

REGULATORY BENEFICIARIES AND
INFORMAL AGENCY POLICY MAKING

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Working Draft

February 1, 2006

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¹ Professor of Law, University of Michigan Law School. Thanks to Steve Croley, Ed Cooper, Lisa Heinzerling, and Riyaz Kanji for useful discussions and suggestions, to Ryan Calo for helpful research, and to the Law School's Cook Fund and outstanding library staff. I also appreciate the valuable comments of Richard Lazarus, Gar Guzy, and other participants at Georgetown's Environmental Research Workshop. Finally, I am very grateful to a number of present and former employees at several federal agencies, who agreed to let me interview them anonymously on the topics discussed in this paper.

I. Introduction

In setting policy, federal regulatory agencies regularly bypass the requirements of the Administrative Procedure Act notice and comment process for issuing legislative rules by using 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 abound. They range from the Forest Service's nonbinding "Directive" system⁴ to the FAA's Advisory Circulars⁵ to the Treasury Department's Examination Handbook.⁶ In response to congressional requests, the Environmental Protection Agency catalogued over 2000 guidance documents it had issued between 1996 and 1999; the Occupational Safety and Health Administration of the Labor

² 5 U.S.C. § 553(b)(3)(A); e.g., Robert 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) (“it is manifest that nonobservance of APA rulemaking requirements is widespread”).

³ See generally Peter Strauss, The Rulemaking Continuum, 41 Duke L.J. 1463, 1470-71 (1992) (presenting anecdotal evidence of “extraordinary volume of [informal] standard-generating activity”); Nina Mendelson, Agency Burrowing: Entrenching Policies and Personnel Before a New President Arrives, 78 N.Y.U.L. Rev. 557, 574 (2003). Todd Rakoff discusses the recent vintage of the term “guidance.” See Todd Rakoff, The Choice Between Formal and Informal Modes of Administrative Regulation, 52 Admin. L. Rev. 159, 159-60 (2000).

⁴ See U.S. Dep’t of Agric. Forest Serv., Overview of the Forest Service Directive System, at <http://www.fs.fed.us/im/directives> (Last visited Sep. 29, 2005).

⁵ See U.S. Federal Aviation Admin., Searchable Repository of Advisory Circulars, http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/MainFrame?OpenFrameSet&CFID=56957&CFTOKEN=71066012&CFID=1409204&CFTOKEN=89169026&CFID=10117451&CFTOKEN=66719376 (last visited Sep. 29, 2005).

⁶ See Office of Thrift Supervision, Examination Handbook, Nov. 2004, at 010.1, available at <http://www.ots.treas.gov/resultsort.cfm?catNumber=42&dl=31&edit=0?catNumber=42> (last visited Aug. 30, 2005) (“describ[ing], for examiners and the thrift industry, certain standards of conduct and prudent operation that [the Treasury Department Office of Thrift Supervision] views as important to the safe and sound operation of savings associations”). For a host of other examples, see Nina Mendelson, Agency Burrowing, 78 N.Y.U.L. Rev. 557, 574 & nn. 57-70.

Department catalogued over 1600.⁷ This dwarfs agency production of notice-and-comment rules. A recent study of FDA suggests that on average, it issues at least twice as many guidances as it does rules.⁸ According to one source, moreover, FDA use of guidance documents continues to follow an upward trend.⁹ Similarly, in calendar year 1999, EPA issued 81 “significant/substantive rules.”¹⁰ Meanwhile, a web search of the EPA website for documents issued over the same period revealed approximately 300 multi-page “interpretive documents” and policy statements.

These documents often closely resemble legislative rules in critical respects, which has led others to call them “nonlegislative rules.”¹¹ Through such documents, an agency may give notice of how it will implement a particular statutory or regulatory regime. For example, EPA has recently issued a major guidance document directed to drinking water treatment plants on how to handle “filter backwash,” the material that is released when water is run backwards through a drinking water filter to clean it.¹² The document

⁷ See Committee on Government Reform, Non-Binding Legal Effect of Agency Guidance Documents, H. Rept. 106-1009, 106th Cong. 2d Sess. 37-466 (2000).

⁸ The Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research have at times issued ten times as many guidances as rules. See Erica Seiguer & John Smith, Perception and Process at the Food and Drug Administration: Obligations and Trade-Offs in Rules and Guidances, 60 Food & Drug L.J. 17, 26 (2005).

⁹ 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.”).

