA guidance expressly states that it is not binding on the EPA or its regulated entities.¹⁶ Particularly since 2000, guidance documents issued by the EPA and other agencies have contained this sort of language, which disclaims any binding legal effect and reserves an agency's discretion to deviate from the guidance's terms.¹⁷

With such a disclaimer, a regulated entity, in theory, need not assume the policy will be the law, but can challenge the agency's position in a later agency enforcement action. Nonetheless, even with the disclaimer, a policy or guidance will, in practice, prompt a regulated entity to change its behavior.¹⁸ The document "still establishes the law for all those unwilling to pay the expense, or suffer the ill-will of challenging the agency in court."¹⁹ Moreover, if the document includes an interpretation of law, that interpretation will receive limited *Skidmore* deference in court, adding to its practical impact on regu-

¹² See U.S. ENVT'L. PROT. AGENCY, IMPLEMENTATION GUIDANCE FOR THE FILTER BACKWASH RECYCLING RULE (2004), available at http://www.epa.gov/safewater/mdbp/guide_fbrt_ig_fnl_06-16-04.pdf.

¹³ National Primary Drinking Water Regulations, 40 C.F.R. § 141.76 (2006).

¹⁴ See U.S. ENVT'L. PROT. AGENCY, *supra* note 12.

¹⁵ *Id.* at vii.

¹⁶ See *id.*

¹⁷ Several major regulatory agencies were criticized in 2000 for failing to provide clear notice of their guidances. See COMM. ON GOV'T REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009, at 8-9 (2000). This criticism probably led the agencies to add disclaimers more systematically. See *infra* note 58 (noting that a guidance may be judicially invalidated if an agency treats it as binding).

¹⁸ See, e.g., Memorandum of Rob Portman to Heads of Executive Departments and Agencies 10 (Jan. 18, 2007), available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-07.pdf> (noting that "[e]ven if not legally binding, such guidance could affect behavior in a way that might lead to an economically significant impact").

¹⁹ Rakoff, *supra* note 3, at 167.

lated entities.²⁰ Finally, despite the lack of formal legal binding effect, agencies increasingly state that they will endeavor to follow guidance document policies.²¹

This phenomenon has led to a vigorous debate among academics,²² members of Congress,²³ and the judiciary²⁴ regarding the legitimacy of policymaking through guidance documents. In the early 1980s, the House and Senate Judiciary Committees approved regulatory reform legislation requiring greater use of notice-and-comment procedures for guidance documents.²⁵ In addition, the now-defunct Administrative Conference of the United States (ACUS)²⁶ repeatedly recommended that agencies adopting guidance use a more public process, including pre-adoption notice and comment for guidance documents having a "substantial impact."²⁷ Congress conducted extensive oversight in 2000. Congress also directly regulated the FDA's issuance of guidances. In the FDA Modernization Act of 1997, Congress clarified that the FDA's guidances were advisory rather than legally binding, and required public participation in some instances.²⁸ Congress further mandated that the FDA issue a binding set of "Good Guidance Practices."²⁹

With the exception of these FDA procedures, however, no other statute requires procedures for agency guidance documents.³⁰ Agency practices vary widely, from seeking no outside views whatsoever to publishing a draft guidance for comment in the Federal Register. In January, 2007, the Office of Management and Budget issued a

²⁰ See *United States v. Mead Corp.*, 533 U.S. 218, 228–29 (2001) (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 139–40 (1944)). Whether interpretive rules should continue to receive *Skidmore* deference is beyond the scope of this paper.

²¹ See *infra* Part II.C.4 (discussing the FDA's Good Guidance Practices and the OMB's Bulletin).

²² See, e.g., Anthony, *supra* note 1; Asimow, *supra* note 11; James W. Conrad Jr., *Draft Guidance on the Appropriate Use of Rules Versus Guidance*, 32 ENV. L. REP. 10,721 (2002); William Funk, *Legislating for Nonlegislative Rules*, 56 ADMIN. L. REV. 1023 (2004); M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV. 1383 (2004); Rakoff, *supra* note 3; Strauss, *supra* note 3.

²³ See, e.g., H.R. REP. NO. 106-1009, at 5.

²⁴ See, e.g., *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987).

²⁵ The Senate bill passed the floor unanimously. See S. 1080, 97th Cong., 128 Cong. Rec. 5297 (daily ed. Mar. 24, 1982). The House bill never came to a vote, however. See H.R. 746, 97th Cong. (1981). In the next Congress, similar legislation was introduced but made little progress. See, e.g., H.R. 220, 98th Cong. (1983); H.R. 2327, 98th Cong. (1983).

²⁶ Although ACUS did receive an authorization for three years' worth of funding, see 5 U.S.C. § 596 (2006) (authorizing three years of appropriations to recreate the Administrative Conference), no funds have yet been appropriated.

²⁷ See 1 C.F.R. § 305.76-5 (1992).

²⁸ See 21 U.S.C. § 371(h)(1) (2000).

²⁹ See *id.* § 371(h)(5). FDA Good Guidance Practices were promulgated by notice-and-comment rulemaking and are now codified at 21 C.F.R. § 10.115 (2006).

³⁰ But see Administrative Procedure Act, 5 U.S.C. § 552(a) (2000) (barring an agency document from having any adverse effect on a person unless it is properly published).

new bulletin providing procedures for “significant” agency documents. Meanwhile, the FAA has stated publicly on the Internet that it will take comment on its Draft Advisory Circulars only from seventeen listed industry organizations.³¹ And judicial review of guidance documents is hard to come by.³²

Some commentators have responded by calling for broad use of notice-and-comment rulemaking for significant policy decisions.³³ Despite the lack of public participation and judicial review, however, most commentators have guardedly defended agency reliance on guidances, arguing that the documents help agencies guide the conduct of lower-level employees.³⁴ In addition, as the argument goes, a guidance document, even without participation or judicial review, beats the alternative: no notice whatsoever of the agency’s implementation or enforcement approaches.³⁵

I want to make a fairly simple point. The debate has generally focused on those whom the agencies regulate. Scholars have largely ignored another important component of the “public” affected by agency regulation: regulatory beneficiaries. This Article focuses not on the direct beneficiaries of agency payments, such as subsidies for health care or housing, but rather on those who benefit indirectly from the regulation of others. These beneficiaries include, for example, employees who expect healthier workplaces, consumers who seek safer products, and those who hope to enjoy and benefit from a cleaner environment.

The case for procedural reform of agency policymaking by guidance becomes considerably stronger once these indirect regulatory beneficiaries are considered. Regulatory beneficiaries have a distinct

³¹ See FED. AVIATION ADMIN., PROCEDURE FOR COMMENTING ON DRAFT ACs, http://www.faa.gov/airports_airtraffic/airports/resources/draft_advisory_circulars/#procedure (last visited Feb. 3, 2007).

³² See *infra* notes 82–91 and accompanying text.

³³ See, e.g., Anthony, *supra* note 1, at 1312–13 (advocating notice-and-comment rulemaking except for interpretive rules that interpret statutory language with a “tangible” meaning).

³⁴ See, e.g., Peter L. Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 ADMIN. L. REV. 803, 808 (2001).

³⁵ See, e.g., *id.* (“Citizens are better off if they can know about these instructions and rely on agency positions, with the assurance of equal treatment such central advice permits, than if they are remitted to the discretion of local agents and to ‘secret law.’”); see also *Hector v. U.S. Dep’t of Agric.*, 82 F.3d 165, 167 (7th Cir. 1996) (“It would be no favor to the public to discourage the announcement of agencies’ interpretations by burdening the interpretive process with cumbersome formalities.”); William R. Andersen, *Informal Agency Advice—Graphing the Critical Analysis*, 54 ADMIN. L. REV. 595, 596–97 (2002) (“The alternative [to informal advice]—having ‘secret law’ regularly applied but unknowable—has never been thought wise in a mature legal system.”); cf. Michael Asimow, *Guidance Documents in the States: Toward a Safe Harbor*, 54 ADMIN. L. REV. 631, 647 (2002) (noting that California agencies have responded to strong procedural requirements by, among other things, “keep[ing] their legal interpretations and policies secret”).

and substantial interest in the way an agency makes policy, and they can suffer unique disadvantages when an agency makes policy through guidance documents. Procedural reform would not necessarily condemn us to a world of “secret” agency law. If an agency’s use of guidance documents were to be subject to more rigorous procedural requirements, the agency would still face significant incentives to make its approaches known to the public in advance.

Part I.A of this Article summarizes the debate on guidance documents to date. Part I.B discusses regulatory beneficiaries and their relationship to administrative agency decision making. Part I.B then analyzes the significant harms faced by regulatory beneficiaries when an agency uses guidance documents. These include reduced access to judicial review and the lack of an opportunity to participate in agency decision making.

Part II discusses some possible responses. It first concludes that neither inaction nor mandatory notice-and-comment rulemaking will provide satisfactory solutions. It then considers a number of better solutions, such as requiring all agencies to apply “good guidance practices” or creating a right to petition for revision or revocation of a guidance document. These solutions offer promise for addressing the concerns of regulatory beneficiaries.

I

GUIDANCE DOCUMENTS AND REGULATORY BENEFICIARIES

A. The Debate to Date

This subpart sets forth three simple examples of agency policymaking through guidance documents to illustrate the basic outlines of the debate. It then summarizes how agencies may use guidance documents. It finally considers the effects of guidances on regulated entities. (The changes in behavior resulting from guidance documents also effectively set policy for regulatory beneficiaries, which I discuss in a later subpart.)

As one example, consider the FDA’s Compliance Policy Guidelines.³⁶ The FDA has the statutory authority to regulate “adulterated” foods sold in interstate commerce.³⁷ The FDA uses guidance documents to describe what it currently views as adulterated food. For example, in 2001, the FDA issued, without notice and comment, a Compliance Policy Guidance for apple juice with more than 50 parts per billion (ppb) of patulin, a naturally occurring but carcinogenic

³⁶ OFFICE OF REGULATORY AFFAIRS, FOOD & DRUG ADMIN., FDA/ORA COMPLIANCE POLICY GUIDES: CHAPTER 5 CONTENTS, http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/ (last visited Feb. 3, 2007).

³⁷ See 21 U.S.C. § 346 (2000).

mold.³⁸ The FDA stated that it would expect its staff to recommend enforcement action against sellers of apple juice with patulin exceeding this level.³⁹

As another example, the Department of Education's program implementing Title IX has largely been accomplished through guidance documents, especially with respect to athletic opportunities for college women.⁴⁰ Since Congress enacted Title IX, the Department of Education has promulgated only one notice-and-comment rule in response to a congressional directive.⁴¹ This 1974 rule generally requires recipients of federal funding that administer athletic programs to "provide equal athletic opportunity for members of both sexes."⁴² The rule contains an unprioritized laundry list of factors for the Department to consider when determining the presence of "equal opportunities."⁴³ The Department of Education has articulated its Title IX policies in a more detailed way only in its guidance documents. For instance, in 1979, in a "Policy Interpretation," the Department announced a detailed set of three factors to assess compliance with Title IX.⁴⁴ The Department has since issued several "clarifications" to

³⁸ See SEC. 510.150 APPLE JUICE, APPLE JUICE CONCENTRATES, AND APPLE JUICE PRODUCTS—ADULTERATION WITH PATULIN, in OFFICE OF REGULATORY AFFAIRS, *supra* note 36, http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg510-150.htm (last visited Feb. 3, 2007) [hereinafter APPLE JUICE]. Consistent with its Good Guidance Practices, the FDA did publish a notice in the Federal Register that the guidance was available and in use at the agency. See Annual Comprehensive List of Guidance Documents at the Food and Drug Administration, 66 Fed. Reg. 53,836 (Oct. 24, 2001) (providing Web pages containing FDA agency guidances).

³⁹ See APPLE JUICE, *supra* note 38.

⁴⁰ See, e.g., OFFICE OF CIVIL RIGHTS, U.S. DEP'T OF EDUC., ADDITIONAL CLARIFICATION OF INTERCOLLEGIATE ATHLETICS POLICY: THREE-PART TEST—PART THREE (2005), *available at* <http://www.ed.gov/about/offices/list/ocr/docs/title9guidanceadditional.pdf> [hereinafter 2005 CLARIFICATION]. Title IX is codified at 20 U.S.C. § 1681(a) (2000).

⁴¹ See Education Amendments of 1974, Pub. L. No. 93-380, § 844, 88 Stat. 484 (1974) (requiring the Secretary of Education to publish rules implementing "the prohibition of sex discrimination in federally assisted education programs which shall include with respect to intercollegiate athletic activities reasonable provisions considering the nature of particular sports").

⁴² 45 C.F.R. § 86.41 (2005).

⁴³ *Id.* The factors include the provision of facilities, equipment, coaching, publicity, and accommodation of the interests and abilities of members of both sexes.

⁴⁴ See Title IX of the Education Amendments of 1972; A Policy Interpretation; Title IX and Intercollegiate Athletics, 44 Fed. Reg. 71,413, 71,418 (Dec. 11, 1979), *available at* <http://www.ed.gov/about/offices/list/ocr/docs/t9interp.html> (outlining three factors for the Department to examine: 1) whether opportunities are "substantially proportionate" to enrollment; 2) whether, if women are underrepresented, athletic programs for them are nonetheless expanding; and 3) whether, if women are underrepresented and athletic programs for them are not expanding, women's "interests and abilities . . . have been fully . . . accommodated").

its policy, including guidance documents issued in 1996⁴⁵ and in 2005.⁴⁶

Another important agency guidance document was issued in the wake of the Supreme Court's 2001 decision in *Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*.⁴⁷ In that case, the Court refused to read the Clean Water Act to authorize federal jurisdiction over isolated, intrastate, nonnavigable wetlands where the sole claimed basis for jurisdiction was the presence of migratory birds.⁴⁸ In response, the EPA issued a legal memorandum announcing changes in its implementation of the Clean Water Act.⁴⁹ This "updated guidance" instructed field staff to refrain from exercising jurisdiction not only over the waters described in the Supreme Court decision, but also over any other intrastate waters not traditionally navigable without seeking prior "formal, project-specific approval" from EPA headquarters.⁵⁰ After the 2006 Supreme Court decision in *Rapanos v. United States*,⁵¹ the EPA further narrowed its guidance by instructing field staff to delay exercising jurisdiction over any waters that are not traditionally navigable.⁵² Although Congress has considered

⁴⁵ OFFICE OF CIVIL RIGHTS, U.S. DEP'T OF EDUC., CLARIFICATION OF INTERCOLLEGIATE ATHLETICS POLICY GUIDANCE: THE THREE-PART TEST (1996), <http://www.ed.gov/about/offices/list/ocr/docs/clarific.html#two> [hereinafter 1996 CLARIFICATION]. For discussion of this measure, see OFFICE OF GEN. COUNSEL, CATHOLIC UNIV. OF AM., NONDISCRIMINATION WITH RESPECT TO STUDENTS (2006), http://counsel.cua.edu/FEDLAW/Title_IXs.cfm. In 1996, the Department indicated that compliance with any of the three prongs, not necessarily the first one, would bring the institution within a Title IX "safe harbor." See 1996 CLARIFICATION, *supra*.

⁴⁶ 2005 CLARIFICATION, *supra* note 40, at iv–v (stating in a "Dear Colleague" letter that online surveys of students would, under certain circumstances, be adequate to document "insufficient interest to support an additional varsity team for the underrepresented sex" allowing the institution to be presumed compliant with the third prong of the three-part test).

⁴⁷ 531 U.S. 159 (2001).

⁴⁸ See *id.* at 171–72.

⁴⁹ See Advanced Notice of Proposed Rulemaking on the Clean Water Act Regulatory Definition of "Waters of the United States," 68 Fed. Reg. 1991, 1995–98 (Jan. 15, 2003).

⁵⁰ *Id.* at 1997–98. The memorandum accompanied an *Advance Notice of Proposed Rulemaking* indicating EPA's interest in revisiting its interpretation of "waters of the United States," those over which the Clean Water Act authorizes the agency to exercise jurisdiction. See 68 Fed. Reg. 1991. EPA ultimately rescinded this advanced notice. See Press Release, U.S. Envtl. Prot. Agency, EPA and Army Corps Issue Wetlands Decision (Dec. 16, 2003), available at <http://www.epa.gov/owow/wetlands/guidance/SWANCC/index.html>.

⁵¹ 126 S. Ct. 2208, 2226–27 (2006) (restricting agency jurisdiction to water resources with a "significant nexus" to traditionally navigable waters).

⁵² See *Hearing Before the Subcomm. on Fisheries, Wildlife, and Water of the S. Comm. on Environment and Public Works*, 109th Cong. (2006) (statement of Benjamin H. Grumbles, Assistant Administrator for Water, United States Environmental Protection Agency, and John Paul Woodley Jr., Assistant Secretary of the Army for Civil Works), available at <http://www.epa.gov/ow/speeches/060801bg.html> ("EPA and the Corps issued immediate guidance to field staff shortly after [*Rapanos*], indicating that . . . to the extent circumstances permit, the field staff should temporarily delay making jurisdictional calls beyond the limits of the traditional section 10 navigable waters . . ."); see also David Loos, *Wetlands: Agencies Urged to*

legislation that would bar the EPA from implementing that guidance,⁵³ this example remains instructive.⁵⁴

Like legislative rules, all of these guidance documents announce broad statements of policy that apply prospectively. As with legislative rules, agencies have developed guidance documents to help implement the agencies' statutory responsibilities. Thus, the FDA's guidance documents are directed at consumers' food-related health risks, the Education Department's at ensuring equal athletic opportunities, and the EPA's at implementing an appropriately scaled water quality protection program.

As a legal matter, each of these guidance documents is exempt from APA notice-and-comment rulemaking requirements as a policy statement, an interpretative rule, or both.⁵⁵ The agency is not legally obligated to assemble a detailed record, disclose its data, prepare extensive analysis, or respond to significant comments.⁵⁶ The guidances are not legally binding upon regulated entities, and they usually are not binding upon the agency either.⁵⁷

Delay Jurisdiction Calls in Wake of Court Decision, GREENWIRE, July 13, 2006 ("Federal wetland regulators are being urged by their superiors in Washington to delay Clean Water Act jurisdictional decisions in the wake of a split Supreme Court decision last month . . .").