¹⁰ Of these rules, 5 were “major” rules with an impact of \$ 100 million or as defined under the Congressional Review Act as having an impact of \$100 million or more on the economy. See <http://www.whitehouse.gov/omb/library/OMBARYTD-1999.html#EPA> (Viewed Sep. 9, 2002). [Note that OMB lists 263 total final rules.]

¹¹ E.g., Michael Asimow, Nonlegislative Rules and Regulatory Reform, 1985 Duke L. Rev. 381; John Manning, Nonlegislative Rules, 72 Geo. W.L. Rev. 893 (2004).

¹² See Environmental Protection Agency, Implementation Guidance for the Filter Backwash Recycling Rule (June 2004), available at http://www.epa.gov/safewater/mdbp/guide_fbrr_ig_fnl_06-16-04.pdf (Last visited Sep. 21, 2005).

implements a regulation—40 C.F.R. 141.76(a)—that occupies less than 1 page of the Code of Federal Regulation. The guidance itself is over 80 pages (over 100, if appendices are counted). EPA is explicit that the guidance may contain material that “go[es] beyond the minimum requirements” of the statute and regulations.¹³

However, the guidance also differs critically in a couple of respects from a legislative rule. Besides the lack of notice and comment, EPA expressly states that the guidance is binding neither on EPA nor on regulated entities. Particularly since 2000, guidance documents issued by EPA and other agencies contain this sort of language, disclaiming any binding legal effect and reserving the agency’s discretion to act at variance with the guidance.¹⁴

Thus, 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. Even with the disclaimer, however, a policy or guidance often evokes significant changes in behavior by those the agency regulates. It “still establishes the law for all those unwilling to pay the expense, or suffer the ill-will of challenging the agency in court.”¹⁵ Moreover, if the document includes an interpretation of law, that interpretation will also receive limited *Skidmore* deference in court, adding to its practical impact on regulated entities.¹⁶ Finally, despite the lack of formal legal binding effect, agencies are increasingly stating they will endeavor to conform to positions taken in guidance documents.¹⁷

This phenomenon has led to a vigorous debate among academics,¹⁸

¹³ See Implementation Guidance at Disclaimer (unpaginated), vii.

¹⁴ Several major regulatory agencies were criticized in congressional oversight in 2000 for failing to provide clear notice of the guidances’ nonbinding effect. See *infra* notes 23-24. See also note 45 (noting prospect that court might invalidate a “guidance” for failure to use notice-and-comment process when agency treats the guidance as binding).

¹⁵ Todd Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 *Admin. L. Rev.* 159, 167 (2000).

¹⁶ See *Skidmore v. Swift*, 323 U.S. 134 (1944); *Mead v. United States*, 533 U.S. 218 (2001). Whether interpretive rules should continue to receive *Skidmore* deference is beyond the scope of this paper.

¹⁷ See *infra* text accompanying notes 178-182 (discussing FDA “Good Guidance Practices” and OMB Draft Bulletin).

¹⁸ Strauss, *supra* note 3; Anthony, *supra* note 2; Rakoff, *supra* note 3; M. Elizabeth Magill, *Agency Choice of Policy Making Form*, 71 *U. Chi. L. Rev.* 13 (2004);

members of Congress,¹⁹ and the judiciary²⁰ regarding the effects and the legitimacy of this sort of policy making. In the early 1980s, the House and Senate Judiciary Committees approved regulatory reform legislation requiring greater use of notice-and-comment procedures for guidance-type documents.²¹ In addition, the now-defunct Administrative Conference of the United States²² (“ACUS”), issued multiple recommendations for increasing the public process accompanying the adoption of guidances or policy statements, including pre-adoption notice and comment for guidance documents with a “substantial impact.”²³ Congress has not only held oversight hearings in the use of guidance documents, including in 2000, but on one occasion did directly regulate the issuance of guidances. In the FDA Modernization Act of 1997, Congress specified the legal effect of FDA guidances (not legally binding, but generally to be adhered to by agency officials), required public participation in some instances, and mandated that the FDA develop and issue a binding set of “Good Guidance Practices.”²⁴

Asimow, *supra* note 11; William Funk, *Legislating for Nonlegislative Rules*, 56 *Admin. L. Rev.* 1023 (2004); James W. Conrad, Jr., *Draft Guidance on the Appropriate Use of Rules versus Guidance*, 32 *Env. L. Rep.* 10721 (2002).

¹⁹ See Committee on Government Reform Report, *supra* note 7.

²⁰ E.g., *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987).

²¹ The Senate bill passed the floor unanimously, but the House bill, H.R. 746 (97th Cong. 2d Sess.) (1982) never came to a vote. See S. 1080, 97th Cong., 1st Sess. 128 *Cong. Rec.* S2713 (daily ed. Mar. 24, 1982) (passage 94-0). In the next Congress, similar legislation was introduced, but made little progress. See H.R. 220 98th Cong. 1st Sess. (1983); H.R. 2327, 98th Cong., 1st Sess. (1983), H.R. 3939, 98th Cong. 1st Sess. (1983); etc.

²² But see also Pub. L. 108-401 (2004) (authorizing three years of appropriations to recreate the Administrative Conference). ACUS thus far has received no funding, however.

²³ ACUS Recommendation 76-5 proposed that agencies provide pre-adoption notice and comment for guidance documents that might have a substantial impact on the public, as well as post-adoption notice and comment procedures for other guidances. See 1 CFR 305.76-5. In recommendation 92-2, ACUS suggested that the agency decide outright whether to issue a policy as a legislative rule or as a nonbinding policy statement, and with respect to the latter, state explicitly that the agency is not treating them as binding. Moreover, ACUS recommended that agencies establish “informal and flexible procedures that allow an opportunity to challenge policy statements.” See 1 CFR 305.92-2.

²⁴ FDAMA section 701, codified at 21 U.S.C. 371(h). FDA’s “Good Guidance Practices” were promulgated by notice-and-comment rulemaking and are now

With the exception of the FDA procedures, however, statutes require no procedures for agency guidance documents.²⁵ Agency practices vary widely from seeking no public comment at all to publishing a draft guidance for comment in the Federal Register.²⁶ Meanwhile, judicial review is hard to come by.²⁷

Some commentators have responded by calling for broad use of notice-and-comment rulemaking for significant policy decisions.²⁸ However, even without public participation and judicial review, most commentators have guardedly defended agency reliance on guidance documents, because such documents can help agencies more consistently supervise lower-level employees. In addition, so the argument goes, a guidance document, even without participation or judicial review, beats the alternative: no notice whatsoever of the agency's approach.²⁹

I want to make a fairly simple point. This debate on guidance documents has generally focused upon those whom the agencies regulate. It

codified at 21 C.F.R. § 10.115.

²⁵ The only exception, apart from FDAMA, appears to be the publication requirements of APA Section 552. That section bars any adverse effect on a person from a guidance document not properly published. See 5 U.S.C. 552(a).

²⁶ See *infra* text accompanying note 108-125. This confirms that agencies may be interested in reaping the gains from streamlined procedures.

²⁷ See *infra* text accompanying notes 64-68; 93-106.

²⁸ E.g., Robert Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?* 41 *Duke L.J.* 1311 (1992) (advocating notice-and-comment rulemaking except for interpretive rules that interpret statutory language with a “tangible” meaning).

²⁹ Peter Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element*, 53 *Admin. L. Rev.* 803, 806 (2001) (“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.’”). Michael Asimow has made a similar point, particularly in the context of state administrative procedures. See 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”). See also William R. Andersen, *Informal Agency Advice—Graphing the Critical Analysis*, 54 *Admin. L. Rev.* 595, 596 (2002) (the alternative to informal advice of “‘secret law’ regularly applied but unknowable—has never been thought wise in a mature legal system”); *Hoctor v. USDA*, 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.”).

has largely ignored another important component of the “public” affected by agency regulation: regulatory beneficiaries. If regulatory beneficiaries are made a primary focus, the case for some sort of procedural reform of agency policymaking-by-guidance is considerably stronger. My focus here is not on those who benefit directly from agency payments (such as subsidies for health care or housing), but rather from the agency regulation of others. These include workers that expect to work in healthier workplaces, consumers that expect to benefit from product safety regulation, and common resource users that expect to benefit from environmental regulation.

This group of regulatory beneficiaries has a distinct and substantial interest in the mode an agency uses to make policy, and it can suffer unique disadvantages from an agency’s use of guidance documents. Moreover, the choice between reliance on nonbinding, nonparticipatory guidance documents and “secret law” may be a false one. If an agency’s use of guidance documents is subject to greater procedural requirements, the agency will nonetheless face significant incentives to make its approaches known to the public in advance.