⁵³ See David Loos, *Water: House Votes to Boost Protection of Non-navigable Waters, Wetlands*, GREENWIRE, May 19, 2006 (discussing a House appropriations rider passed in May 2006); see also David Loos, *Wetlands: Supreme Court Ruling Breathes Life into Clean Water Bill*, GREENWIRE, June 30, 2006 (suggesting that the *Rapanos* decision may spur congressional action to clarify the scope of the Clean Water Act).

⁵⁴ Other examples abound. For instance, the FDA has used guidance documents to suggest that pharmaceutical companies may advertise their products on television without supplying detailed information on risks and benefits. See U.S. DEP'T OF HEALTH & HUMAN SERVS. ET AL., GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999), available at <http://www.fda.gov/cder/guidance/1804fn1.pdf>. Several agencies within the Treasury Department are using a guidance document to suggest means of reducing risks to consumers and to the banking industry from nontraditional mortgage products, such as "interest only" mortgages. See Interagency Guidance on Nontraditional Mortgage Product Risks, 71 Fed. Reg. 58,609 (Oct. 4, 2006).

⁵⁵ See 5 U.S.C. § 553(b)(A) (2000).

⁵⁶ See *id.*; see also *Lincoln v. Vigil*, 508 U.S. 182, 195–97 (1993) (holding that interpretive rules and policy statements do not require adherence to notice-and-comment procedures, including submission of written data by the agency).

⁵⁷ Agencies generally add disclaimers to this effect. See, e.g., U.S. ENVTL. PROT. AGENCY, PRODUCERS' COMPLIANCE GUIDE FOR CAFOs, at ii (2003), available at http://www.epa.gov/npdes/pubs/cafo_prod_guide_entire_doc.pdf (noting that the document "does not impose legally binding requirements on any party, including EPA, States, or the regulated community"); OFFICE OF REGULATORY AFFAIRS, U.S. FOOD & DRUG ADMIN., FDA COMPLIANCE POLICY GUIDES: INTRODUCTION, http://www.fda.gov/ora/compliance_ref/cpg/introduction.html (last visited Feb. 3, 2007) ("The statements made in the CPG are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended for internal guidance."); Mendelson, *supra* note 6, at 574 n.70 (listing other agency documents containing disclaimers).

Occasionally, an agency will take the position that a guidance document is binding as a matter of law. See Interpretation of Medicaid Days in Medicare DSH Adjustment Calculation, HCFA Ruling No. 97-2 [Dec. 1996–June 1997 Transfer Binder] Medicare & Medicaid

As a consequence, the agency cannot base an enforcement action solely on a regulated entity's noncompliance with a guidance document.⁵⁸ So the seller of apple juice containing 60 ppb of patulin remains free to argue that the FDA's position that its juice is adulterated is arbitrary, capricious, or otherwise not authorized by statute. Likewise, a university remains free to argue that despite not satisfying any of the Education Department's "three factors," it still offers equal athletic opportunities to women.⁵⁹ A court may give limited deference to an agency's statutory interpretation in a guidance document, but the court will not treat it as binding.⁶⁰

Nonetheless, guidance documents often have rule-like effects on regulated entities. Regulated entities often comply with the policies announced in guidance documents, thereby alleviating the agency's burden of enforcement. For example, the apple juice producer may keep patulin levels below 50 ppb to avoid FDA enforcement and the accompanying hassle and penalties. If the penalties for shipping adulterated foods are steep and the costs of compliance are not, the rational juicer will not risk a challenge to the policy in an enforcement action. It will simply conform.⁶¹

By the same token, universities will generally comply with the Title IX guidances. Doing so saves universities the money and time required to respond to an agency inquiry into a potential violation.⁶² Universities may also want to maintain a good long-term relationship with the department and to avoid negative media attention. As a re-

Guide (CCH) ¶ 45,105, at 45,105 (Feb. 27, 1997) ("HCFA . . . statements of policy and interpretation . . . are binding on all HCFA components . . .").

⁵⁸ See Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 DUKE L.J. 1497, 1501 (1992); Strauss, *supra* note 34, at 816. Courts have struck down agency attempts to bind a regulated entity through a policy or guidance because those documents failed to conform with APA rulemaking provisions. See, e.g., *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020–21 (D.C. Cir. 2000); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988); *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 949 (D.C. Cir. 1987). But see *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) (dismissing a petition for review of an EPA decision due to lack of jurisdiction over a claim about EPA guidances).

⁵⁹ Similarly, if a statute provides a private right of action, a consumer or regulatory beneficiary cannot simply rely upon a showing of a regulated entity's violation of a policy or a guidance to establish liability. See *Smith v. Metro. Sch. Dist. Perry Twp.*, 128 F.3d 1014, 1033 (7th Cir. 1997).

⁶⁰ See *United States v. Mead Corp.*, 533 U.S. 218, 226–28 (2001); *Christensen v. Harris County*, 529 U.S. 576, 587 (2000); *Skidmore v. Swift & Co.*, 323 U.S. 134, 139–40 (1944).

⁶¹ See Conrad, *supra* note 22, at 10,724 ("At some level, any document announcing an agency's intentions will have some practical effect of coercing regulated entities' behavior, even if those intentions are tentative or subject to challenge before the agency.").

⁶² This concern is especially salient given that any citizen can initiate an inquiry into a university's Title IX compliance with a simple administrative complaint to the Education Department's Office for Civil Rights. See Office for Civil Rights, U.S. Dep't of Educ., *Questions and Answers on OCR's Complaints Process*, <http://www.ed.gov/about/offices/list/ocr/qa-complaints.html> (last visited Feb. 3, 2007).

sult, universities may seek negotiated settlements in response to Department of Education inquiries rather than risk facing formal enforcement actions.

Meanwhile, agencies have several reasons to prefer using guidance documents to following the APA notice-and-comment procedure. First, issuing a guidance is relatively cheap compared with the costs of notice-and-comment rulemaking.⁶³ The agency also retains flexibility to change the guidance inexpensively and quickly.⁶⁴ These increased costs undoubtedly sharpen the incentive to use guidance documents. The agency may also hope to forestall expensive litigation over the policy's validity and avoid the possibility of an adverse judicial ruling. Since guidance documents are generally not published in the Federal Register,⁶⁵ they are also less likely to be subject to congressional oversight or attention in the media. As described in more detail below, guidances have not been subject to executive oversight either.⁶⁶ In short, by issuing a guidance document, an agency can obtain a rule-like effect while minimizing political oversight and avoiding the procedural discipline, public participation, and judicial accountability required by the APA. The prospect of "compliance for less" is almost certainly among the reasons that agencies use guidance documents rather than go through the effort of notice-and-comment rulemaking.⁶⁷ Meanwhile, the lack of procedural discipline can raise

⁶³ See generally U.S. OFFICE OF MGMT. & BUDGET, DRAFT 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS 6 (estimating total costs for 45 reviewed rules at approximately \$4 billion, but containing no data for the other 4,043 final rules published during the same period). In an overview of 42 significant notices of proposed rulemaking, William F. West calculated the average interval between the formal initiation of research on a policy issue and the publication of a proposed rule to be 4.3 years; the average length of the comment periods was 2.2 years. William F. West, *Formal Procedures, Informal Processes, Accountability, and Responsiveness in Bureaucratic Policy Making: An Institutional Policy Analysis*, 64 PUB. ADMIN. REV. 66, 69 (2004).

⁶⁴ See Strauss, *supra* note 34, at 808 ("The more costly it becomes to generate regulations, and the fewer resources agencies have available to pay those costs, the greater will be the temptation to find other means to generate policy—shortcutting a desirable, even necessary public process.").

⁶⁵ The only exception is a "publication rule." See 5 U.S.C. § 552(a) (2000) (stating that a rule must be published in the Federal Register before the agency can rely on it). This statute might be better read, however, as requiring publication for rules that qualify for a subject-related exception from 5 U.S.C. § 553. See *id.* § 553(a) (2000) (excepting benefits rules).

⁶⁶ See *infra* note 78 and accompanying text. Shortly before this piece was to go to press, President Bush issued Executive Order 13,422, which will permit the OMB to seek consultation on "significant" guidance documents. See *infra* Part II.C.4.

⁶⁷ As Conrad has argued, agencies may also issue policies in guidance documents to avoid contentious issues. See Conrad, *supra* note 22, at 10,725 ("Faced with politically sensitive issues of law with vocal proponents on both sides, agencies are often tempted to craft compromise positions in guidances that are frequently 'draft' or 'interim.'"). The controversy may arise inside the agency as well as outside it. See, e.g., Richard G. Stoll, *Court Strikes Heavy Blow to "Rulemaking" Through Informal Guidance Documents*, 31 ENV'T REP. 1284, 1285

the risk of agency action that serves rent-seeking interests or does not properly engage public preferences. This has led legislators and scholars to complain about agencies' illegitimate use of guidance documents.⁶⁸

By issuing a policy in a guidance document, an agency will forgo some benefits it might have received from notice-and-comment rulemaking. The agency will not, for example, receive useful information from previously unknown sources, and its decision will not be subjected to the discipline of having to respond to comments received.⁶⁹

An agency can have very good reasons to use a guidance document unrelated to its resemblance to a legislative rule. For instance, an agency may simply wish to supervise its employees. Agencies rely on handbooks, directives, and other similar guidance documents to ensure that lower-level employees complete forms correctly and make consistent (and thus more predictable) decisions.⁷⁰ Legislative rules could serve the same purpose, but guidance documents allow the agency to supply information to lower-level employees more cheaply and without risking an outside suit based on later noncompliance with the legislative rule.⁷¹ An agency may also use guidance documents to experiment with new approaches to implementing a program before

(2000) (describing internal disagreements within EPA over stringency of controls and use of guidances to avoid contention).

⁶⁸ See, e.g., *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (criticizing agency use of guidance documents to disseminate legal requirements); COMM. ON GOV'T REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009, at 9 (2000) ("[A]gencies have sometimes improperly used guidance documents as a backdoor way to hyppass the statutory notice-and-comment requirements for agency rulemaking and establish new policy requirements."); Anthony, *supra* note 1; Joel E. Hoffman, *Public Participation and Binding Effect in the Promulgation of Nonlegislative Rules: Current Developments at FDA*, ADMIN. & REG. L. NEWS, Spring 1997, at 1, 1 ("[M]any agencies have responded [to the expense and complexity of rulemaking requirements] by increasingly resorting to other, less formal methods for announcing regulatory norms and expectations."); Manning, *supra* note 11, at 893 ("Because [nonlegislative rules] often have the look and feel of rules promulgated through notice-and-comment procedures, they risk enabling agencies to make an end run around that more formal process.").

⁶⁹ See Robert A. Anthony & David A. Codevilla, *Pro-ossification: A Harder Look at Agency Policy Statements*, 31 WAKE FOREST L. REV. 667, 677 (1996); Asimow, *supra* note 11, at 403 ("A rule is likely to be a better product if its drafters must consider seriously alternatives that they might have overlooked or take account of practical problems that otherwise would crop up only after a rule goes into effect. In addition, an agency may receive more cooperation and less obstruction from regulated interests that have had a hand in shaping the rules within which they must function.").

⁷⁰ See Strauss, *supra* note 34, at 842-43.

⁷¹ See, e.g., *Schweiker v. Hansen*, 450 U.S. 785, 789 (1981) (per curiam) (holding that the Social Security Administration's Claims Manual is not hindning upon an agency); *id.* at 790 n.5 (remarking that nonbinding guidance with occasional erroneous administration is preferable to no rules at all); Lisa Schultz Bressman, Essay, *Schechter Poultry at the Millennium: A Delegation Doctrine for the Administrative State*, 109 YALE L.J. 1399, 1415-16 (2000) (discussing administrative limiting rules).

committing the policies to the binding, less flexible form of the legislative rule.⁷² Finally, because an agency cannot realistically define and set forth every nuance of its approach in a rule document, guidance documents may supplement legislative rules. It would be highly cumbersome to require rulemaking every time a detail is explained or amplified.

From the perspective of a regulated entity, however, an agency's use of a policy or guidance document raises significant reliance concerns. Unlike a notice-and-comment rule, the agency is generally not bound to comply with the statement in the guidance document.⁷³ Guidance documents sometimes contain explicit disclaimers to this effect. Indeed, courts will rarely hold an agency to the terms of such a document.⁷⁴

Moreover, although they may participate informally to some degree,⁷⁵ regulated entities generally lack the entitlement they would possess in rulemaking to participate in the guidance development process.⁷⁶ Besides the extent of public access, the agency also has discretion regarding how much data to disclose. The agency is not obligated to respond to comments or to supply the "concise general statement of their basis and purpose" that the APA would require for rulemaking.⁷⁷

Guidance documents receive very limited review from Congress and the White House. For example, guidance documents to date

⁷² For example, the EPA recently issued an "Interpretive Statement" stating that it did not have jurisdiction to require a Clean Water Act permit before pesticides are sprayed over navigable waters. See *Application of Pesticides to Waters of the United States in Compliance With FIFRA*, 70 Fed. Reg. 5093, 5095 (Feb. 1, 2005). EPA then finalized the position in a notice-and-comment rule. See *Application of Pesticides to Waters of the United States in Compliance with FIFRA*, 71 Fed. Reg. 68,483 (Nov. 27, 2006). For a catalogue of agency motivations in issuing these policies and guidances, see M. Elizabeth Magill, *Agency Self-Regulation 15-19* (Oct. 2006) (unpublished manuscript, on file with author).

⁷³ See *supra* note 57 and accompanying text.

⁷⁴ See, e.g., *Schweiker*, 450 U.S. at 789 (finding agency claims manual not binding); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538 (D.C. Cir. 1986) (declining to dismiss Labor Department enforcement action that did not conform to Labor Department guidelines on citing companies for their contractors' violations). For additional case law analysis and citations, see William Funk, *When Is a "Rule" a Regulation? Marking a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 ADMIN. L. REV. 659, 661-62 (2002); Mendelson, *supra* note 6, at 575 n. 71; see also *supra* text accompanying note 21 (noting increased internal and external pressure upon agencies to conform to guidance terms).

⁷⁵ See, e.g., Cary Coglianese, Richard Zeckhauser & Edward Parson, *Seeking Truth for Power: Informational Strategy and Regulatory Policymaking*, 89 MINN. L. REV. 277, 327-28 (2004) (discussing extensive reliance by regulators on informal interaction); Strauss, *supra* note 34, at 805 (discussing Nuclear Regulatory Commission's reliance on informal consultation).

⁷⁶ See *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 252-53 (2d Cir. 1977) (invalidating agency rule for failure to disclose data and respond to significant comments).

⁷⁷ See 5 U.S.C. § 553(c) (2000).

have been exempt from the Office of Management and Budget (OMB) review normally applied to legislative rules.⁷⁸ On January 18, 2007, however, President Bush issued Executive Order 13,422, which gives OMB the option to demand consultation with an agency prior to its issuing a “significant” guidance document.⁷⁹ Given OMB’s resource constraints, it is unclear how frequently it will exercise this option. Meanwhile, guidance documents also are not subject to Congressional Review Act requirements.⁸⁰ While Congress can, of course, exercise oversight of any agency action, such oversight is generally ad hoc. Congressional review of policy and guidance documents is highly limited at best.⁸¹

Finally, judicial review of these decisions is often difficult to obtain. If a guidance document is not signed by the head of the agency, is a staff-level document, or states it is not binding, then a policy contained in the document may not be considered a “final agency action.”⁸² Even if a court considers the document to be a final action, it may not be “ripe” for review outside the context of a particular situation.⁸³ Courts have only occasionally recognized the immediate practical effect a guidance document may have as a basis for finding the document ripe for review.⁸⁴ More often, courts have declined to re-

⁷⁸ See Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,737 (Sept. 30, 1993). While the OMB posted for comment a Proposed Bulletin for Good Guidance Practices in November 2005, that document does not appear to provide for OMB review of any particular guidance document prior to release. See Rachel Urdan, *OMB Plan to Expand Guidance Reviews Could Delay Key EPA Policies*, INSIDE EPA ENVTL. NEWSSTAND (Sept. 22, 2005).

⁷⁹ See Exec. Order No. 13,422, 72 Fed. Reg. 2703 (Jan. 18, 2007). “Significant” guidance documents include those that lead to an annual effect of more than \$100 million on the economy or raise novel legal or policy issues. See *id.*

⁸⁰ See 5 U.S.C. §§ 801–08 (2000). Nor are guidances subject to a number of other statutory requirements for studies, coordination, or justification, including the Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 601 (2000), and the Paperwork Reduction Act, 44 U.S.C. § 3502 (2000).

⁸¹ This is partly due to the sheer volume of these documents. Moreover, the GAO has generally noted with respect to rulemaking that efforts to increase congressional oversight have been relatively unsuccessful. See *Federal Rulemaking: Past Reviews and Emerging Trends Suggest Issues that Merit Congressional Attention: Hearing Before the Subcomm. on Commercial and Administrative Law of the H. Comm. on the Judiciary*, 108th Cong. (2005) (statement of J. Christopher Mihm, Managing Director, Strategic Issues), available at <http://judiciary.house.gov/media/pdfs/mihm110105.pdf> (“[O]ur reviews suggest that mechanisms to increase congressional influence, such as procedures for Congress to disapprove proposed rules, appear to have been less able [than presidential mechanisms] to influence changes in agencies’ rules to date.”).

⁸² See, e.g., *Nat’l Automatic Laundry & Cleaning Council v. Schultz*, 443 F.2d 689, 701–02 (D.C. Cir. 1971).

⁸³ See, e.g., *Nat’l Ass’n of Home Builders v. Norton*, 415 F.3d 8, 14 (D.C. Cir. 2005) (refusing to review a survey protocol for butterflies developed by the Fish and Wildlife Service because the document was non-binding).

⁸⁴ See, e.g., *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380–81 (D.C. Cir. 2002); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020–23 (D.C. Cir. 2000); *Clean Air Implementation*

view the guidance document, especially if the agency has specifically disclaimed any binding effect.⁸⁵

A regulated entity may, in theory, challenge the policy set forth in a guidance if the agency uses it as the basis for an enforcement action.⁸⁶ This is because an enforcing agency cannot rely solely on non-compliance with the guidance to support an enforcement action.⁸⁷ Instead, the agency must defend its understanding of statutory and regulatory requirements⁸⁸—say, that apple juice with more than 50 ppb patulin should be understood to be “adulterated” under the statute. This gives the regulated entity a chance to litigate the legality and rationality of the agency’s position.