Section II(A) summarizes the debate on guidance documents to date. Section II(B) discusses regulatory beneficiaries and their relationship to administrative agency decision making. Section II(B) then turns to an analysis of the distinct costs to beneficiaries’ ability to obtain judicial review and to participate in agency decisionmaking when an agency issues a policy in a guidance document rather than a rule. Section III discusses a number of responses to the problem of guidance documents. It first concludes that neither inaction nor requiring across-the-board notice-and-comment rulemaking is likely to be satisfactory. It then overviews a number of more appropriate solutions, including requiring all agencies to apply “good guidance practices” and creating a right to petition for revision or revocation of a guidance document. Such solutions offer promise for addressing the concerns of regulatory beneficiaries.

II. Guidance Documents and Regulatory Beneficiaries

A. The Debate to Date

I set forth three simple examples to help show the basic outlines of the debate. I then briefly summarize the effects of guidance documents on agencies and regulated entities. The changes evoked by guidance documents also have the effect of setting policy for regulatory beneficiaries, which I discuss in greater detail below.

For one example, FDA’s Center for Food Safety and Applied Nutrition issues Compliance Policy Guidances. The FDA enforces against “adulterated

foods” sold in interstate commerce,³⁰ and the FDA uses guidance documents to describe what it currently views as “adulterated food.” In 2001, FDA issued, without notice and comment, a compliance policy guidance for apple juice with more than 50 ppb patulin, a naturally occurring but carcinogenic mold. FDA stated that it would expect its staff to recommend enforcement action against sellers of apple juice with patulin exceeding this level.³¹

For another, the Department of Education’s program implementing Title IX has largely been accomplished through guidance documents, especially with respect to athletic opportunities for collegiate women.³² Since Congress enacted Title IX, the Department has promulgated only one notice and comment rule, in 1974, in response to a Congressional directive.³³ The 1974 rule generally requires federal funding recipients with athletic programs to “provide equal athletic opportunity for members of both sexes.” The rule contains an unprioritized laundry list of factors for the Department to consider in determining the presence of “equal opportunities.”³⁴ The Department has specified its Title IX policies in a more detailed way only in its guidance

³⁰ 21 U.S.C. § 346 provides in relevant part: “Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 342(a) of this title; but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 342(a) of this title. . . .”

³¹ See FDA CFSAN Compliance Policy Guide Sec. 510.150, available at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg510-150.htm (Last visited Aug. 3, 2005). 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 Department of Health and Human Services, Annual Comprehensive List of Guidance Documents at the Food and Drug Administration, 66 Fed. Reg. 53836 (Oct. 24, 2001).

³² See 20 U.S.C. 1681.

³³ See Pub. L. 93-380 § 844, Aug. 21, 1974, 88 Stat. 612 (requiring Secretary of Education to publish rules implementing “prohibition of sex discrimination in federally assisted programs, including reasonable regulations for intercollegiate athletic activities considering the nature of the particular sports”). The rule appears at 45 C.F.R. 88.41.

³⁴ The factors include the provision of facilities, equipment, coaching, publicity, and accommodation of the interests and abilities of members of both sexes. See 45 C.F.R. 88.41.

documents. In 1979, in a “Policy Interpretation,” the Department of Education announced a far more specific series of three alternate tests to assess compliance (by, for example, looking at whether opportunities are “substantially proportionate” to enrollment; whether, if women are underrepresented, athletic programs for them are nonetheless expanding; or, whether women’s interests and abilities have been fully accommodated).³⁵ The Department has since issued several “clarifications” in guidance documents including in 1996 and in 2005.³⁶

Finally, in January, 2003, following the Supreme Court’s decision in *Solid Waste Agency of Northern Cook County v. United States Army Corps of Engineers*³⁷ refusing to read the Clean Water Act to authorize federal jurisdiction over isolated, intrastate, nonnavigable wetlands where the sole claimed basis for jurisdiction is migratory bird presence, the EPA issued a legal memorandum announcing changes in its Clean Water Act implementation.³⁸ 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 [Headquarters] approval.”³⁹ The guidance ended up being rescinded at the end of 2003,⁴⁰ but

³⁵ See Department of Education, A Policy Interpretation: Title IX and Intercollegiate Athletics, 44 Fed. Reg. __ (Dec. 11, 1979).

³⁶ In 1996, the Department indicated that compliance with any of the three prongs, not simply the first one, would bring the institution within a Title IX “safe harbor.” More controversially, in 2005, when the Department, in a “Dear Colleague letter,” stated that on-line surveys of students would, under certain circumstances, be adequate to document “insufficient interest to support an additional varsity team for the underrepresented sex” so that the institution would be presumed compliant with Title IX. See Additional Clarification on Intercollegiate Athletics Policy: Three-Part Test—Part Three (Mar. 17, 2005), at 4-8, available at www.ed.gov (Last visited Aug. 9, 2005).

³⁷ 531 U.S. 159 (2001).

³⁸ See EPA and Army Corps, “Joint Memorandum,” 68 Fed. Reg. 1995-1998 (Jan. 15, 2003)

³⁹ 68 Fed. Reg. at 1997. The memorandum also was coupled with 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. 68 Fed. Reg. at 1991.

⁴⁰ For links to the relevant December 2003 EPA announcement and press release, see <http://www.epa.gov/owow/wetlands/guidance/SWANCC/index.html> (Last visited Sep. 29, 2005).

the example remains instructive.⁴¹

All these guidance documents are broad and prospective in their application, like legislative rules. Like legislative rules, the agencies have implicitly developed the guidance documents with regard to statutory goals. The FDA guidance documents are aimed at food-related health risks faced by consumers; the Education Department's at ensuring equal athletic opportunities for collegiate women; and 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 interpretive rule, or both.⁴² The agency is not legally obligated to assemble a detailed record, disclose its data, prepare extensive analysis, or respond to significant comments.⁴³ The guidances are not legally binding upon regulated entities and generally not upon the agency either.⁴⁴

⁴¹ Of course, other examples abound. EPA has recently issued an "interpretive statement" disclaiming jurisdiction to require a Clean Water Act permit before pesticides are sprayed over navigable waters, see Environmental Protection Agency, Application of Pesticides to Waters of the United States in Compliance With FIFRA, 70 Fed. Reg. 5095 (Feb. 1, 2005). The Food and Drug Administration has used guidance documents to suggest that pharmaceutical companies may advertise their products on television without supplying detailed information on risks and benefits. See Food & Drug Administration, Guidance for Industry: Consumer-Directed Broadcast Advertisements (Aug., 1999), available at <http://www.fda.gov/cder/guidance/1804fnl.htm> (Last visited Jan. 10, 2006).

⁴² See 5 U.S.C. § 553(c).

⁴³ United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 252 (2d Cir. 1977).

⁴⁴ Generally, agencies add disclaimers to this effect. See, e.g., U.S. Environmental Protection Agency, Producers' Compliance Guide for CAFOs, Nov. 2003, at ii (noting that document "does not impose legally binding requirements on any party, including EPA, States, or the regulated community"), available at <http://cfpub.epa.gov/npdes/afo/compliance.cfm#copy> (Last visited Sep. 29, 2005), U.S. Food & Drug Admin., Compliance Policy Guides Introduction ("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."), available at http://www.fda.gov/ora/compliance_ref/cpg/introduction.html (Last visited Sep. 29, 2005); Mendelson, Agency Burrowing, *supra* note 3, at 574 n. 70 (listing other agency documents).

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 Guide (CCH) para. 45,105 (Feb. 27, 1997) ("HCFA Rulings [including statements of policy and interpretation] are binding on all HCFA components . . .").

As a consequence, the agency cannot base a later enforcement action solely on the fact of noncompliance with a guidance document.⁴⁵ So, the seller of apple juice with 60 ppb patulin remains free to argue that the FDA's position that its juice is adulterated is arbitrary and capricious or not authorized by statute; the university remains free to argue that despite not satisfying any of the Education Department's "three factors," it is nonetheless supplying equal athletic opportunities to women. A court may give limited deference to an agency's statutory interpretation in such a document, but will not treat it as binding.⁴⁶

Nonetheless, these documents often have rule-like effects on regulated entities – thereby changing the world for regulatory beneficiaries as well. When a policy is issued through a guidance document, regulated entities often comply with the policy and do not put the agency to the burden of bringing an enforcement action. So, the apple juice producer may try to keep patulin levels below 50 ppb to avoid FDA enforcement and the accompanying hassle and penalties. Especially if the penalties for shipping adulterated foods are steep and the costs of compliance are not, the juicer will not take its chances on challenging the policy in an enforcement action. It will simply conform.⁴⁷

By the same token, universities, a major group of regulated entities, generally comply with the Title IX guidances. This way, they can avoid dealing with the time and expense of responding to agency inquiries into potential violations. (Any citizen can initiate an inquiry with a simple administrative complaint to the Department's Office of Civil Rights.) Universities also may be sensitive to the need to maintain a good long-term relationship with the Department, as well as good press coverage. Most often these inquiries are resolved not through the filing of an enforcement action, but through a negotiated settlement.