The regulated entity may rationally forgo this opportunity, however, by complying with the policy and thus avoiding an enforcement action.⁸⁹ The choice between compliance and challenge will depend on just how problematic the regulated entity perceives the agency’s decision to be. If an agency decision seems truly meritless, thus increasing the likelihood of success upon judicial review, the regulated entity may elect not to comply and will wait for a judicial enforcement action in which the policy can be challenged. In a closer case, the

Project, 150 F.3d 1200, 1204 (D.C. Cir. 1998); *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320–21 (D.C. Cir. 1988).

⁸⁵ See, e.g., *Util. Air Regulatory Group v. EPA*, 320 F.3d 272, 278–79 (D.C. Cir. 2003) (holding unripe a challenge to EPA manual provisions requiring greater monitoring in permits); *Truckers United for Safety v. Fed. Highway Admin.*, 139 F.3d 934, 938 (D.C. Cir. 1998) (finding informal statements unripe); *Aulenback, Inc. v. Fed. Highway Admin.*, 103 F.3d 156, 167 (D.C. Cir. 1997); see also *Ohio Forestry Ass’n v. Sierra Club*, 523 U.S. 726, 726 (1998) (finding forestry plans not ripe for review); *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 892–93 (1990) (holding the “land withdrawal review program” not a discrete agency action ripe for review).

The court reviewed the FDA guidance document on genetically modified materials in *Alliance for Bio-integrity v. Shalala*, but apparently no finality or ripeness argument was advanced. See 116 F. Supp. 2d 116, 171 (D.D.C. 2000) (rejecting arguments that the statement implicated FDA’s exercise of enforcement discretion and was hence unreviewable). Although the court held that the policy statement provided a “focal point” for review, it nonetheless declined to find the guidance to be an “agency action” for purposes of NEPA’s environmental review requirement. See *id.* at 174.

In *Utility Air Regulatory Group v. EPA*, the D.C. Circuit also relied on the nonbinding nature of the EPA Manual statements to find that the statements did not injure the plaintiff in any “imminent or redressable manner,” leaving the plaintiff without standing to challenge the agency statements. 320 F.3d at 278.

⁸⁶ This opportunity has led a number of courts to find that no hardship will flow from denying review of a guidance at the outset, reinforcing the conclusion that the guidance is not ripe for review. See, e.g., *Util. Air Regulatory Group*, 320 F.3d at 279; *Gen. Elec.*, 290 F.3d at 381.

⁸⁷ See *supra* note 58 and accompanying text.

⁸⁸ See 5 U.S.C. § 552(a) (2000).

⁸⁹ See Strauss, *supra* note 34, at 817 (“[I]n some circumstances conformity may be so simple, and the consequences of disregarding a publication rule that would be upheld may be so severe, as to make those who learn of a publication rule unwilling to take the risk of its concrete application to them.”).

regulated entity may weigh the costs of compliance against the chances of success on review, the risk and size of possible financial and other penalties (such as bad publicity), and the costs of litigating against the agency position in the event the agency brings an enforcement action. If compliance is not expensive, for example, the regulated entity may never challenge the policy. The regulated entity's opportunity to challenge an agency policy at the time an agency enforces it is often inferior to the pre-enforcement challenges frequently available for notice-and-comment rules. Although a pre-enforcement challenge does impose litigation costs, it generally allows the regulated entity to learn whether an agency policy is valid before it must decide whether to invest in compliance. Moreover, litigation costs may be lower in a pre-enforcement challenge to a rule because regulated entities may pool their funds through a trade association which then challenges the rule.⁹⁰ By contrast, in the enforcement setting, the regulated entity will usually elect individual representation.⁹¹

Despite these limits on agency accountability to regulated entities, scholars have generally reacted to agency reliance on guidance documents with the guarded conclusion that this practice is better than nothing.⁹² While a regulated entity's interests in certainty and in its opportunity to challenge policy may suffer when an agency embodies the policy in a guidance, a regulated entity can nonetheless receive very valuable information about an agency's enforcement plans by reviewing guidance documents.⁹³ Moreover, such documents enable agencies to manage their numerous employees who have contact with the public, reducing the risk of arbitrary decisions and increasing the chances that individual agency employees will treat like cases alike.⁹⁴ Indeed, they are "important encouragements to agency regularity and even-handedness."⁹⁵

⁹⁰ The apparent preference of trade associations for pre-enforcement challenges to rules supports this intuition. *See, e.g., United Transp. Union v. Foster*, 205 F.3d 851, 855 (5th Cir. 2000).

⁹¹ Of course, the foregoing discussion assumes that the regulated entity is unhappy with the agency policy. For reasons of regulatory certainty, the regulated entity would probably prefer a favorable policy to be in the form of a binding rule. Nonetheless, a favorable guidance document is clearly preferable to no statement from the agency at all.

⁹² *See, e.g., Asimow, supra* note 11, at 388 ("It opens a window on an agency's decisional process and thus enables a person who is detrimentally affected to make an informed argument to the correct staff member that an exception should be made. It permits everyone who must deal with the agency equal access to vital information, thus diminishing the advantage held by experienced professionals or former agency staff members."); *Strauss, supra* note 34, at 808 ("Citizens are better off if they can know about [agency instructions to responsible bureaucrats] and rely on agency positions, with the assurance of equal treatment such central advice permits, than if they are remitted to the discretion of local agents and to 'secret law.'").

⁹³ *See supra* note 35 and accompanying text.

⁹⁴ *See supra* note 34 and accompanying text.

⁹⁵ *Strauss, supra* note 34, at 809.

B. Regulatory Beneficiaries and Agency Accountability

While the scholars who defend guidances have considered the interests of citizens in their discussion, citizens are not all the same. Thus far, my overview—as well as the scholarly debate itself—has focused primarily on those whom the agency directly regulates. However, this discussion has not adequately considered others whose behavior is not directly regulated, but who nonetheless benefit from an agency's program.⁹⁶ I turn now to a discussion of these indirect regulatory beneficiaries and how they fare when agencies develop policy through guidance documents.

The beneficiaries of statutes most obviously include people who directly benefit from government action, such as those who receive cash or services from, say, Social Security or Medicaid. Direct beneficiaries possess the classic “new property” of Charles Reich.⁹⁷ Agencies generally know about direct beneficiaries because they receive benefits either directly from the agency itself or from an implementing state or local agency.⁹⁸

My concern is with a different group: indirect regulatory beneficiaries that gain from government action but lack any focused or direct relationship with the agency.⁹⁹ These groups benefit from the government's regulation of others.¹⁰⁰ Of the countless statutes passed

⁹⁶ Sunstein challenges this distinction, arguing that agency rules often create a bundle of rights and responsibilities for all interested parties. See Cass R. Sunstein, *What's Standing After Lujan? Of Citizen Suits, "Injuries," and Article III*, 91 MICH. L. REV. 163, 186–88, 196–97 (1992).

⁹⁷ See Charles A. Reich, *The New Property*, 73 YALE L.J. 733, 734–36 (1964) (arguing that much individual wealth now comes from benefit claims against the government and that such claims warrant a similar legal status to traditional property interests). Reich's argument was largely accepted in *Goldberg v. Kelly*, 397 U.S. 254, 262 (1970) (holding that the Constitution requires due process before revocation of welfare benefits).

⁹⁸ See Reich, *supra* note 97, at 740–43 (listing kinds of benefits that entities receive directly from the government).

⁹⁹ There may also be a class of indirect regulatory cost-bearers. For example, consumers may pay higher electric bills as a result of environmental regulation of power plants, but lack a direct relationship with government. I do not focus on this class here, but it is worth noting that the concerns raised in this Article generally affect such a class less. The interests of these cost-bearers are often aligned with those of the major cost-bearers of the program, the regulated entities. That may mean they receive virtual representation in agency proceedings and litigation. Moreover, regulated entities may have an incentive to organize these parties to assist in lobbying before the agency or the courts. For example, power plants and businesses in Michigan advocating for less environmental regulation of utilities are also asserting the interests of consumers. See, e.g., Mike Johnston, *State Mercury Rule: Added Costs without Added Benefits*, MIBIZ, Oct. 2, 2006 (presenting Michigan Manufacturers Association argument against Michigan rule regulating power plant mercury emissions based on “significant costs for individual consumers and businesses”), available at <http://www.mibiz.com/absolutenm/templates/coltemplate.asp?articleid=9912&zoneid=64>.

¹⁰⁰ Cf. Richard B. Stewart & Cass R. Sunstein, *Public Programs and Private Rights*, 95 HARV. L. REV. 1193, 1202–03 (1982) (describing a class that benefits when “government

by Congress to serve the “public interest,”¹⁰¹ many regulatory statutes, including those aimed at pharmaceutical safety, workplace safety, and protecting the environment, are meant to benefit identified groups other than those directly regulated.

For example, in response to reports of lead in Boston’s tap water and carcinogenic chemicals in tap water in Pittsburgh and New Orleans, Congress enacted the Safe Drinking Water Act, which regulates drinking water suppliers to protect tap water users.¹⁰² As another example, under the Federal Meat Inspection Act, the U.S. Department of Agriculture (USDA) has the authority to ensure the quality of American beef by regulating and inspecting beef slaughterhouses.¹⁰³ While these statutory schemes are intended to benefit tap water drinkers and beef consumers, the schemes rarely lead to direct interaction between tap water drinkers and the EPA or between beef consumers and the USDA.¹⁰⁴

Focusing specifically on these regulatory beneficiaries might implicate a number of doctrinal issues, including the question of who could claim the benefit of constitutional due process requirements or have standing to seek judicial review of agency actions. Each of these issues has been the focus of significant scholarship.¹⁰⁵ For example, while courts almost automatically conclude that a regulated entity has standing to challenge agency action, recognition of standing for regulatory beneficiaries is more recent and its scope more subject to de-

decisions are implemented against private persons through the coercive exercise of official power”). The agency process issues faced by another category of indirect beneficiaries—citizens who benefit from government spending, such as on highways, libraries, or parkland acquisition—are beyond the scope of this paper.

¹⁰¹ Many statutes fall within this extremely wide range. See, e.g., Egg Research and Consumer Information Act, Pub. L. No. 93-428, § 2, 88 Stat. 1171, 1171 (1974) (codified as amended at 7 U.S.C. § 2701 (2000)) (“It has long been recognized that it is in the public interest to provide an adequate, steady supply of fresh eggs readily available to the consumers of the Nation.”); Department of Education Organization Act, Pub. L. No. 96-88, § 102, 93 Stat. 668, 670 (1979) (codified as amended at 20 U.S.C. § 3402 (2000)) (finding the creation of the Department of Education to be in the public interest).

¹⁰² See Pub. L. No. 93-523, 88 Stat. 1660 (1974) (codified as amended at 42 U.S.C. § 300(f)–(j) (2000)). See generally James L. Agee, *Protecting America’s Drinking Water: Our Responsibilities Under the Safe Drinking Water Act*, EPA J., March 1975, at 2, 3, available at <http://www.epa.gov/history/topics/sdwa/07.htm>.

¹⁰³ 21 U.S.C. §§ 601–695 (2000).

¹⁰⁴ Occasionally a statute will provide for an advisory committee with regulatory beneficiaries among its members. See, e.g., 42 U.S.C. §§ 2851–2853(d) (2000) (requiring creation of federal scientific advisory committee on toxicological methods).

¹⁰⁵ See generally Stewart & Sunstein, *supra* note 100. For an example of a due process analysis that does consider a regulatory beneficiary’s interests, see *Brock v. Roadway Express*, 481 U.S. 252, 262 (1987) (considering a whistleblower’s interest in not being discharged, as well as his employer’s interest in having the unrestricted ability to employ at will).

bate.¹⁰⁶ Regulatory beneficiaries sometimes have a statutory right to enforce the regulatory regime, as with citizen suits and express and implied private rights of action.¹⁰⁷

I will save these debates on standing or due process for another day. Rather, my argument is that we should focus more consciously on the interests of regulatory beneficiaries in the design of administrative procedures. I will not attempt a comprehensive typology of regulatory beneficiaries. However, one can fairly say that for each of the regulatory statutes thus far mentioned, and for countless others, there is a class of persons who obtain tangible benefits from the regulation of others.¹⁰⁸ Some also obtain benefits we might view as more abstract or ideological. For example, childless members of minority groups might benefit more abstractly from IRS enforcement of tax code provisions revoking advantages to discriminatory schools.¹⁰⁹ Regulatory beneficiaries may be specifically named in the statute that benefits them. They may have fought in Congress to obtain passage of the statute, or Congress may otherwise have suggested that the statute should benefit these segments of the public. Alternatively, it may simply have been widely understood that the statute was meant to regulate one segment of society while indirectly benefiting another group. For example, the statute governing the generation of hazardous air pollution regulates industrial emitters largely for the benefit of neighbors and workers.¹¹⁰

In the vast majority of these regulatory statutes, Congress has not set the precise standards of conduct itself but has left it to administrative agencies to fill in the blanks.¹¹¹ We already recognize the strength of regulated entities' interests in this implementation by recognizing their constitutional standing to challenge agency action and requiring due process before agencies impose sanctions.¹¹² Moreo-

¹⁰⁶ See, e.g., Daniel A. Farber, *Uncertainty as a Basis for Standing*, 33 HOFSTRA L. REV. 1123 (2005); William A. Fletcher, *The Structure of Standing*, 98 YALE L.J. 221 (1988); Reich, *supra* note 97.

¹⁰⁷ See Stewart & Sunstein, *supra* note 100, at 1202-16.

¹⁰⁸ I focus here on regulatory statutes, but procurement and public works statutes also have indirect beneficiaries, such as drivers on newly repaved highways and other users of public projects.

¹⁰⁹ See *Allen v. Wright*, 468 U.S. 737, 750 (1984). The question of whether standing should be expanded to encompass such groups is beyond the scope of this paper.

¹¹⁰ See Clean Air Act, 42 U.S.C. § 7412(d) (2000) (requiring "the maximum degree of reduction" in hazardous air emissions); *id.* § 7412(f)(1)(C) (requiring investigation of "the actual health effects with respect to persons living in the vicinity of sources").

¹¹¹ See, e.g., 21 U.S.C. § 346 (2000) (allowing the Secretary to promulgate regulations defining adulterated levels of foods "to such extent as he finds necessary for the protection of public health").

¹¹² See, e.g., PETER L. STRAUSS, *ADMINISTRATIVE JUSTICE IN THE UNITED STATES* 315 (2d ed. 2002) ("[S]tanding is not an issue for those who object to regulation of their own conduct.").

ver, statutes often grant regulated entities procedural protections beyond what the Constitution requires. We should see the interests of regulatory beneficiaries in the way an agency carries out its mandate as real interests, and ensure that beneficiaries too are among those that can hold an agency accountable.

In some settings, a particular regulatory beneficiary's loss of expected benefits may not be as serious as the loss suffered by a regulated entity possibly facing fines or stringent permit requirements. In other settings, however, such as those involving health, beneficiary losses might be the significant ones. Consider the power plant that emits excessive pollution, aggravating the asthma of nearby residents. At a minimum, regulatory beneficiaries have a substantial interest—at least as significant as that of regulated entities—in holding the agency accountable for doing the job that Congress set before it. Why should tap water drinkers have any less interest than water treatment plants in how the EPA sets standards for drinking water? Why should neighbors of a power plant have any less interest than a power plant operator in how the EPA sets Clean Air Act hazardous air pollutant standards for such plants?

The interests of regulatory beneficiaries in many such programs delegated to agencies are undeniable and significant, and we should ensure that these groups can hold the agencies accountable. “[E]nforcement of public policy directives is a crucial task of modern government,”¹¹³ and regulatory beneficiaries have an enormous stake in the proper implementation of those directives.

What might it mean for regulatory beneficiaries to hold an agency accountable? Putting this question in context requires briefly examining the major theories of the administrative state. As a theoretical matter, scholars have struggled to locate a source of democratic legitimacy for administrative agencies, which the Constitution does not mention and whose officials are not directly elected.¹¹⁴ One view is that the agency is an agent of the major “democratic” branches of government, either Congress, the Executive, or both.¹¹⁵ This “transmission belt” model assumes that Congress has made all relevant value judgments in the authorizing statute and that the agency is merely a technocratic implementing machine.¹¹⁶ This view has long been out of favor given the reality that agencies may—and regularly do—make

¹¹³ Edward Rubin, *The Myth of Accountability and the Anti-administrative Impulse*, 103 MICH. L. REV. 2073, 2105 (2005).

¹¹⁴ See, e.g., Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2260–62 (2001) (discussing the legitimacy of agency self-control and the “transmission belt” model).

¹¹⁵ See, e.g., *id.* at 2272–309 (discussing agency control under Presidents Reagan and Clinton).

¹¹⁶ See, e.g., *id.* at 2255–60 (discussing and criticizing the transmission belt model).

value-laden policy choices.¹¹⁷ Instead, in view of the discretion Congress typically grants agencies—which renders judicial enforcement less effective—and the ad hoc nature of congressional oversight, scholars have increasingly relied on presidential control as a source of democratic legitimacy for the administrative state.¹¹⁸ As I have discussed elsewhere, presidential control can supply legitimacy for executive branch agencies only to a certain extent: presidential resources to monitor agencies are limited, and presidential elections very imperfectly communicate the public's preferences on agency policies.¹¹⁹ Some civic republican scholars have argued that agency deliberations are legitimate because they are intrinsically democratic, supplying an opportunity for a truly deliberative decision-making process in which all viewpoints are effectively represented.¹²⁰ However, the legitimacy of these deliberations critically depends upon the agency officiating over a genuinely participatory, rather than a skewed, decision-making process.¹²¹ Similarly, neopluralists view agency decisions as legitimate because the agency can formulate policy by aggregating information and preferences received from a wide variety of interest groups.¹²²

Agency accountability is an important component under any of these theories of the administrative state's legitimacy. In other words, the agency must be regularly obligated to disclose and justify its actions, and the agency's authority must be limited by meaningful constraints, whether internal or external.¹²³ Suppose we adopt one of the

¹¹⁷ See Richard B. Stewart, *Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1676 (1975).

¹¹⁸ See Kagan, *supra* note 114, at 2326–27; Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 91–92 (1985); Mendelson, *supra* note 6, at 580–81.