⁴⁵ Strauss, *supra* note 29; Ronald M. Levin, Nonlegislative Rules and the Administrative Open Mind, 41 Duke L.J. 1497, 1501 (1992). To the extent an agency attempts to rely on a policy or guidance to bind the regulated entity, the courts will strike the action down for failure to conform to APA rulemaking provisions. See *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987); *McLouth Steel Products Corp. v. Thomas*, 838 F.3d 1317 (D.C. Cir. 1988); *Appalachian Power v. United States*, 208 F.3d 1018 (2000); but see *Molycorp v. EPA*, 197 F.3d 543 (D.C. Cir. 1999).

⁴⁶ See *Mead v. United States*; *Christensen v. Harris County*; *Skidmore v. Swift*. Again, while such a document may receive deference in court, a consumer/regulatory beneficiary invoking a private right of action or bringing a citizen suit also cannot simply rely upon a showing of a regulated entity's violation of a policy or a guidance.

⁴⁷ See also Conrad, *supra* note 18, at 10724 ("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.").

A regulated entity may not only refrain from taking action that it previously believed might be permitted, but also may engage in activity that it previously perceived might be regulated. For example, the FDA issued a draft guidance document in 1997 suggesting that broadcast pharmaceutical advertising need not fully summarize medication side effects on the air. Under the terms of the guidance, FDA would view the manufacturer as having made “adequate provision” for informing consumers as long as the ad referred the consumer either to information available elsewhere, through, say, a toll-free number or webpage. Prior to the issuance of the draft guidance in 1997, pharmaceutical companies engaged in very little direct-to-consumer advertising because of uncertainty about the “adequate provision” legal requirement and the challenge of producing commercially effective 30-second television ads containing the drug’s label information. The 1997 guidance “has been credited with clearing the way for the largest spending increase in the history of pharmaceutical advertising.”⁴⁸

Meanwhile, issuing a guidance is relatively cheap, compared with notice-and-comment rulemaking, and the agency also retains flexibility to change the guidance cheaply. The agency may also hope to delay expensive litigation or a judicial ruling that results in invalidation of the policy. The prospect of “compliance for less” is almost certainly among the reasons that agencies use guidance documents, rather than going through the effort of notice-and-comment rulemaking.⁴⁹ The increasing costs of rulemaking requirements⁵⁰ undoubtedly sharpen this incentive.⁵¹ This is the source of

⁴⁸ See Joseph McMenamin, Samuel L. Tarry, Jr., and Dennis J. Whelan, *FDA Guidance on Drug Promotion; Pulling the Net From Beneath Consumer-Directed Advertising*, *Product Liability Law & Strategy*, Oct. 1999, at 1 (available on Lexis). The “adequate provision” requirement appears in FDA regulations at 21 C.F.R. 202.1(e)(1).

⁴⁹ As Conrad has argued, agencies also may issue policies in guidance documents to avoid contentious issues. Conrad, *supra* note 18, at 10725 (“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. E.g., Richard G. Stoll, *Court Strikes Heavy Blow to ‘Rulemaking’ Through Informal Guidance Documents*, 31 *Env’t. Rep.* 1284, 1285 (June 16, 2000) (describing internal disagreements within EPA over stringency of controls and use of guidances to avoid contention).

⁵⁰ Strauss, *supra* note 29, 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.”). See generally Office of Management and 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 remainder of 4088 final rules published during same period). In an overview of 42 significant notices of proposed rulemaking, West calculated the average interval between

criticisms from judges and scholars that agencies are using guidance documents illegitimately because they can obtain a rule-like effect without the procedural discipline, public participation, and judicial accountability required by the APA.⁵²

In addition, the lack of procedural discipline raises the risk of an agency action that serves “rent-seeking” interests or does not properly respond to public preferences. Further, because it is not a rule and generally is not published in the Federal Register, the action is likely to be subject to less presidential or congressional oversight or attention in the media.

Meanwhile, the agency forgoes benefits it might have received from notice-and-comment rulemaking. These include the receipt of useful information from sources not previously known to the agency and the decisionmaking discipline imposed by having to respond to comments received.⁵³

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 (Jan./Feb. 2004)

⁵¹ The only exception is a “publication rule,” 5 U.S.C. § 552(a), which must be published before the agency can rely upon it. This might be better read, however, as requiring publication for rules that qualify for a substantive exception from 5 U.S.C. § 553 (See 5 U.S.C. § 553(a) (excepting benefits rules)).

⁵² Anthony, *supra* note 2; House Committee on Government Reform, *Non-Binding Legal Effect of Agency Guidance Documents*, H. Rep. 106-1009, 106th Cong. 2d Sess. 9 (2000) (“[A]gencies have sometimes improperly used guidance documents as a backdoor way to bypass the statutory notice-and-comment requirements for agency rulemaking and establish new policy requirements.”); Joel E. Hoffman, *Public Participation and Binding Effect in the Promulgation of Nonlegislative Rules: Current Developments at FDA*, 22 *SPG Admin. & Reg. L. News* 1 (1997) (“[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 (2004) (“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.”).

⁵³ Asimow, *Nonlegislative Rules*, *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.”); Robert Anthony & David Codevilla, *Pro-Ossification: A Harder Look at Agency Policy Statements*, 31 *Wake Forest L. Rev.* 667, 677 (1996).

Agencies may, of course, have highly legitimate reasons to use guidance documents unrelated to their resemblance to a legislative rule. Some guidance documents are not aimed particularly at regulated entities, but like the agency handbook, serve as extremely useful supervisory tools for agencies.⁵⁴ Agencies rely on handbooks, directives, and other similar guidance documents so that lower-level employees will make more consistent (and relatively predictable) decisions. Legislative rules would serve the same purpose, of course, but when an agency uses guidance documents, it can supply information to lower level employees more cheaply and without risking an outside suit based on noncompliance with the rule.⁵⁵

Agencies may also use guidance documents to experiment with new approaches to implementing programs before committing the policies to the binding, less flexible form of the legislative rule.⁵⁶ Finally, it is unrealistic to think that every nuance of a legal rule can be defined by the agency and set forth in the rule document itself. Agencies cannot anticipate every case or define every word, and it would be highly cumbersome to require them always to use the rulemaking process when they do attempt to bring greater detail to the scheme they implement.

From the perspective of a regulated entity, compared with a notice-and-comment rule, an agency's use of a policy or guidance document can raise significant reliance concerns. The agency is generally not bound to comply with the statement in the guidance document. Guidance documents sometimes contain explicit disclaimers to this effect. Agency counsel also may argue to a court in a particular case that the agency need not act in conformity with the guidance. Courts generally will not hold an agency to the terms of such a document.⁵⁷ The concern may be somewhat lessened, however, given current

⁵⁴ See Strauss, *supra* note 29; Magill, *supra* note 18.

⁵⁵ See Lisa Bressman, *Schechter Poultry at the Millennium*, 109 Yale L.J. 1399, 1415 (2000) (discussing administrative limiting rules); e.g., *Schweiker v. Hansen*, 450 U.S. 785, 790 n. 5 (1981) (per curiam) (finding Social Security Administration claims manual not binding upon agency and remarking that it is better to have nonbinding guidance and tolerate occasional erroneous administration than to have no rules at all).

⁵⁶ For a catalog of agency motivations in issuing these policies and guidances, see M. Elizabeth Magill, *Agency Self-Regulation* (draft 2005) (on file with author).

⁵⁷ E.g., *Schweiker v. Hansen*, 450 U.S. 785, 789 (1981); *Brock v. Cathedral Bluffs Shale Oil Co.*, 174 F.3d 206 (D.C. Cir. 1999) (declining to dismiss Labor Department enforcement action that did not conform to Labor Department guidelines on citing companies for their contractors' violations). Additional caselaw analysis and citations appear at Mendelson, *Agency Burrowing*, *supra* note 3, at 575 n. 71 and in William Funk, *When is a "Rule" a Regulation? Marking a Clear Line Between Nonlegislative Rules and*

pressure on agencies to act in conformity with their guidance documents.

Moreover, regulated entities generally have no entitlement to participate in the guidance development process or to receive a response from the agency.⁵⁸ While regulated entities may participate informally to some degree, as described in greater detail below, public access is at the agency's option, as is how much data to disclose. Nor is the agency obligated to respond to comments or to supply the "concise statement of basis and purpose" that the APA would require for rulemaking.⁵⁹

Guidance documents receive highly limited review from Congress and the White House. These sorts of guidances and policy documents are not currently, for example, subject to the Office of Management and Budget review normally applied to rules.⁶⁰ (While the Office of Management and Budget posted for a 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.⁶¹) Nor are these guidance documents subject to Congressional Review Act requirements.⁶² While Congress can, of course, conduct oversight of any agency action it wishes, such oversight is generally ad hoc. Congressional

Legislative Rules," 54 Admin. L. Rev. 659, 661 (2002). See also *supra* text accompanying note 17 (noting increased internal and external pressure upon agencies to conform to guidance terms).