¹¹⁹ See Mendelson, *supra* note 6, at 617–19 (arguing that presidential elections are generally a poor method of discerning public preferences on particular agency policies).

¹²⁰ See *id.* at 585; Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1515 (1992).

¹²¹ See Seidenfeld, *supra* note 120, at 1515. Matthew Adler has critiqued these “proceduralist” civic republican and pluralist theories on the ground that they are either purely instrumental without any independent value, or unjustified because public participation cannot transform a nonoptimal result into one preferred from the welfare perspective. See Matthew D. Adler, *Beyond Efficiency and Procedure: A Welfarist Theory of Regulation*, 28 FLA. ST. U. L. REV. 241, 267–88 (2000). Adler's account suffers, however, from a failure to recognize critical practical uncertainties in the process as well as the possibility that preferences may not be well-formed prior to the deliberation, but instead may be developed through the dialogic process. See Daniel Rodriguez, *Regulatory Incrementalism and Moral Choices: A Comment on Adlerian Welfarism*, 28 FLA. ST. U. L. REV. 375, 389 (2000) (suggesting that given regulatory incrementalism, “certain procedural forms are more likely correlated with efficient regulation”).

¹²² See IAN AYRES & JOHN BRAITHWAITE, *RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE* 87 (1992); Stewart, *supra* note 117, at 1712 (detailing similarities between the administrative and legislative processes).

¹²³ See Mendelson, *supra* note 6, at 577–78; see also Gerald E. Frug, *The Ideology of Bureaucracy in American Law*, 97 HARV. L. REV. 1276, 1284 (1984) (observing that various mod-

principal-agent models, such as the transmission belt model or the presidential control model. In that case, a regulatory beneficiary seeking to hold an agency accountable for a policy decision would want to invoke the authority of Congress or the President to constrain the agency's actions and to see that it is properly implementing the relevant statute, thus conforming to the path set by the principal. The regulatory beneficiary might also wish to invoke the authority of the courts to enforce an agency's compliance with various governing statutes and with the requirements of the Administrative Procedure Act, including the "arbitrary or capricious" standard.¹²⁴

Due to serious resource constraints facing both the political branches and the person or entity wishing to invoke oversight, however, a regulatory beneficiary or regulated entity cannot be sure of gaining access to genuine presidential or congressional oversight. Moreover, judicial oversight is relatively deferential. The APA "arbitrary or capricious" review standard is weak; meanwhile, courts also defer to agency legal interpretations under *Chevron*,¹²⁵ or less strongly under *Skidmore*¹²⁶ and *Mead*.¹²⁷ Nonetheless, judicial review continues to represent an important external check on agency action not only because judges can demand transparency and rationality from an agency, but also because an individual or entity—assuming it can meet threshold conditions such as standing—can invoke judicial review more easily than congressional oversight.

Under a civic republican or neopluralist model,¹²⁸ each of which takes an agency-centered approach to legitimacy, a regulatory beneficiary would want the opportunity to supply information to the agency and to participate fully in the agency's decision-making process. In a neopluralist model, participation would help ensure that the agency considers (and aggregates) the full range of interests. In a civic republican model, participation by all affected groups, including regulatory beneficiaries, would increase the likelihood that the agency's process will thoroughly engage relevant viewpoints and that the agency's decision will thus be perceived as legitimate.¹²⁹

Thus, the principal-agent theories suggest that whether regulatory beneficiaries can hold an agency accountable for implementing a

els of administrative agencies are aimed at characterizing bureaucracies as being "under control").

¹²⁴ 5 U.S.C. § 706(2)(A) (2000) (requiring a finding that agency action not be "arbitrary, capricious, an abuse of discretion, or otherwise contrary to law").

¹²⁵ *Chevron, U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837 (1984).

¹²⁶ *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

¹²⁷ *United States v. Mead Corp.*, 533 U.S. 218 (2001).

¹²⁸ See *supra* notes 120–22 and accompanying text.

¹²⁹ See generally Mendelson, *supra* note 6, at 585–88 (describing the neopluralist and civic republican conceptions of legitimacy).

particular statutory program will depend on the ability of beneficiaries to invoke external mechanisms of control. Courts are especially important, since they are likely to be more broadly accessible than congressional or presidential oversight processes. The civic republican and neopluralist models stress the importance of regulatory beneficiary participation, including the extent to which beneficiaries have access to agency processes and whether the agency directly engages their perspectives. As the next section describes, however, when an agency uses guidance documents rather than rulemaking to set policy, regulatory beneficiaries suffer significant losses to all these means of accountability.

C. Regulatory Beneficiaries, Guidance Documents, and Agency Accountability

The original question remains: when an agency chooses to issue a policy in the form of a guidance rather than a rule, what are the consequences for regulatory beneficiaries? Close analysis suggests that this choice interferes with critical tools that regulatory beneficiaries can use to hold agencies accountable for the policy choices they make. Regulatory beneficiaries lose significant access both to the courts and to their ability to participate in agency decision making.¹³⁰ In turn, regulatory beneficiaries are less likely to view agency choices as legitimate.

1. *Loss of Judicial Review Opportunities*

First, when an agency enunciates its approach to enforcing regulatory standards in a guidance rather than a rule, it will likely deny a regulatory beneficiary the opportunity for judicial review that is eventually afforded to a regulated entity. As already noted, neither regulatory beneficiaries nor regulated entities have easy access to judicial review of a guidance document.¹³¹ Even assuming that standing to

¹³⁰ Like regulated entities, regulatory beneficiaries may also lose access to executive and congressional oversight when an agency elects to make policy through guidance documents. See *supra* notes 78–81 and accompanying text.

¹³¹ See *supra* text accompanying notes 82–85.

sue can be shown,¹³² a guidance document may not be considered final agency action or ripe for review.¹³³

The regulated entity, however, can challenge the agency policy at the time of enforcement. The scholarly defense of guidance documents has largely turned on this eventual access to judicial review. In the widely quoted words of E. Donald Elliott, who defended letting an agency choose between rulemaking and taking a policy position in an enforcement action, "As in the television commercial in which the automobile repairman intones ominously 'pay me now, or pay me later,' the agency has a choice. . . ."¹³⁴ The regulated entity will have the ultimate ability to make the agency "pay," in the sense of compelling the agency to mount a defense of its policy.

A regulatory beneficiary, in contrast, may never have that opportunity. Take the Clean Water Act guidance instructing EPA staff not to assert jurisdiction over *any* intrastate waters not traditionally navigable without formal, project-specific approval from the agency's headquarters.¹³⁵ This policy was undoubtedly welcomed by regulated entities, who could look forward to saving the costs of a discharge permit, effluent control, or of mitigation requirements prior to filling a wetland. But allowing easier destruction of wetlands might trouble environmentalists. Similarly, assume that the FDA's choice of a tolerable patulin level in apple juice, while welcomed by juicers, is one that consumer groups believe inadequately protects public health. In both

¹³² While many have argued that standing for regulatory beneficiaries is insufficiently broad, *see, e.g.*, Cynthia R. Farina, *Standing*, in *A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES* 17, §§ 2.032–.033 (John F. Duffy & Michael Herz eds., 2005); Fletcher, *supra* note 106, at 255–65, a regulatory beneficiary's standing to challenge a policy statement is unlikely to differ much from the beneficiary's ability to challenge a notice-and-comment rule. However, a plaintiff may have greater difficulty making the factual showing that the threatened injury is sufficiently "concrete" or "immediate," since that will depend on agency adherence to the guidance, regulated entity compliance, or both.

¹³³ *See generally* *Abbott Labs. v. Gardner*, 387 U.S. 136 (1967) (reversing the Third Circuit's ruling that the suit for a pre-enforcement injunction and declaratory judgment that drug regulations were invalid was not ripe for adjudication); *Nat'l Automatic Laundry & Cleaning Council v. Schultz*, 443 F.2d 689, 694–704 (D.C. Cir. 1971) (holding that appellants seeking a pre-enforcement declaratory judgment on the applicability of the Fair Labor Standards Act had a ripe controversy).

¹³⁴ E. Donald Elliott, *Re-inventing Rulemaking*, 41 DUKE L.J. 1490, 1491 (1992) ("[The agency] can go through the procedural effort of making a legislative rule now and avoid the burdens of case-by-case justification down the road, or it can avoid the hassle of rulemaking now, but at the price of having to engage in more extensive, case-by-case justification down the road. The central point is, however, that this is and should remain the agency's choice.").

¹³⁵ *See* Advanced Notice of Proposed Rulemaking on the Clean Water Act Regulatory Definition of "Waters of the United States," 68 Fed. Reg. 1991, 1997 (Jan. 15, 2003). The memorandum also was coupled with an *Advance Notice of Proposed Rulemaking on the Clean Water Act Regulatory Definition of "Waters of the United States,"* indicating the EPA's interest in revisiting its interpretation of "waters of the United States," those over which the Clean Water Act authorizes the agency to exercise jurisdiction. *See id.* at 1991.

cases, the part of the policy that concerns consumers or environmental users will be realized primarily through agency decisions not to bring enforcement actions. Such agency inaction is generally immune from review.¹³⁶ Further, if apple juice producers or other regulated entities elect to change their conduct to comply with the guidance's terms, this will also reduce the prospect of enforcement litigation. Again, no enforcement actions will mean no judicial oversight.

Even when an agency seeks to vindicate its policy by filing an enforcement action against a regulated entity, a regulatory beneficiary's ability to get a hearing on its challenge to that policy will not be guaranteed. Suppose, for example, that in the case of the EPA guidance on intrastate waters, a regulated entity deposits "fill" in traditionally navigable intrastate waters without seeking a permit. The Army Corps of Engineers then brings an enforcement action. A regulatory beneficiary, such as a neighbor who boats on these waters, would be hard-pressed to use this action to challenge the guidance's policy on more isolated intrastate waters. The boater would face several obstacles. First, Federal Rule of Civil Procedure 24(a) might not entitle the boater to intervention.¹³⁷ The boater would first need to prove that her interests were not adequately being represented by the agency, a difficult argument because both parties would presumably take the position that the defendant was violating the statute. Under some circumstances, the boater might nonetheless be able to succeed by arguing that a court decision upholding the agency's policy as valid and nonarbitrary under the statute would impair the boater's interests.

On the other hand, the boater would also face strong arguments that the court could resolve the enforcement action without addressing the overall legality of the policy, that any resolution of those issues

¹³⁶ See *Heckler v. Chaney*, 470 U.S. 821, 831–32 (1985). If a beneficiary possesses a private right of action, however, or the statute provides for citizen suits, the beneficiary could litigate the policy issue in that setting. See *infra* Part II.C.5 (discussing availability of citizen suits). Of course, an agency can always decline to address an issue altogether. Under some circumstances, a regulatory beneficiary will prefer inadequate agency guidance to none at all. Consistent failure to implement a statute, however, is more likely to lead to congressional and presidential oversight.

The APA provides that any person may petition an agency to issue, amend, or repeal a rule. See 5 U.S.C. § 553(e) (2000). An agency's denial of such a petition is subject to judicial review. However, the APA imposes no time limit upon an agency's response to such a petition. See *id.*

¹³⁷ See FED. R. CIV. P. 24(a) (2006) ("Upon timely application anyone shall be permitted to intervene in an action . . . when the applicant claims an interest relating to the property or transaction which is the subject of the action and the applicant is so situated that the disposition of the action may as a practical matter impair or impede the applicant's ability to protect that interest, unless the applicant's interest is adequately represented by existing parties.").

would be dicta, and that the boater's interests would therefore not be impaired.¹³⁸ The boater might further find it difficult to assert a cognizable practical "interest" that a judicial ruling might impair, as Rule 24(a) requires. While some courts have held that any substantial interest, including an economic stake, will satisfy the rule, others have required a showing of a "legally protected interest"—a challenging showing for an indirect regulatory beneficiary.¹³⁹

Perhaps the case for intervention would be stronger with a guidance document such as the FDA's patulin guidance. Suppose the FDA brings an enforcement action to stop the sale of apple juice with 60 ppb patulin as "adulterated," and in doing so argues that any level above 50 ppb is adulterated.¹⁴⁰ Suppose further that consumers argue that the statute requires the FDA to treat juice with any level above 30 ppb patulin as adulterated. In this situation, the consumer perhaps could successfully argue that its interests would be impaired by a judicial ruling upholding the FDA position that anything above 50 ppb is adulterated.¹⁴¹ Even in this case, the court might still conclude that it could resolve the enforcement action without reaching the issue raised by consumers.

A regulatory beneficiary could also seek permissive intervention in this kind of suit.¹⁴² Permissive intervention decisions, however, are highly discretionary with the district court.¹⁴³ Moreover, to obtain permissive intervention, the regulatory beneficiary would need to

¹³⁸ Conceivably, the agency could argue that the defendant's apple juice contained 60 ppb of patulin, and the defendant could respond that the marketed apple juice contained only 40 ppb of patulin. At this point, the consumer could respond that notwithstanding the agency's position, the statute requires the court to conclude that the juice is adulterated. However, this will rarely be the case. In addition, if the agency invoked its policy in the context of an affirmative action benefiting a regulated party—say, issuing a license to operate a nuclear power plant or waste disposal facility—a regulatory beneficiary would be able to intervene to challenge the guidance.

¹³⁹ Compare *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. USDA*, 143 F. App'x 751, 753 (9th Cir. 2005) (rejecting "economic expectancy" as a protected interest for the purposes of intervention), and *Graham v. Evangeline Parish Sch. Bd.*, 223 F.R.D. 407, 433 (W.D. La. 2004) (rejecting an interest in children attending a neighborhood school as a sufficiently protected interest to warrant intervention), with *Liberte Capital Group v. Capwill*, 126 F. App'x 214, 220 (6th Cir. 2005) (finding a banks' "vested interest" sufficient to justify permissive intervention), and *Fund for Animals v. Norton*, 322 F.3d 728, 732–33 (D.C. Cir. 2003) (allowing a Mongolian ministry to intervene as of right in an environmental group's suit challenging the Interior Department's listing of certain sheep as threatened rather than endangered). See generally 7C CHARLES ALAN WRIGHT ET AL., *FEDERAL PRACTICE AND PROCEDURE* § 1908, at 271 (2d ed. 1986) (discussing the level of interest that courts typically require).

¹⁴⁰ See *supra* notes 36–39 and accompanying text.

¹⁴¹ See WRIGHT ET AL., *supra* note 139, § 1908, at 302 ("[S]everal cases now have held that stare decisis by itself may, in a proper case, supply the practical disadvantage that is required for intervention under Rule 24(a)(2).").

¹⁴² See FED. R. CIV. P. 24(b) (2006).

¹⁴³ See WRIGHT ET AL., *supra* note 139, § 1913, at 378.

show that it could have maintained the claim as a separate lawsuit—in other words, that independent grounds for jurisdiction exist.¹⁴⁴ While the regulatory beneficiary could surely point to issues of law and fact common to its claim and the enforcement action, such as whether the agency's position in the litigation is proper under the statute and nonarbitrary, the beneficiary might face the same threshold obstacles of proving standing and ripeness that would have impeded review of the guidance in the first place. Moreover, a judge who perceives that a beneficiary is trying to "creat[e] whole new lawsuits" may be reluctant to grant intervention.¹⁴⁵ In short, even if the agency files enforcement litigation, a regulatory beneficiary's ability to use the suit to litigate the rationality and legality of the policy stated in the guidance is uncertain at best.

Finally, even if enforcement actions could serve as a vehicle for regulatory beneficiaries to attack a statute, regulatory beneficiaries will often have a hard time learning about these actions, making them unlikely to be able to participate in settlement negotiations.¹⁴⁶ When a regulated entity receives notice of an agency enforcement action, it may well invite support by a trade association.¹⁴⁷ However, the regulated entity is highly unlikely to invite intervention by, say, consumers who wish to see the agency more aggressively interpret the statute it is enforcing.

2. *Loss of Opportunities to Participate*

When an agency issues a policy in a guidance document, regulatory beneficiaries also are likely to have less access to the agency decision-making process. As a formal matter, regulatory beneficiaries and

¹⁴⁴ See *Diamond v. Charles*, 476 U.S. 54, 76 (1986) (O'Connor, J., concurring) ("The words 'claim or defense' manifestly refer to the kinds of claims or defenses that can be raised in courts of law as part of an actual or impending law suit . . ."); *Ranchers Cattlemen Action Legal Fund*, 143 F. App'x, at 754 (interpreting Rule 24 to require "independent grounds for jurisdiction"); *Jones v. Prince George's County*, 348 F.3d 1014, 1017–18 (D.C. Cir. 2003) (requiring a party seeking permissive intervention to show standing); *EEOC v. Nat'l Children's Ctr.*, 146 F.3d 1042, 1046 (D.C. Cir. 1998) (noting that Rule 24(b) requires would-be intervenors to have "an independent ground for subject matter jurisdiction"). But see *EEOC*, 146 F.3d at 1046 (noting that circuit precedent seems to "allow[] intervention even in situations where the existence of any nominate 'claim' or 'defense' is difficult to find" (quotation omitted)).

¹⁴⁵ See *S. Cal. Edison Co. v. Lynch*, 307 F.3d 794, 804 (9th Cir. 2002) (quoting *Donnelly v. Glickman*, 159 F.3d 405, 412 (9th Cir. 1998)).

¹⁴⁶ On the other hand, consent decrees entered under some statutes are reviewed for consistency with the "public interest." See, e.g., *Massachusetts v. Microsoft Corp.*, 373 F.3d 1199, 1236–37 (D.C. Cir. 2004). In theory, then, regulatory beneficiaries could still challenge a settlement prior to entry on the ground that the relief obtained by the government is inadequate.

¹⁴⁷ Cf. *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 674 (D.C. Cir. 1973) (holding a challenge brought by trade association to FTC issuance of octane ratings rule as beyond FTC's rulemaking authority).

regulated entities are on the same footing when agencies issue guidances. Neither is entitled—as any member of the public would be if the agency elected to use rulemaking¹⁴⁸—to receive agency data or an agency response to comments on the policy.¹⁴⁹

As a practical matter, however, regulatory beneficiaries will generally have less access to agency process than regulated entities when an agency issues a policy in a guidance document. First, it is worth noting that agencies have employed a wide range of processes in issuing guidances. Agencies are not, of course, generally required to seek outside views on their guidance materials, and some agencies indeed seek none. For example, for opinion letters issued by the Wage and Hours Division of the Department of Labor, even those taking a broad, prospective position, the agency asks for no outside comment.¹⁵⁰ Treating opinion letters as more akin to individual adjudications, the Labor Department has decided to forgo the views and information it might have received had it decided to seek public comment or hold public meetings. Neither regulated entities nor regulatory beneficiaries can participate.

However, other agencies, including other divisions of the Labor Department, do regularly seek outside views on significant guidances and policy documents.¹⁵¹ An agency may thereby hope to gather new information or identify significant problems with the policy. The agency may also hope to flush out any controversy or political opposition, especially from groups that can invoke oversight from Congress, the White House, or both. By responding to such concerns in advance, the agency might avoid oversight altogether. Indeed, agencies often claim greater legitimacy for their policies after seeking public input.¹⁵²

Among those agencies that do solicit public views, some will do so for guidances in a manner very similar to notice-and-comment

¹⁴⁸ This is not to say that a regulatory beneficiary could automatically obtain judicial review of the agency's failure to respond to the beneficiary's comment in the notice-and-comment process.

¹⁴⁹ See *supra* note 56 and accompanying text.

¹⁵⁰ See Portal-to-Portal Act, 29 U.S.C. § 259 (2000). These opinion letters represent an unusual case. By statute, relying on the opinion letters affords a safe harbor to regulated entities. See *id.* Thus, although they, like guidance documents issued by other agencies, are generally phrased in a broad, prospective manner, they are binding in a way that other guidance documents are not. Nonetheless, the Labor Department practices are instructive.

¹⁵¹ See, e.g., Interview with Anonymous (Aug. 11, 2005) (on file with author); *infra* text accompanying notes 156–57.

¹⁵² See, e.g., Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, at 15 (noting that providing public comment on guidance documents can prompt “greater public confidence in and acceptance of the ultimate agency judgments. For these reasons, agencies sometimes follow the notice-and-comment procedures of the APA even when doing so is not legally required”).

rulemaking. Congress has instructed the FDA to develop procedures for guidance documents;¹⁵³ for so-called "Level 1 Guidances," the FDA has bound itself to publish notice of the draft guidance and invite comment either in the Federal Register or on the Internet.¹⁵⁴ The National Organic Program (NOP) of the Department of Agriculture has issued a "notice" detailing a similar set of procedures for guidance documents.¹⁵⁵ Other agencies have expressed a nonbinding public commitment to reach out to a wide array of interested groups. For example, the Coast Guard has publicly stated that it will circulate draft guidance documents known as "Navigation and Vessel Inspection Circulars" to "all affected and interested parties" for "technical and policy comments," though it has supplied no explanation of how those parties will be identified.¹⁵⁶ In addition, the EPA's 2003 Public Involvement Policy states that the policy's fundamental premise is to "ensure that decision-making processes are open and accessible to all interested groups, including those with limited financial and technical resources, English proficiency, and/or past experience participating in environmental decision-making."¹⁵⁷ The policy encourages EPA officials to reach out through numerous methods, such as by including all citizens that request involvement or by developing a contact list based on a group's past expression of interest.¹⁵⁸ On the other hand, the EPA has not clearly defined a set of actions outside of rulemaking to which the policy will apply, noting only that it will seek outside comment when the Administrator or other top officials determine that a particular action "warrant[s] public participation."¹⁵⁹ None of these procedures is identical to notice-and-comment rulemaking. For example, none of the agencies thus far have committed to respond to public comments, as the APA requires for notice-and-comment rulemaking. Nonetheless, these measures represent real efforts to engage the public on proposed policies.

¹⁵³ See *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987).

¹⁵⁴ See Good Guidance Practices, 21 C.F.R. § 10.115(g) (ii) (2006).

¹⁵⁵ See National Organic Program: Development, Issuance, and Use of Guidance Documents, 70 Fed. Reg. 5129, 5131 (Feb. 1, 2005) ("For example, these [Good Guidance Practices] provide that the public will have an opportunity to comment on and suggest areas for guidance development or revision and to submit draft guidances for possible adoption by the program."). Whether the procedures legally bind the agency is unclear. Compare *id.* at 5131 (noting that agency will "adhere" to the procedures), with *id.* at 5133 (describing "appeal" process through agency supervisory ranks with no mention of judicial review).

¹⁵⁶ COAST GUARD, U.S. DEP'T OF HOMELAND SEC., NVIC FLOWCHART, available at <http://www.uscg.mil/hq/g%2Dm/nvic/NVIC%20Flowchart.pdf> (last visited Feb. 3, 2007).

¹⁵⁷ OFFICE OF POLICY, ECON., & INNOVATION, U.S. ENVTL. PROT. AGENCY, PUBLIC INVOLVEMENT POLICY OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY 1 (2003), available at http://www.epa.gov/reg3wcmd/ca/pdf/public_involvement_policy.pdf [hereinafter PUBLIC INVOLVEMENT].

¹⁵⁸ See *id.* at 8.

¹⁵⁹ *Id.* at 3.

Agencies may be prompted to make more such efforts by the new OMB Bulletin for Agency Good Guidance Practices, which was issued in January, 2007, and which is not yet in effect.¹⁶⁰ That bulletin directs agencies to gather comments (though agencies are generally not directed to respond to comments) prior to issuing “significant” guidance documents, particularly those with a greater than \$100 million annual effect upon the economy.¹⁶¹

Very often, however, agencies do not solicit comment widely, but instead make ad hoc decisions regarding to whom a draft guidance document will be “floated.” Peter Strauss has described the Nuclear Regulatory Commission’s process of guidance development when he served as general counsel: “[T]hese guidance instruments, which the Commission expected to be the product of informal consultation by responsible staff with affected parties, were supervised by the Commission in only a general way.”¹⁶² Agency officials tend to reach out to organizations that have already frequently communicated with the agency. One agency reportedly lists organizations that have recently commented on significant rulemaking on related issues and uses that as a starting point for public outreach.¹⁶³ In the words of another agency employee who was sometimes responsible for soliciting outside comment on guidance documents, “I had a list of people I’d already met at other meetings.”¹⁶⁴ An employee from another agency stated that after attending meetings on a particular issue, he would “become aware of which [national, Washington, D.C.-based] organizations were focused on issues.”¹⁶⁵ Again, however, this process is often highly arbitrary. In the words of another former employee, “Some groups might have greater access to meetings than others based on connections to those in positions of authority.”¹⁶⁶

Even among regulated entities affected by a proposed agency policy, there may be wide variation in involvement. Seiguer and Smith interviewed industry representatives in a study of FDA guidance document development and found that some representatives felt closed out of the process, finding it “opaque.”¹⁶⁷ Meanwhile, other inter-

¹⁶⁰ See Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, at 1 (providing that bulletin will be effective 180 days after bulletin’s publication in the Federal Register). The new bulletin is discussed in greater detail below. See *infra* Part II.C.4.

¹⁶¹ Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, at 15.

¹⁶² Strauss, *supra* note 34, at 805.

¹⁶³ See Interview with Anonymous (Aug. 11, 2005) (on file with author).

¹⁶⁴ Interview with Anonymous (Sept. 22, 2005) (on file with author).

¹⁶⁵ Interview with Anonymous (Sept. 23, 2005) (on file with author).

¹⁶⁶ Interview with Anonymous (Jan. 17, 2006) (on file with author).

¹⁶⁷ See Seiguer & Smith, *supra* note 9, at 30.

viewees found FDA staff to be “very responsive” and felt that merely picking up the phone would afford them easy access.¹⁶⁸

Agency participation decisions sometimes formally and expressly give advantages to regulated entities compared with other members of the public. For example, the FAA has adopted an exclusionary approach in its development of “advisory circulars,” a major category of guidance documents concerning aviation safety. The FAA has posted on the Internet a list of seventeen associations of regulated entities and related businesses from which it welcomes comments on draft advisory circulars.¹⁶⁹ The FAA’s posting states, “[W]e generally accept comments only from recognized industry organizations. If you would like to comment on a Draft Advisory Circular, please submit your comments to one of the organizations listed below, as appropriate.”¹⁷⁰ The FAA list does not include any airplane passenger or consumer safety organizations.¹⁷¹ Similarly, despite the EPA policy document discussed above,¹⁷² the EPA’s position on compliance guides for small entities is that it will circulate those guidance documents only to small business representatives, not others.¹⁷³

The FDA’s Good Guidance Practices rule also creates asymmetrical public participation. The FDA has formally committed to seek public input before issuing so-called Level 1 guidances, which are directed primarily to regulated industry and which set forth initial interpretations of statutory or regulatory requirements, address unusually complex or controversial issues, or set forth changes in interpretation or policy that are of more than a minor nature.¹⁷⁴ In general, the FDA will publish draft guidances of this sort in advance of finalizing

¹⁶⁸ See *id.*

¹⁶⁹ FED. AVIATION ADMIN., *supra* note 31.

¹⁷⁰ *Id.*

¹⁷¹ For example, the FAA list omits the International Aviation Safety Association, whose Web site can be found at <http://www.iasa.com.au/folders/menu/index.htm> (last visited Feb. 3, 2007).

¹⁷² See *supra* notes 157–59 and accompanying text.

¹⁷³ See U.S. ENVTL. PROT. AGENCY, REVISED INTERIM GUIDANCE FOR EPA RULEWRITERS: REGULATORY FLEXIBILITY ACT AS AMENDED BY THE SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT, at 61 (1999), available at <http://www.epa.gov/sbrefa/documents/iguid99.pdf> (“Small entity representatives should typically be involved in reviewing the draft compliance guide after the rule is promulgated so that we have the benefit of their comments and advice in preparing the final version of the guide. Generally, draft compliance guides should not be released to outside parties prior to the rule’s promulgation.”). But see KAY LEHMAN SCHLOZMAN & JOHN T. TIERNEY, ORGANIZED INTERESTS AND AMERICAN DEMOCRACY 344 (1986) (citing a study documenting “hostility toward business among the occupational safety and health professionals at the Occupational Safety and Health Administration”).

¹⁷⁴ See Good Guidance Practices, 21 C.F.R. 10.115(c) (2006) (defining Level 1 guidances); 21 C.F.R. 10.115(g)(1) (setting forth procedures for Level 1 guidances). See also the Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961, 8968 (Feb. 27, 1997) (discussing FDA approach).

them, *except* where those documents are “presenting a less burdensome policy that is consistent with public health.”¹⁷⁵ One can imagine that for some “less burdensome” policies, regulatory beneficiaries might have something to say on whether the policy is consistent with public health.

The NOP has followed the FDA’s lead, both by systematizing public participation in guidance development and by stating that it generally will not seek advance public input on a significant guidance if the “guidance presents a less burdensome policy that is consistent with the purposes of the Act and implementing regulations.”¹⁷⁶

Even without overtly excluding regulatory beneficiaries, as the FAA appears to do, regulatory agencies that consult only ad hoc on draft guidance documents will likely deemphasize participation by regulatory beneficiaries. This is for straightforward reasons wholly unrelated to “capture” of agencies by interest groups (though capture, if present, could worsen such lack of access).¹⁷⁷ First, because an agency will often directly interact with regulated entities, the agency is more likely to know the identities of regulated groups. Given time and resource constraints upon the agency, it is more convenient and less expensive to reach out to these known entities as a sounding board for policy development.¹⁷⁸ Second, the agency may have a greater interest in maintaining a good long-term relationship with regulated entities because it must constantly deal with them and because it has an interest in procuring their compliance with the statutory regime. Meanwhile, the agency may lack a direct relationship with regulatory beneficiaries. Therefore, an agency official may have greater difficulty identifying the appropriate groups or individuals to contact and less interest in maintaining a long-term relationship with these groups. Third, regulated entities are likely to have valuable information—often superior to that of the agency—regarding the policy’s costs and feasibility.¹⁷⁹ In contrast, while regulatory beneficiaries may have valuable information on a policy’s effects, they are likely to have less infor-

¹⁷⁵ The Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. at 8968.

¹⁷⁶ National Organic Program: Development, Issuance, and Use of Guidance Documents, 70 Fed. Reg. 5129, 5131 (Feb. 1, 2005).

¹⁷⁷ For a discussion of agency capture, see generally Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039 (1997).

¹⁷⁸ See West, *supra* note 63, at 70 (“[Public] participation [in pre-rulemaking agency discussions] was bounded by administrators’ past experience and by their sense of who the significant players were.”).

¹⁷⁹ See, e.g., CORNELIUS M. KERWIN, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY 189 (3d ed. 2003) (noting that agencies may seek information from interest groups “especially when dealing . . . with production processes and technology or business practices”).

mation regarding feasibility. Consequently, regulators may emphasize informal interaction with regulated entities.¹⁸⁰

Further, certain characteristics of regulatory beneficiaries may lead them to be less involved in policy development. First, learning about the existence of guidances before they are finalized can be difficult and expensive unless the agency chooses to give public notice or else initiates contact. Regulatory beneficiary groups may have fewer resources to devote to this sort of information gathering.¹⁸¹ Second, if regulatory beneficiary groups are diffuse or poorly organized, they may face significant obstacles to organizing in a way that fully represents their interests. Consider, for example, any statute passed to benefit the "public health and welfare," such as air and water quality regulation, automobile or food safety regulation, consumer product legislation, or toxic substances legislation. The intended beneficiaries of these statutes represent extraordinarily large and diffuse groups, including not only those who currently benefit from these laws but also many who cannot yet self-identify (such as future asthma sufferers, in the case of air quality regulation, or fetuses, in the case of toxics and food safety regulation). Beginning with Mancur Olson's work, there is an enormous literature on the organizational difficulties these groups face; the literature suggests these groups will have a relatively difficult time—given the extent of their interest—obtaining information about agency actions and participating fully in the agency decision-making process.¹⁸²

Third, regulatory beneficiaries may lack the political clout that might otherwise motivate an agency to seek their approval.¹⁸³ They

¹⁸⁰ See Coglianese, Zeckhauser & Parson, *supra* note 75, at 327–28 (noting that advisory committees give "regulators and industry representatives opportunities to . . . build relationships that can lead to productive informal interaction" and arguing that this informal interaction provides superior opportunities for regulators to gather information from regulated entities). See generally SCHLOZMAN & TIERNEY, *supra* note 173, at 331 (discussing the extent to which "interest organizations [may] provide agency staff with policy ideas and useful technical information, including forecasts and policy analyses . . . facilitat[ing] an easy two-way flow of information . . . [and] the development of mutual trust").

¹⁸¹ See SCHLOZMAN & TIERNEY, *supra* note 173, at 171–72.

¹⁸² See, e.g., MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION* 5–65 (1971); SCHLOZMAN & TIERNEY, *supra* note 173, at 171–72; JAMES Q. WILSON, *POLITICAL ORGANIZATIONS* 33–35 (1973) (describing incentives, including solidarity and purposive, that may cause individuals to join groups); James Q. Wilson, *The Politics of Regulation*, in *THE POLITICS OF REGULATION* 366–70 (James Q. Wilson ed., 1980) (describing circumstances under which groups are likely to organize).

Moreover, even when formed, these groups may not represent the wide range of views present in the general public. See, e.g., LAWRENCE S. ROTHENBERG, *LINKING CITIZENS TO GOVERNMENT* 266 (1992) ("The claim that there exists a brave new world of organizations that constitutes a strong, countervailing representation of the public will must be viewed with considerable hesitancy").

¹⁸³ See SCHLOZMAN & TIERNEY, *supra* note 173, at 357 ("Organized interests enjoy influence in bureaucratic decision making not because agencies are captive to organized

may be less able to invoke political oversight mechanisms such as OMB review or congressional oversight.¹⁸⁴ For example, when Congress considered proposals to reform the environmental statute relating to hazardous waste cleanup in the 1990s, companies lobbying to weaken the law “outnumber[ed] environmental groups by 30 to 1.”¹⁸⁵ The point here is not that regulatory beneficiary groups completely lack resources or political clout, but simply that their resources may not correspond to the breadth and depth of their interests in a particular agency action. Finally, regulated entities may have more to lose and more to spend than regulatory beneficiaries, giving them both a greater incentive and a greater ability to participate in the process.¹⁸⁶ Schlozman and Tierney’s systematic study of organized interest groups documents that “the pressure community is heavily weighted in favor of business organizations . . . at the expense of two other kinds of organizations: groups representing broad public interests and groups representing the less advantaged.”¹⁸⁷ Subsequent studies suggest that businesses and trade associations dominate contacts with agencies during rulemaking over environmental and transportation issues.¹⁸⁸

Similarly, while EPA officials are careful to include environmentalists whenever they contemplate issuing a significant policy change in a guidance, they may call only the representatives of a Washington, D.C.-based organization that has previously expressed interest, rather than posting the guidance publicly or contacting a wide range of environmental groups.¹⁸⁹ Again, this decision appears to be made on an ad hoc basis. In addition, the lack of advance public notice is likely to

groups but because agencies need their support and know that the most important weapon in the arsenal of organized interests is the ability to make trouble for bureaucrats.”).

¹⁸⁴ Admittedly, the same problem may exist with respect to notice-and-comment rulemaking. In that case, however, the agency has an enforceable obligation to respond to any significant comment submitted during the rulemaking process, whether or not the commenter possesses political clout.

¹⁸⁵ See Bill McAllister, *Guns for Hire*, WASH. POST, June 18, 1998, at A23 (quoting a U.S. Federal Advocacy Office of the State Public Interest Research Groups report stating that only five environmental groups were working to strengthen the law, compared with 150 lobbying firms and in-house corporate lobbyists, paid for by ninety-nine companies).

¹⁸⁶ See KERWIN, *supra* note 179, at 182 (“As James Q. Wilson has noted, people are more likely to get involved in politics and government decision making to save something that is threatened than to gain something new.”).

¹⁸⁷ See SCHLOZMAN & TIERNEY, *supra* note 173, at 68.

¹⁸⁸ See KERWIN, *supra* note 179, at 182–83 (summarizing relevant studies but also noting reasons that groups representing other interests may now be finding a foothold); *id.* at 184 (summarizing an agricultural marketing order program finding participation by “ultimate consumers” in product-safety standard setting to be “nominal at best”).

¹⁸⁹ The public involvement policy described above, *supra* notes 157–58 and accompanying text, is not to the contrary. That policy leaves it to staff to “exercise judgment” in “designing public involvement,” including “[i]dentify[ing] the interested and affected public.” PUBLIC INVOLVEMENT, *supra* note 157, at 5–6.

particularly disadvantage highly interested individuals or very small organizations that represent only a subset of regulatory beneficiaries.¹⁹⁰

These concerns may well affect the content of a guidance document. If the agency hears from a wider variety of regulatory beneficiaries, it might respond to the intensity of their views or receive new information. Without outside involvement, the agency's value choices might be less responsive to public values or not engage them at all.¹⁹¹ For example, in 2003, the EPA proposed a guidance that would permit wastewater treatment plants to "blend" partially treated sewage with fully treated sewage in "wet weather,"¹⁹² a measure that would save the plants, and the cities that owned them, many millions of dollars without violating permit limits for wastewater. However, the EPA did not informally "float" the guidance but instead published a draft guidance for comment.¹⁹³ After receiving 98,000 comments, including a strong response from environmental public interest groups that expressed concern that discharged water would have higher levels of viruses and parasites, the EPA decided in 2005 not to finalize the guidance.¹⁹⁴

Similarly, when a rule is published for notice and comment, an agency may receive comments from "interested individuals in the hinterland," in one official's words.¹⁹⁵ These individuals may happen to know a lot about the subject matter of the proposed rule, but the agency would not otherwise have known to contact them. For example, when the EPA published a recent rule on sewage treatment for comment, one set of comments received from an individual was so valuable that the agency decided to fly the person, who turned out to be the engineer operating a small water treatment plant, to agency offices to give agency staff more specific feedback on small-system needs.¹⁹⁶ The agency may forgo such opportunities for constructive

¹⁹⁰ See, e.g., *infra* note 196 and accompanying text (describing an individual who filed a public comment on a water treatment rule and then became intrinsically involved in the agency decision-making process).

¹⁹¹ See Mendelson, *supra* note 6, at 586 (discussing agency-centered conceptions of political legitimacy).

¹⁹² National Pollutant Discharge Elimination System (NPDES) Permit Requirements for Municipal Wastewater Treatment Discharges During Wet Weather Conditions, 68 Fed. Reg. 63,042 (proposed Nov. 7, 2003).

¹⁹³ See *id.*

¹⁹⁴ Another possibility is that the agency correctly anticipated controversy over this policy, and thus decided to offer it for public comment. For less controversial, more run-of-the-mill policies, public comment might make little difference in outcome and thus might constitute a waste of agency resources. This is one reason I advocate permitting citizens to initiate a dialogue with the agency through a petition process rather than requiring a comment process for every significant statement of policy. See *infra* Part II.C.1.

¹⁹⁵ Interview with Anonymous, *supra* note 164.

¹⁹⁶ See *id.*

input when it formulates a policy in a guidance document rather than a rule.

Apart from potentially less favorable policy, lack of involvement creates other costs for regulatory beneficiaries. If one sees the administrative process as an important civic republican substitute for other forms of democratic dialogue, such as election-related deliberation, regulatory beneficiaries may feel excluded from the community of debate. Because of this inability to have their views heard in the decision-making process, regulatory beneficiaries may perceive a particular policy decision as illegitimate.¹⁹⁷

In short, when agencies issue their policies in the form of guidance documents rather than notice-and-comment rulemaking, regulatory beneficiaries lose significant access to judicial review as well as opportunities to participate directly in agency decision making. These are some of regulatory beneficiaries' most valuable tools for holding an agency accountable. Accordingly, some reform of agency process is warranted.¹⁹⁸

II SOME SOLUTIONS

Both regulated entities and regulatory beneficiaries suffer costs when an agency issues a particular policy in a guidance document rather than a rule. Regulatory beneficiaries suffer distinct costs, however, because they have less access to judicial review and typically also have less access to agency processes. So, what is the solution?

Rather than advocating a single solution, I now examine two prevailing proposals and then turn to other, more promising alternatives.

¹⁹⁷ See, e.g., Frank I. Michelman, *Formal and Associational Aims in Procedural Due Process*, in NOMOS XVIII: DUE PROCESS 126, 126–29 (J. Roland Pennock & John W. Chapman eds. 1977). See generally Lawrence H. Tribe, *Structural Due Process*, 10 HARV. C.R.-C.L. L. REV. 269 (1975) (arguing that individual involvement in judicial decision-making processes increases the perceived legitimacy of judicial decisions).

¹⁹⁸ Under some circumstances, regulatory beneficiaries might conceivably prefer the unregulated issuance of guidances. For example, suppose that agency employees, unconstrained by judicial or political oversight, would tend to favor regulatory beneficiary interests. In that case, increasing the cost of issuing guidance documents would mean fewer actions that benefit regulatory beneficiaries. Meanwhile, if greater legal constraints were imposed, they might mostly empower regulated entities to influence the direction of agency decision making. As the text discusses, the prospect that guidance documents will regularly favor regulatory beneficiaries seems unlikely because of the procedural disadvantages faced by regulatory beneficiaries and the significant incentives agencies have to respond to regulated entity concerns. Bagley and Revesz also argue strongly against the possibility that agencies will be “overzealous” in pursuing their regulatory goals. See Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1286 (2006). If guidance documents did tend to be relatively favorable to regulatory beneficiaries compared with policies issued through rulemaking, however, regulatory beneficiaries would undoubtedly be less interested in procedural reform.

The two prevailing proposals are to allow the unregulated issuance of guidance documents or to subject all guidance documents to notice-and-comment rulemaking. Each proposal seems unsatisfactory. The proponents of allowing agencies to issue guidance documents unchecked incorrectly assume that the alternative is a world of "secret law"; the second proposal suffers because of the disadvantages of reducing every feature of agency implementation to a rule. Among more promising alternatives are proposals to permit citizens to petition an agency to revise or repeal a guidance document, along the lines of section 553(e) of the APA;¹⁹⁹ to require guidance documents to be treated as precedent; and, as the OMB has begun to do in limited settings, to require agencies to adhere to "good guidance practices."²⁰⁰

A. The No-Action Alternative

A number of commentators have advocated against further procedural regulation of guidance documents.²⁰¹ Although the use of guidance documents clearly has costs for both regulated entities and regulatory beneficiaries, these commentators fear that the sheer cost of notice-and-comment proceedings would deter agencies from publishing anything on the implementation of their programs. Strictly regulating guidance documents might thus deprive the public of valuable information. As the argument goes, a world with guidance documents, whatever the resulting injury to procedural fairness, social goals, or reliance interests, is still superior to a world of "secret law," completely ad hoc decision making, or adjudication.²⁰²

With respect to regulated entities, it seems likely that if the FDA has adopted a de facto policy on patulin in apple juice, or if the Education Department has adopted a de facto policy on Title IX compliance, then an apple juice producer or university would prefer to know the policy before the agency files an enforcement action. Regulatory beneficiaries would seem to be in the same position. This may have been Congress's view when it enacted 5 U.S.C. § 552(a)(3) as part of

¹⁹⁹ 5 U.S.C. § 553(e) (2000).

²⁰⁰ See *infra* note 252 and accompanying text.

²⁰¹ See, e.g., Andersen, *supra* note 35; Strauss, *supra* note 34.

²⁰² See, e.g., Manning, *supra* note 11, at 930; Strauss, *supra* note 34; see also *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1111–12 (D.C. Cir. 1993) ("[T]he ability to promulgate such rules, without notice and comment, does not appear more hazardous to affected parties than the likely alternative. . . . [Congress's purpose] is not advanced by . . . driv[ing] agencies into pure ad hocery—an ad hocery, moreover, that affords less notice, or less convenient notice, to affected parties.").

the Freedom of Information Act, barring an agency from relying on an unpublished document in dealing with a private party.²⁰³

However, this risk of loss from agency policymaking in secret is almost certainly overstated. Even if guidance documents and policy statements were somehow off-limits to agencies, or if agencies were required to use notice-and-comment rulemaking to issue them, a world of secret law would be highly unlikely. Despite the cost of enhanced procedures, agencies face other very significant incentives to go public with their policies.

First, simple good-government concerns may motivate an agency to make its positions public. An agency head may wish to treat regulated entities fairly—or at least to be perceived as treating them fairly—and thus to give the public notice of the agency's plans. Alternatively, congressional directives, such as statutes concerned with small-entity compliance, may motivate or even require agency employees to make positions public.²⁰⁴ Thus, even the rationally cost-minimizing agency will face significant incentives to issue its policies publicly even if the agency could not issue guidance documents.

Perhaps more importantly, an agency's failure to disclose its policy positions or interpretations would likely undermine its relations with regulated entities, which strongly prefer to operate in an atmosphere of certainty. In some settings, the agency will face pressing demands from regulated entities for advance notice of its policies.²⁰⁵ Agency officials typically like relations with regulated entities to remain cordial, not only because they frequently interact with regulated entities, but also because those entities can be a critical source of information.²⁰⁶ Further, if they are well-organized, regulated entities may be able to invoke political discipline against agency action.²⁰⁷ Even in less urgent settings, failing to disclose policy positions in advance may alienate members of Congress concerned with compliance assistance.²⁰⁸

²⁰³ Strauss, *supra* note 34, at 806 (“[Congress] was aware of the importance of publication rule practice and chose *only* the requirement of publication as its legislative response; putting an end to secret law, not additional proceduralization, was its aim.”).

²⁰⁴ See, e.g., Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 601 (2000).

²⁰⁵ See Manning, *supra* note 11, at 930 (“[W]here the regulatory stakes are high and the demand for advance technical specifications is urgent (e.g. nuclear power plant licensing), an agency may feel obliged to set forth the needed specifications in a meaningful way in advance of a licensing proceeding.”).

²⁰⁶ See Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 834 (2003) (describing informational “capture” hypotheses).

²⁰⁷ See Stewart, *supra* note 117, at 1712.

²⁰⁸ Congress will sometimes pass compliance assistance measures in statutes addressed to agencies. See, e.g., Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 801(C)(2)(A) (2000); see also Seiguer & Smith, *supra* note 9, at 19 n.9 (citing this statute as a reason small businesses have more influence in the development of regulations).

Finally, secrecy may cost an agency in court. Under some circumstances, the failure to disclose a particular interpretation of a statute or regulation will interfere with an agency's ability to obtain penalties for statutory or regulatory violations.²⁰⁹ A number of circuit court decisions have held that due process bars agencies from imposing penalties, refusing to grant licenses, or taking action resembling a forfeiture based on a statutory or regulatory violation (including injunctions requiring the expenditure of money) unless the regulated entity had clear notice of the conduct required.²¹⁰ Under this precedent, the regulated entity must know with "ascertainable certainty" based on public agency statements that its conduct was regulated.²¹¹ Courts have been willing to accept public notice from an agency not only in a notice-and-comment rule but also in a guidance document.²¹² However, if guidance documents become less attractive to agencies, due process will still serve as a powerful incentive for agencies not to hide their enforcement approaches.

In short, agencies are unlikely to relegate all their policies to secrecy if guidance documents become more heavily regulated. This intuition is confirmed by the fact that agencies issue guidance documents publicly announcing their policies even when they are not required to do so. While it is surely less expensive than issuing notice-and-comment rules, guidance development can also require significant agency resources. An agency may need to develop data to issue the guidance—such as the health effects of patulin—or conduct a significant internal dialogue before arriving at a final position. Yet an agency may proceed to issue the guidance because of the substantial benefits of publicizing its position, even in a way that does not bind regulated entities. Many of the same incentives that drive agencies to issue guidance documents would still prompt them to do so—or even

²⁰⁹ See generally Kieran Ringgenberg, Comment, *United States v. Chrysler: The Conflict Between Fair Warning and Adjudicative Retroactivity in D.C. Circuit Administrative Law*, 74 N.Y.U. L. REV. 914 (1999) (exploring tensions between due process doctrine and the doctrine permitting retroactive effects of adjudications).

²¹⁰ See, e.g., *Excel Corp. v. U.S. Dept. of Agric.*, 397 F.3d 1285, 1298 (10th Cir. 2005) (holding that fair notice requirements did not apply to a cease-and-desist order); *SBC Commc'ns v. FCC*, 373 F.3d 140, 147–51 (D.C. Cir. 2004) (upholding FCC enforcement because SBC had fair notice of its policy); *WHX Corp. v. SEC*, 362 F.3d 854, 859–61 (D.C. Cir. 2004) (invalidating a cease-and-desist order because of lack of fair warning of the SEC's interpretation of a rule); *Trinity Broad. of Fla. v. FCC*, 211 F.3d 618, 628 (D.C. Cir. 2000); *United States v. Chrysler Corp.*, 158 F.3d 1350, 1357 (D.C. Cir. 1998) (barring recall of cars with a particular seat belt anchor); *Gen. Elec. Co. v. EPA*, 53 F.3d 1324, 1332 (D.C. Cir. 1995).

²¹¹ See *Gen. Elec.*, 53 F.3d at 1329; Ringgenberg, *supra* note 209, at 925 (citing the D.C. Circuit's position that pre-enforcement efforts to obtain compliance can also satisfy the notice requirement).

²¹² See *Gen. Elec.*, 53 F.3d at 1329.

to issue rules—if agency use of guidance documents were more heavily regulated.

Of course, these incentives will not cause an agency to reissue every guidance as a rule. Rulemaking is not cheap. If guidance documents are unavailable to the agency, rulemaking's cost and loss of administrative flexibility might lead an agency to publicly state its policies less often or in less detail. If due process does not require a public statement of agency position, if Congress is not particularly interested, or if the agency is uninterested in maintaining positive relations with regulated entities, the agency may not invest resources in issuing helpful information. An agency that focuses more on projects, such as highway building, rather than enforcement of statutory or regulatory standards, may also face fewer incentives to use rulemaking to set policy.

It is difficult to predict which guidances would be lost if all guidance development required meeting rulemaking standards. An agency surely would issue fewer policies that are legally indefensible or highly controversial. On the other hand, regulated entities would continue to demand certainty regarding the sort of conduct that might lead to enforcement action; those demands would likely prompt agencies to continue publishing this information.

In any event, the argument that policies, guidances, and interpretive rules are better than nothing²¹³ fails to resolve the question of whether we should regulate the agency issuance of guidance documents. Even if an agency faces higher costs in issuing guidance documents, it surely will not completely hide its policy positions. Meanwhile, the argument fails to take account of the costs that the unregulated use of guidance documents imposes on regulatory beneficiaries.

B. Requiring Notice-and-Comment Rulemaking

So, should the other oft-proposed reform be the solution? That is, should an agency be required to issue every significant aspect of its policies in the form of a notice-and-comment rule, as Anthony has advocated?²¹⁴ Although this approach would give regulatory beneficiaries full participation rights in agency decision making and make agency positions legally binding, this position also has an underlying flaw: an agency cannot and probably should not attempt to fully specify its policies. As already noted, the high cost of rulemaking could

²¹³ See *supra* note 92 and accompanying text.

²¹⁴ See Anthony, *supra* note 1. Anthony's position includes an exception for agency interpretations that do not add any substantive terms to an underlying rule or statute. However, distinguishing a "nonsubstantive" interpretation from one that has a substantive effect would be difficult at best.

lead to less information from the agency about its policies (though, as I argue, it would not leave us with a world of secret law and ad hoc adjudication).²¹⁵ Moreover, an agency cannot reasonably be expected to foresee every possible instance in which its policy may be applied. For the unforeseen or unforeseeable case, it may be desirable for an agency to retain flexibility to design just results.²¹⁶

Further, such an approach, as others have observed, would raise issues of judicial competence.²¹⁷ Judges enforcing a new regime would face even greater demands than under current law to distinguish between "significant" agency policy statements that require full-blown process and those that do not. Clearly, not every piece of paper that an agency publicly issues regarding its programs and policies should be subjected to notice-and-comment rulemaking. Thus, judges would be presented with a difficult question of degree. As John Manning has argued, judicial reluctance under current law to "impose even a mild rulemaking obligation upon agencies may reflect judicial administrability concerns similar to those that deter judges from enforcing the nondelegation doctrine."²¹⁸ Manning argues that "[judges] should hesitate before invalidating a nonlegislative rule on the ground that it reflects an impermissible degree of policymaking outside the process of notice-and-comment rulemaking."²¹⁹ He reaches this conclusion because the inquiry "turns on distinguishing interpretation from policymaking," a difficult question because the two are typically so intertwined.²²⁰

C. More Palatable Proposals

1. *Citizens' Right to Petition*

An intermediate, process-focused solution might offer another option. Along the lines of section 553(e) of the APA, which authorizes petitions to revise or repeal agency rules, citizens could be entitled to receive notice of a guidance document's issuance and to petition the agency to revise or repeal the document (assuming the agency has not already complied with section 553's notice and com-

²¹⁵ See *supra* Part II.A.

²¹⁶ See, e.g., Mashaw, *supra* note 118, at 86; Mark Seidenfeld, *Bending the Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 ADMIN. L. REV. 429, 440-41 (1999); cf. Strauss, *supra* note 34, at 808 ("Particularly in a society that has come to believe standards are a better instrument of regulation than detailed command-and-control rules, even an ideal level of rulemaking will generate an enormous range of issues on which interpretation and policy analysis will be required."). But see KERWIN, *supra* note 179, at 174 ("[A]ny clarification [in marginal cases] will have the effect of transforming a gray area into one that is black and white, and this change alone may be enough to trigger a protest.").

²¹⁷ See, e.g., Manning, *supra* note 11, at 896.

²¹⁸ *Id.*

²¹⁹ *Id.* at 914.

²²⁰ *Id.* at 916.

ment procedures).²²¹ The agency would have a limited time to respond substantively, say, 180 days. In response, the agency could modify the guidance document or give reasons why the document should not be changed.²²² To avoid the specter of multiple successive petitions on a single document, the agency could publish a notice inviting citizens to file all related petitions within a limited period.²²³ The statute should also bar pro forma petitions by clearly requiring a petitioner to submit significant supporting facts or arguments. On judicial review, an agency could defend itself by arguing that the submission did not require a substantive response. The agency could also respond by publishing the guidance for a full notice-and-comment proceeding, which would have the advantage of flushing out any other guidance detractors.²²⁴ As with other such petitions, the agency's response, or its failure to respond by a statutory deadline, would be subject to judicial review.²²⁵

No similar right appears to exist under current law. Despite some commentators' statements that the language of the APA supplies an obvious right to file such a petition under section 553,²²⁶ the few

²²¹ The Administrative Conference of the United States's recommendation for a post-effective date comment period for nonlegislative rules (coupled with pre-adoption notice-and-comment for significant rules) has some similarities. See 1 C.F.R. § 305.76-5 (1992). Like a petition process, the recommendation would require the agency to respond to comments on the guidance document after issuing it. These comments would be closer in time to the guidance's issuance. It is unclear whether that would make the agency more willing to consider the comments, since there would have been less reliance on the guidance, or less willing, on the theory that the agency would be unwilling to revisit a decision to which it had just committed. In addition, the recommendation would apply to all guidances unless the agency explained why a comment period would not be in the public interest. That process would likely burden the agency more than a petition process.

²²² The proposal should confirm that an agency can revise a guidance document or interpretive rule without notice-and-comment rulemaking, thereby overruling the D.C. Circuit holdings on interpretive rules in *Alaska Prof'l Hunters Ass'n v. FAA*, 177 F.3d 1030, 1033-35 (D.C. Cir. 1999) and *Paralyzed Veterans of Am. v. D.C. Arena*, 117 F.3d 579, 587 (D.C. Cir. 1997). These holdings have been subject to considerable criticism. See, e.g., Michael Asimow & Robert A. Anthony, *A Second Opinion? Inconsistent Interpretive Rules*, ADMIN. & REG. L. NEWS, Winter 2000, at 16; Richard J. Pierce Jr., *Distinguishing Legislative Rules from Interpretive Rules*, 52 ADMIN. L. REV. 547, 563-66 (2000); Strauss, *supra* note 34, at 809-11 (advocating "free revision" of publication rules).

²²³ I am grateful to Jonathan Molot for proposing this solution to the problem of successive petitioning. The statute could nonetheless permit a later petition if it is based on grounds arising after the initial petitioning period.

²²⁴ For example, the D.C. Circuit will generally not consider an argument raised in opposition to a rule unless it has been raised in the rulemaking proceeding. See, e.g., *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1148-50 (D.C. Cir. 2005); *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002).

²²⁵ Cf. *Advocates for Highway & Auto Safety*, 429 F.3d at 1144-45 (discussing the timing of petitions filed pursuant to a Federal Motor Carrier Safety Administration notice-and-comment procedure).

²²⁶ See Michael Asimow, *California Underground Regulations*, 44 ADMIN. L. REV. 43, 44 n.5 (1992); Asimow, *supra* note 11, at 424 & n.225 (suggesting that the public can petition to repeal or amend a nonlegislative rule under 5 U.S.C. § 553(e)); William V. Luneberg, *Peti-*

courts to opine on the issue have flatly and unanimously disagreed, finding that no right to petition an agency to revise or repeal an interpretive rule or policy statement exists under current law.²²⁷ A petition process would confer several advantages on regulatory beneficiaries. First, a regulatory beneficiary could engage an agency on the substance of a guidance document. The agency would be obligated to respond in a reasoned way, including disclosing data relevant to the arguments. This obligation would parallel an agency's obligations to respond to significant comments in rulemaking²²⁸ or, in an enforcement action, to defend its position against a regulated entity's challenges.²²⁹ Requiring an agency to supply coherent reasons for its guidances in response to petitions would in turn make judicial review of these documents more effective.

tioning Federal Agencies for Rulemaking: An Overview of Administrative and Judicial Practice and Some Recommendations for Improvement, 1988 WIS. L. REV. 1, 13–14.

Section 553 of the APA contains poorly drafted language exempting guidance documents from rulemaking requirements:

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice

5 U.S.C. § 553(b) (2000) (emphasis added). Read plainly, that provision might seem to exempt guidance documents only from 553(b), the notice requirements, since the language exempts guidances only from “this subsection” and not from 553(e), the subsection that provides the petition right. On the other hand, courts have uniformly read the language to exempt guidance documents not only from the notice requirements of 553(b) but also from the comment and “concise general statement” requirements of a different subsection, 553(c). See, e.g., *Lincoln v. Vigil*, 508 U.S. 182, 196–97 (1993). Therefore, “subsection” should be read as a scrivener’s error, and the correct reference should be “section.” In that case, the best reading of the exemption in 553(b) is that it applies to all of 553, including 553(e).

²²⁷ See *Atchison, Topeka, & Santa Fe Ry. Co. v. Pena*, 44 F.3d 437, 442 (7th Cir. 1994) (en banc) (“[I]nterested parties do not have the right to petition the agency for review of its interpretive rulings as they do with respect to agency rules.”) (citing 5 U.S.C. § 553(e)); *Nat’l Wrestling Coaches Ass’n v. U.S. Dep’t of Educ.*, 263 F. Supp. 2d 82, 128 (D.D.C. 2003) (“Section 553, by its terms, does not apply ‘to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice’ unless notice or hearing is required by statute.” (quoting 5 U.S.C. § 553(e))), *aff’d on other grounds*, 366 F.3d 930, 948 (D.C. Cir. 2004); *United Transp. Union v. Del. & Hudson Ry. Co.*, 977 F. Supp. 570, 574 n.2 (N.D.N.Y. 1997) (“In addition, interested parties do not have the right to petition the agency for review of its interpretive rulings as they do with respect to agency rules.”) (citing 5 U.S.C. § 553(e)).

Even if section 553(e)’s right to petition did apply to guidance documents, it imposes no time limitations upon an agency’s response to a petition. Administrative Procedure Act legislative history suggests that Congress meant for agencies to resolve section 553(e) petitions “promptly,” but that language is not in the statute, and courts thus far have read no meaningful deadline into section 553(e).

²²⁸ Cf., e.g., *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977) (discussing the necessity of disclosing scientific data to commenters in a notice-and-comment process).

²²⁹ See Levin, *supra* note 58, at 1500 (“The essence of the agency’s duty . . . should be an obligation to allow the challenger to present a case, and second, to respond meaningfully to that case.”).

Petitioning might also prompt agencies to identify more significant and controversial policies earlier, as well as to use a more thorough, participatory process for these policies. The agency might consult with a wider array of interest groups in order to forestall later petitions or, on the most significant issues, might elect notice-and-comment rulemaking. As argued above, broader consultation may affect the substance of an agency policy. Regulatory beneficiaries, like regulated entities, will likely value the entitlement to express their views to the agency and to participate in the policymaking process.²³⁰

Compared with a requirement to use notice-and-comment rulemaking for all nontrivial matters of policy, enforcing a petition process requirement would raise fewer issues of judicial competence.²³¹ The inquiry on judicial review would be a familiar one: Is the agency's decision as formulated in the guidance arbitrary and capricious? Has the agency considered the relevant factors, including any relevant information and arguments presented by petitioners? Is the agency's policy authorized by statute? Does the agency's decision represent a clear error of judgment?²³²

This proposal could raise some concerns. Most important is cost, especially if expenses were high enough to compel agencies to substantially cut back on issuing policies. How costly a petition process might be is, of course, an empirical question. The costs would be a function of the number of petitions and the amount of agency resources required to resolve each petition, including any later litigation over the agency's response. The worst-case scenario would be a revision petition or multiple successive petitions regarding each of the vast number of agency guidance documents, followed by significant litigation. In this scenario, the costs are potentially overwhelming.²³³

²³⁰ See KERWIN, *supra* note 179, at 189 (noting that interest groups highly value the opportunity to participate in notice-and-comment rulemaking). See generally Adler, *supra* note 121.

²³¹ Cf. notes 217–20 and accompanying text.

²³² See, e.g., *Motor Vehicle Manufacturers Ass'n of the United States v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43–59 (1983); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 408–22 (1971); *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

²³³ Agencies already spend a considerable portion of their rulemaking budgets on meeting statutory deadlines, often under court order. See, e.g., Robert Fischman, *The Problem of Statutory Detail in National Park Establishment Legislation and Its Relationship to Pollution Control Law*, 74 DENV. U. L. REV. 779, 799 (1997) ("The EPA priorities are now so driven by meeting congressional deadlines that the agency cannot comprehensively plan effectively to implement broad goals, such as reducing exposure to contaminants that generate the greatest health risks."); Natalie M. Henry, *Resources Panel to Review FWS, NOAA Budget Requests*, ENV'T & ENERGY DAILY, Apr. 30, 2001 (reporting that the fiscal year 2001 budget for listing and critical habitat was depleted after only two months due to litigation-driven deadlines); *Water Quality and Wetlands: Clean Water Act*, 2002 A.B.A. SEC. ENV'T, ENERGY, & RESOURCES (YEAR IN REV. 2001) 356, 369 ("In practice, review [under the Clean Water Act effluent limitation guidelines] occurs much less frequently, and in recent years, the

The costs associated with these petitions, however, would still surely be lower than the cost of across-the-board rulemaking. In fact, petitions would be unlikely for the vast number of truly routine guidance documents aimed at regulated entities and those that simply boil down statutory or regulatory requirements or give uncontroversial compliance examples. Barring pro forma petitions and requiring an agency to solicit all related petitions and resolve them simultaneously would also likely cut petitioning costs. An attorneys' fee award for truly unfounded petitions could perhaps further reduce such costs.

Another potential concern is that by the time a petition is filed, the agency decision-making process would already have concluded. Consequently, an agency might not be truly open-minded and willing to revisit its earlier decision, preventing a regulatory beneficiary from effectively engaging the agency in a meaningful dialogue on its policy.

Nonetheless, the petition process would likely improve upon the status quo for regulatory beneficiaries. First, the existence of a petition right would encourage an agency to consider a wider range of views before issuing guidances. Second, the potential for meaningful judicial review of the agency's response would encourage an agency to thoughtfully consider each petition. While an agency's commitment to its proposed policy might render petitioning less effective, the petition process would still provide a participation opportunity equivalent to that afforded in notice-and-comment rulemaking. Although the agency might have committed to a limited set of policy alternatives at the time a proposed rule is published, for example,²³⁴ an agency would still need to demonstrate that it had directly responded to the regulatory beneficiary's concern.

A third potential concern is that a petition process could increase the influence of regulated entities as well as regulatory beneficiaries. Compared with regulated entities, regulatory beneficiary organizations are comparatively disadvantaged. An agency also could spend more time responding to petitions from regulated entities than those from regulatory beneficiaries.²³⁵ This would cause the agency to seek regulated entity participation earlier in the process. Consequently, as

agency's priorities and schedules for reviewing effluent limitation guidelines have been driven largely by court-imposed consent decrees.").

²³⁴ See, e.g., Marissa Martino Golden, *Interest Groups in the Rule-Making Process: Who Participates? Whose Voices Get Heard?*, 8 J. PUB. ADMIN. RES. & THEORY, 245, 261-62 (1998) (noting that in most rulemakings analyzed agencies tend to side with those who supported their initial rule); West, *supra* note 63, at 69 (summarizing data suggesting that most notices of proposed rulemaking articulated "tentative conclusions" to policy problems rather than "open-ended solicitations of policy recommendations").

²³⁵ On the other hand, some regulated entities may moderate their petitions or refrain from filing in order to maintain a good long-term relationship with the agency.

with informal consultation, political access, and, at times, judicial review,²³⁶ the petition process might unevenly benefit regulated entities.²³⁷

That better-funded, better-organized parties might make better use of a process open to all is hardly surprising. Others have proposed ways to rectify this resource imbalance.²³⁸ Whether this is a serious indictment of the proposal depends on how we understand the agency decision-making process. (After all, no one is suggesting closing the courts altogether because the wealthy can better avail themselves of judicial review.) If agencies just added up the number of expressed interests in deciding which policies to select, and if all regulated entities had already had an adequate opportunity to participate absent a petition process—both dubious assumptions—then creating yet another opportunity for regulated entities might exacerbate the existing imbalance with little benefit for regulatory beneficiaries.

On balance, however, a formal petitioning opportunity is likely to help regulatory beneficiaries by enabling them to engage the agency with significant arguments. The prospect of a petition would encourage an agency to seek input earlier from a broader array of groups, an especially valuable change if the agency decision-making process is seen as at least partly deliberative.²³⁹ Thus, the petition right would require an agency to consider new substantive viewpoints, including those of regulatory beneficiaries, in its policy decisions.²⁴⁰ Moreover, if an agency became overwhelmed by extensive petitions on a controversial issue from regulated entities and decided instead to

²³⁶ See, e.g., Amy Sinden, *In Defense of Absolutes: Combating the Politics of Power in Environmental Law*, 90 IOWA L. REV. 1405, 1443 (2005) (noting imbalance of resources favoring regulated entities in regulatory litigation); Cass R. Sunstein, *Reviewing Agency Inaction After Heckler v. Chaney*, 52 U. CHI. L. REV. 653, 669 (1985) ("Often political remedies are more readily used by well-organized members of regulated classes than by regulatory beneficiaries, who must overcome substantial barriers to the exercise of political power.").

²³⁷ See, e.g., Golden, *supra* note 234, at 245, 255 (noting that among randomly selected Clinton-era rulemakings, EPA and NHTSA rulemakings had "extremely limited participation by public interest or citizen advocacy groups," while HUD commenters included citizen advocacy groups and individual citizens).

²³⁸ See AYRES & BRAITHWAITE, *supra* note 122, at 82.

²³⁹ See *supra* notes 120–22 and accompanying text (discussing the civic republican and neopluralist visions of the administrative state).

²⁴⁰ Another concern about a petition process is that citizens with a narrow view of the public interest, rather than a democratically accountable agency, might somehow drive policymaking priorities. Commentators have raised similar concern over statutory provisions contemplating Labor Department responses to individual opinion letter requests and granting a safe harbor for operation in compliance with a position taken in an opinion letter. See, e.g., Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 211–13 (2006) (discussing *Christensen v. Harris County*, 529 U.S. 576 (2000)). Here, however, no petition could be filed unless the agency has already selected an issue for its agenda by issuing a guidance document.

use notice-and-comment rulemaking, this would also have substantial benefits for regulatory beneficiaries.

2. *Notice-and-Comment Rulemaking for "Important" Policy Decisions*

This proposal is a more palatable variant of the previously discussed proposal calling for notice-and-comment rulemaking for all guidances. It would require notice-and-comment rulemaking not for every new policy decision but only for "important" policy decisions. The agency would be subject to the corresponding obligations to make the policy binding, to disclose data, to respond to comments, and to be subject to judicial review.²⁴¹

This proposal would be less costly and cumbersome than a more expansive rulemaking requirement. For the policies subject to this rulemaking requirement, regulatory beneficiaries could engage the agency more effectively and obtain judicial review. This would in turn prompt the agency to reason through the policy more carefully. While regulated entities still might file more comments, chances are good that regulatory beneficiary views would receive more attention in a comment process than through informal consultation on a guidance.²⁴²

However, such a policy would still place a difficult burden on judges to distinguish the "important" policies from the other ones.²⁴³ By comparison, when courts currently decide whether a guidance is actually a rule, they focus largely on whether the policy is effectively binding.²⁴⁴ That approach overlooks nonbinding policies that should have been issued by rulemaking because they evoke a significant change in behavior among regulated entities and meet some level of "significance." On the other hand, the focus on the binding quality of an agency statement represents a standard that judges can readily apply.

²⁴¹ Cf. Administrative Procedure Act, 5 U.S.C. § 553 (2000).

²⁴² Susan Yackee and Jason Yackee have presented an effective empirical analysis suggesting that agencies respond disproportionately to business comments filed in rulemaking. See Jason Webb Yackee & Susan Webb Yackee, *A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy*, 68 J. POL. 128 (2006). However, the Yackees do not compare the level of responsiveness in rulemaking to other agency decision-making methods, such as informal consultation. See *id.* Rulemaking is still likely to supply regulatory beneficiaries with a greater opportunity to be heard than informal consultation.

²⁴³ See, e.g., Strauss, *supra* note 34, at 811–12 (suggesting that rulemaking requirements for guidances could impose upon courts the task of deciding that a particular rule is "insufficiently specific," and "fail[s] to articulate important policy conclusions it could reasonably have been expected to reach").

²⁴⁴ See *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 946 (D.C. Cir. 1987) (noting that FDA action levels are legislative rules subject to notice-and-comment requirements because they are binding).

Determining whether a policy is “important,” however, would not only require a judge to distinguish interpretation from policymaking, but would also have to be done in the context of the particular program. The risk is that judges would be unwilling to apply the standard with any stringency, undermining the effectiveness of requiring broader notice-and-comment rulemaking.²⁴⁵

The other moderate alternatives may be superior in this respect. In the petition process, an affected party could engage the agency with a nonfrivolous argument on any guidance or policy that the affected party perceives to be significant. Judicial review would be confined to familiar issues of review of agency action. Similarly, the “good guidance practices” approach below would permit an agency, rather than a judge, to identify the controversial or significant policy decisions that require a higher degree of process.

3. *Guidances as Precedent*

Strauss and Manning have both discussed another intermediate solution: allowing courts to treat published agency guidance documents as precedent.²⁴⁶ Under this view, an agency would have to supply a reason for departing from a position taken in a guidance document. While courts could apply this approach more easily than having to identify “significant” or “important” agency policies that would be subject to rulemaking, the proposal is largely unhelpful from the perspective of the regulatory beneficiary.

The Strauss and Manning proposals primarily benefit the regulated entity facing an agency enforcement action. To return to the FDA’s patulin guidance stating that apple juice with more than 50 ppb patulin will be considered “adulterated,” suppose an apple juice maker ships juice with 45 ppb patulin in interstate commerce. The FDA brings an enforcement action, arguing despite the guidance that

²⁴⁵ See *supra* note 218 and accompanying text (discussing Manning’s argument that judicial hesitation to apply even a “mild” rulemaking requirement reflects doubts about judicial competence).

²⁴⁶ See Manning, *supra* note 11, at 929–37; Strauss, *supra* note 34, at 843–49. Strauss more clearly specifies that guidance documents would have precedential effect for agencies. Thus, agencies would be required to justify any departure from them, but courts would not. Strauss makes clear, for example, that agency counsel should not attempt to argue that the mere violation of a policy in a guidance document warrants fines but should instead focus on the violation of the underlying binding statute or regulation. *Id.* at 843–44. Manning suggests that agencies could rely directly on a guidance document if the document contained “reasoning adequate to support the adjudicative decision.” Manning, *supra* note 11, at 933–34. While a court could thus consider challenges to agency reasoning in the context of an enforcement action, this approach would nonetheless increase the difficulties faced by regulatory beneficiaries. Such an approach would not prompt agencies to consult widely on their policies. Moreover, because of the precedential value a court might accord a guidance, regulated entities are more likely to follow its terms, further reducing judicial review of the policy it embodies.

45 ppb patulin should be considered to render the juice adulterated. Rather than treat the guidance document as nonbinding according to its terms, Strauss and Manning would permit the producer to argue that the agency must be held to the terms of the guidance, and the enforcement action dismissed, unless the agency can provide reasons for deviating. Thus, the FDA would have to explain why 45 ppb should be seen as adulterated, given its earlier, presumably reasoned position in the guidance.

This proposal would increase the consistency of agency behavior and permit greater reliance on agency statements by regulated entities. However, the approach implicitly presumes that the guidance itself is valid and has properly implemented the social policy that the statute embodies. It thus does comparatively little for regulatory beneficiaries, who have no opportunity to argue that the choice of 50 ppb is arbitrary, capricious, or contrary to the statute's language or goals of protecting public health.²⁴⁷

Regulatory beneficiaries would receive no new opportunity to make such arguments if the agency adhered to the policy in an enforcement action. This approach would also presumably not increase the ripeness or reviewability of these documents on direct review, since the document would remain formally nonbinding.²⁴⁸ Indeed, assigning precedential value to guidance documents could result in courts according these statements even greater deference than under current law.

Even if beneficiaries agreed with the position taken in the guidance document, the beneficiary could not require an agency to bring an enforcement action in accordance with its (nonbinding) guidance. A decision to refrain from enforcement is generally unreviewable.²⁴⁹

However, where an agency's primary function is not to enforce regulatory standards, but instead to manage a resource, according a guidance document precedential effect would conceivably serve the

²⁴⁷ Manning recognizes this position in his statement that an agency should be permitted to rely on a guidance document in an adjudication only if the guidance document is "reasoned." See Manning, *supra* note 11, at 933–34. A party could thus argue in enforcement litigation that the agency position is unreasoned. See *id.* However, this does not resolve whether a court would permit a regulatory beneficiary to intervene to challenge the reasoning of a guidance document. Moreover, such an opportunity would exist only if the agency brought enforcement litigation, the prospect of which would be further reduced if a guidance document had precedential value. See *supra* notes 137–45 and accompanying text (discussing the difficulty of intervention for regulatory beneficiaries).

²⁴⁸ See *supra* Part I.C.1 (discussing the difficulty of obtaining judicial review for regulatory beneficiaries). Strauss suggests that courts should find that "centrally generated publication rules likely to significantly affect private conduct are ordinarily 'final agency action' subject, if ripe, to judicial review." Strauss, *supra* note 34, at 811. However, this does not seem a significant change from current law. See *id.* at 819 (suggesting that staff level guidances could not be considered "final"); *supra* notes 82–89 and accompanying text.

²⁴⁹ See *Heckler v. Chaney*, 470 U.S. 821, 837–38 (1985).

interests of regulatory beneficiaries. For example, the beneficiaries of public land might be able to obtain review of the final action of the land management agency. These beneficiaries could argue that the agency action should be vacated because the agency had failed to provide a reasonable justification for acting at variance with the guidance document.²⁵⁰

4. *Agency Self-Regulation and Good Guidance Practices*

Another moderate proposal would require agencies to devise more inclusive guidance development procedures, such as the FDA's Good Guidance Practices or the EPA's Public Involvement Policy.²⁵¹ The OMB Bulletin for Agency Good Guidance Practices, issued in January, 2007,²⁵² for example, requires agencies to gather comment for "significant" guidance documents,²⁵³ by which OMB means circumstances in which an agency provides "important policy direction on a broad scale."²⁵⁴ Under the FDA's Good Guidance Practices, the agency must solicit comment before issuing a so-called "Level 1 guidance."²⁵⁵

For most guidances, the agency is only obligated to accept comments; it need not offer a public response.²⁵⁶ Like the guidance-as-precedent approach,²⁵⁷ the FDA's Good Guidance Practices and the OMB Bulletin also include a conformity norm. That is, agency employees' actions must conform to the terms of a guidance unless there

²⁵⁰ Similarly, if the agency issued a guidance helpful to beneficiaries regarding when it would license a particular activity, a beneficiary could challenge a license that did not conform to the guidance's requirements.

²⁵¹ See *supra* notes 157–59 and accompanying text (discussing the EPA's Public Involvement Policy).

²⁵² See Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18.

²⁵³ See *id.* at 19 (defining "significant" guidance documents as those anticipated to have a \$100 million or greater annual effect upon the economy, to materially alter rights and obligations of entitlement recipients, or to raise novel legal or policy issues).

²⁵⁴ *Id.* at 11.

²⁵⁵ See *supra* text accompanying note 174.

²⁵⁶ The FDA Good Guidance Practices require no response to comments. See Administrative Practices and Procedures: Good Guidance Practices, 65 Fed. Reg. 56,468, 56,470 (Sept. 19, 2000). For most guidance documents, the OMB bulletin does not require response either. See Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, § III.2.a (stating that no response to comments is required); *id.* § VI (stating that the bulletin creates no enforceable rights). Section IV, which would require an agency to take public comment on an economically significant guidance document prior to issuance, does require a response to comments. See *id.* §§ IV.1.iii–iv. However, it is unclear whether OMB would review the agency guidance document for compliance with this requirement. See *supra* text accompanying note 79 (discussing Executive Order 13,422). Meanwhile, the bulletin imposes no binding obligation that could raise the prospect of judicial review. See Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, § VI.

²⁵⁷ See *supra* Part II.C.3.

is an "appropriate justification" for deviation accompanied by supervisory review.²⁵⁸

These sorts of practices do provide regulatory beneficiaries with a greater opportunity to submit comments on a proposed guidance to the agency. This in turn would increase the information available to the agency about any relevant technical issues and public preferences. Further, a beneficiary could comment on a guidance document in draft form rather than waiting until issuance.

However, these proposals for improved self-government still retain important shortcomings. First, because agencies need not respond to comments, these proposals do not ensure that the agency will meaningfully engage the comments it receives. Comments from an entity with significant political clout will, of course, receive attention, as such comments would have in any event. Although well-intentioned civil servants will undoubtedly endeavor to read comments from other sources, the lack of a response obligation, combined with time and resource constraints, make these proposals less likely to address the concerns of regulatory beneficiaries. Research has not turned up any reports on whether the FDA's Good Guidance Practices have prompted public participation or affected the content of FDA decisions.²⁵⁹ Further, although the FDA procedures have been codified in a binding legislative rule, no reported judicial opinions address the FDA's compliance with the procedures.²⁶⁰

Second, the conformity norm included in the FDA's Good Guidance Practices does not fully address critical concerns of regulatory beneficiaries. As discussed above, beneficiaries still receive no new opportunity to argue that the policy in the guidance does not adequately implement the statutory goals.²⁶¹

Although the OMB's bulletin would go a step beyond the FDA's Good Guidance Practices, it also is unlikely to address regulatory beneficiary concerns. One aspect helpful to regulatory beneficiaries is the

²⁵⁸ See Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, § II.1.b. The OMB proposal also requires an agency to accept comment on a guidance at any time, including comments suggesting revision or reconsideration. See *id.* § III.2.a.

²⁵⁹ The FDA did report in 2000, based on an undisclosed "informal internal survey," that "[Good Guidance Practices] have generally been beneficial and effective in standardizing the agency's procedures for development, issuance, and use of guidance documents, and that FDA employees have generally been following GGP's." See Administrative Practices and Procedures: Good Guidance Practices, 65 Fed. Reg. 7321, 7322-23 (Feb. 14, 2000). However, the FDA did not discuss public participation and has provided no further details.

²⁶⁰ See 21 U.S.C.A. § 371(h)(5) (West 1999) (lacking any notes of cases under this statute requiring the FDA to codify good guidance practices); *id.* (West Supp. 2006) (same).

²⁶¹ See *supra* Part II.C.3.

Bulletin's requirement that an agency respond to comments on "economically significant" guidances and those that "adversely affect in a material way the economy or a sector of the economy."²⁶² OMB expects economically significant guidances, which are those with an anticipated annual economic effect of \$100 million or more, to represent only a "relatively narrow" subcategory of significant guidances, however.²⁶³ For all other guidances, the agency would retain the choice whether to provide notice and comment opportunities.²⁶⁴

Further, as with the FDA's Good Guidance Practices, even this aspect of the new Bulletin privileges regulated entity interests over those of regulatory beneficiaries. Agencies are to respond to comments on "economically significant" guidances and those with an adverse economic effect.²⁶⁵ These are likely to include guidance documents that prompt significant or expensive increases in regulated entity responsibility. Agencies would not, however, have to respond to comments on guidances likely to be of greater interest to regulatory beneficiaries—those that tend to reduce economic burdens by reducing regulatory compliance burdens or that generate a material adverse effect upon the environment, public health or safety, or local or tribal governments or communities.

Moreover, an agency that failed to take or respond to comments on guidance documents would be accountable only to OMB. The OMB's Good Guidance Practices would not create rights enforceable in courts.²⁶⁶ OMB review alone is not likely to be particularly helpful to regulatory beneficiaries. Lisa Bressman and Michael Vandenberg have recently presented historical evidence suggesting that OMB's tendency is to intercede on behalf of regulated entities.²⁶⁷

²⁶² Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, at 9.

²⁶³ See *id.* (noting that the definition of "economically significant guidance document" includes only a relatively narrow category of significant guidance documents).

²⁶⁴ See *id.* (stating that agencies may determine which guidance documents "merit advance notice-and-comment and a response-to-comments document" and which do not); *id.* at 18 (noting that while post-promulgation notice and comment is encouraged, an agency is not required to provide it if such procedures are not "feasible or appropriate").

²⁶⁵ *Id.* at § 1.5. By comparison, a "significant regulatory action" under Executive Order 12,866, which is subject to OMB review, includes any regulatory action with a material adverse effect upon productivity, competition, jobs, the environment, public health or safety, local or tribal governments or communities. Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,738 (Sept. 30, 1993), *reprinted as amended in* 6 U.S.C. § 501 (2000).

²⁶⁶ See Memorandum of Rob Portman to Heads of Executive Departments and Agencies, *supra* note 18, § V.

²⁶⁷ Bressman and Vandenberg argue further that OMB generally attempts to reduce the costs of rules and the burdens they place upon regulated entities. See Lisa Schultz Bressman & Michael P. Vandenberg, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control*, 105 MICH. L. REV. 47, 74–75 (2006) (arguing, based on interviews with political officials at the EPA, that the OMB tends to undercut regulatory efficiency by consistently interceding in agency processes on behalf of regulated entities).

Finally, while brand-new Executive Order 13,422 allows OMB to request consultation with an agency prior to its issuance of any "significant" guidance document,²⁶⁸ it is unclear, given OMB's resource constraints and small staff, how frequently OMB will choose to invoke that authority. Again, OMB consultation may not be particularly responsive to the concerns of regulatory beneficiaries.

Rakoff has suggested that placing the agency's obligation to respond to public comment (or to comply with its policies) "beyond the purview of the courts" may matter little either to the agency or to regulated industry.²⁶⁹ For example, regulated entities participated extensively in the development of the Good Guidance Practices.²⁷⁰ The relationship between the FDA and businesses in this "highly regulated industry" involves "repeat players,"²⁷¹ fostering greater cooperation without judicial review.

As I suggest above, however, where regulatory beneficiaries lack a direct relationship with an agency, they also may lack the "repeat player" relationship that prompts the agency to seek their views or engage their comments.²⁷² In that case, a regulatory beneficiary would likely benefit substantially from the ability to invoke judicial review or other methods of external oversight. Then the agency would be accountable for attending to the views of the regulatory beneficiary.

In short, the opportunity to comment provided by agency self-regulation efforts is helpful. But without judicial review or some similar opportunity to hold agencies accountable for taking regulatory beneficiaries' concerns into account, self-regulation, under the new OMB Bulletin or otherwise, is unlikely to fully address those concerns.

5. *Expanding Citizen Suits*

Another proposal encourages regulatory beneficiaries to use citizen suits or other private enforcement suits to obtain judicial review of an agency's policy choice. While citizen suit provisions are common in environmental laws governing pollution, they are rare in other con-

Nicholas Bagley and Richard Revesz have also argued persuasively that "many of the features of OMB review create a profound institutional bias against regulation." See Bagley & Revesz, *supra* note 198, at 1262. But see Croley, *supra* note 206, at 874-75 (arguing that regulated entities and regulatory beneficiaries have equivalent access to the OMB). Further, the disadvantages regulatory beneficiaries face in the agency setting may also impede their ability to gain assistance from the OMB as agencies develop guidance documents. See *supra* notes 180-89 and accompanying text.

²⁶⁸ See Exec. Order 13,422, *supra* note 79.

²⁶⁹ Rakoff, *supra* note 3, at 169.

²⁷⁰ See *id.*

²⁷¹ *Id.* at 169-70. But see Golden, *supra* note 234, at 263 (noting the absence of "repeat players" in eleven randomly selected NHTSA, EPA, and HUD rulemakings).

²⁷² See *supra* notes 177-79 and accompanying text.

texts.²⁷³ Indeed, even in the context of environmental laws, citizen suits face significant statutory and constitutional limits.²⁷⁴ Outside the securities and civil rights contexts, private rights of action are infrequently implied.²⁷⁵

Regulatory beneficiaries' concerns over inadequate agency enforcement of statutory provisions could be addressed by expanding citizen enforcement provisions to encompass obligations under a broader array of health, safety, and environmental laws. Moreover, broadening the availability of citizen suits would increase regulatory beneficiaries' ability to hold agencies externally accountable for their implementation of a statute. Regulatory beneficiaries could use these enforcement actions as a vehicle for litigating the interpretation of the underlying statute or regulation. To the extent a citizen suit defendant relies upon an agency interpretation or position (such as one contained in a guidance), the regulatory beneficiary could obtain judicial review without first having to go to the agency.²⁷⁶ The agency would have to present its position to the court either indirectly, through its guidance document, or directly, through an amicus brief.

Admittedly, a regulatory beneficiary could obtain judicial review of the agency position only in the context of an enforcement action against a third party, which would require a statutory or regulatory violation that the regulatory beneficiary could detect and document.

²⁷³ A January 2007 Westlaw search of the United States Code Annotated for "citizen suits," "citizen enforcement," or "private enforcement" turned up only twenty-five provisions authorizing suits against private parties. Nineteen of these concerned environmental or energy-use issues. *But see* 15 U.S.C. § 2073 (2000) (product safety); *id.* § 2102 ("hobby protection"); 49 U.S.C. § 14707 (2000) (registration requirements for transportation providers).

²⁷⁴ *See, e.g.,* *Friends of the Earth v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 175 (2000) (applying standing doctrine to citizen suits); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107–08 (1998) (same); *Gwaltney of Smithfield v. Chesapeake Bay Found.*, 484 U.S. 49, 64–66 (1987) (requiring citizen suits under the Clean Water Act to allege continuing or repeated violations).

²⁷⁵ *See* Bradford C. Mank, *Can Administrative Regulations Interpret Rights Enforceable Under Section 1983? Why Chevron Deference Survives Sandoval and Gonzaga*, 32 FLA. ST. U. L. REV. 843, 853 & n.64 (2005) (listing examples of implied private rights of action); Susan J. Stabile, *The Role of Congressional Intent in Determining the Existence of Implied Private Rights of Action*, 71 NOTRE DAME L. REV. 861, 866–67 & nn.32, 34 (1996) (suggesting that apart from the securities area, courts are reluctant to imply private rights of action); Stewart & Sunstein, *supra* note 100, at 1206; Michael A. Mazzuchi, Note, *Section 1983 and Implied Rights of Action: Rights, Remedies, and Realism*, 90 MICH. L. REV. 1062, 1074–78 (1992).

²⁷⁶ Even in direct review of an agency rule, courts now require presentation of the issue to the agency first. *See Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002). Further, the court would likely apply *Skidmore* deference when reviewing an agency interpretation not contained in a notice-and-comment rule or formal adjudication. *See United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). *But see* *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (stating that agency interpretations are "entitled to respect," but only to the extent that they are persuasive (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))).

Further, such lawsuits would be subject to resource constraints. Filing a lawsuit is considerably more expensive than submitting comments or filing a petition with receptive agency officials.

The proposal also has other, more significant shortcomings. An expansion of citizen enforcement schemes is unlikely to be politically viable in the current climate, which seems adverse to litigation. Even current citizen suit provisions raise significant constitutional issues under Articles II and III of the U.S. Constitution.²⁷⁷ Finally, these provisions may interfere with an enforcement agency's legitimate weighing of a "wide variety of . . . managerial, political, and substantive considerations" in deciding whether to bring a claim.²⁷⁸

CONCLUSION

The debate over agency guidance documents to date has been incomplete because scholars have neglected the interests of regulatory beneficiaries. When an agency chooses to issue a policy in a guidance document rather than a rule, regulatory beneficiaries lose the crucial ability to participate in the agency decision and to obtain judicial review of it. This occurs even though the agency may be implementing statutes that Congress enacted to help the beneficiaries. Consequently, regulatory beneficiaries should have greater procedural rights with respect to agency policymaking. Further empirical research is warranted regarding issues such as agency efforts to include regulatory beneficiaries in their decision making, and the impact, if any, that comments from outsiders have on agency decision making.

In the meantime, there is a clear need for reform to protect the interests of regulatory beneficiaries as agencies issue guidance documents. One or more of the above proposals—creating a right to petition, providing greater notice-and-comment rulemaking opportunities, or requiring good guidance practices—would better enable regulatory beneficiaries to engage an agency directly on the substance of an issued policy statement. Ideally, the solution would include judicial review to hold agencies accountable for complying with the new procedures. These reforms would also move significantly toward ensuring, more generally, that agency procedures better recognize and incorporate the legitimate interests of regulatory beneficiaries in agency policy.

²⁷⁷ See *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771–73 (2000) (holding that bounty cannot solve standing problems and identifying Article II issues with citizen enforcement); see also *supra* note 274 (citing other standing cases).

²⁷⁸ Stewart & Sunstein, *supra* note 100, at 1210.