⁵⁸ See *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977). There is often a heavy reliance on informal information-gathering. 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); e.g., Strauss, *supra* note 29, at 805 (noting that NRC expected guidance developed by staff to "be the product of informal consultation by responsible staff with affected parties," but "were supervised by the Commission in only a general way").

⁵⁹ See 5 U.S.C. § 553.

⁶⁰ See Exec. Ord. 12,866, 58 *Fed. Reg.* 51735 (1993).

⁶¹ See Rachel Urdan, *OMB Plan to Expand Guidance Reviews Could Delay Key EPA Policies*, *Inside EPA*, Sep. 22, 2005.

⁶² 5 U.S.C. §§ 801-808. Nor are they 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, and the Paperwork Reduction Act, 44 U.S.C. § 3501-3520.

review of policy and guidance documents is highly limited at best.⁶³

Finally, judicial review of these decisions is often difficult to obtain. A policy contained in a guidance document may not be considered “final agency action” (if it is a staff level document or is not signed by the head of the agency or even, on occasion, if the agency presents it as not binding)⁶⁴ or, even if it is, it may not be “ripe for review” outside the context of a particular situation. Courts have only occasionally recognized the “practical effect” a guidance document may immediately have as a ground for finding the document ripe for review. More often, courts have declined to review the guidance document, especially if the agency has specifically disclaimed any binding effect of the document.⁶⁵

⁶³ This is in part due, of course, to the sheer volume of these documents. Congressional oversight of rulemaking also might be further reduced, if rulemaking volume were to increase substantially. The GAO has generally noted with respect to rulemaking that efforts to increase congressional oversight have been relatively unsuccessful. See General Accounting Office, Testimony of J. Christopher Mihm, Federal Rulemaking: Past Reviews and Emerging Trends Suggest Issues that Merit Congressional Attention, Rept. GAO-06-228T, Nov. 1, 2005, at 6 (“Our 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 influence mechanisms] to influence changes in agencies’ rules to date.”).

⁶⁴ See *National Automatic Laundry v. Schultz* and other cases. In *National Ass’n of Home Builders v. Norton*, the D.C. Circuit refused to review, as not final, a survey protocol for butterflies developed by the Fish and Wildlife Service. The court reasoned that although the agency’s decisionmaking process was at an end, the document was not binding and no effects upon the legal rights and obligations flowed from it. See 403 F.3d 8, 14 (D.C. Cir. 2005).

⁶⁵ See *Utility Air Regulatory Group v. EPA*, 320 F.3d 272 (D.C. Cir. 2003) (holding unripe challenge to EPA manual provisions requiring greater monitoring in permits); *Truckers United for Safety v. Fed. Hwy. Admin.*, 139 F.3d 934, 938 (D.C. Cir. 1998) (finding informal statements unripe); *Aulenback, Inc. v. Fed. Hwy. Admin.*, 103 F.3d 156, 167 (D.C. Cir. 1997). See also *Ohio Forestry Ass’n v. Sierra Club*, 523 U.S. 723, 726 (1998) (finding forestry plans not ripe for review); *Lujan v. National Wildlife Federation*, 497 U.S. 871 (1990) (“land withdrawal review program” not a discrete agency action ripe for review). But see *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); *McLouth Steel v. Thomas*, 838 F.2d 1317 (D.C. Cir. 1988); *Clean Air Implementation Project*, 150 F.3d 1200, 1204 (D.C. Cir. 1998). The court reviewed the FDA guidance document on genetically modified materials in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp.2d 166 (D.C. D.C. 2000), but no finality or ripeness argument was apparently made in opposition to review. 116 F. Supp. 2d at 171 (rejecting arguments that 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

Later on, a regulated entity can, in theory, challenge the policy if it forms the basis for an enforcement action.⁶⁶ Since the agency cannot rely on the simple fact of noncompliance with a policy to support an enforcement action, the regulated entity can litigate the legality and rationality of the agency's understanding of statutory and regulatory requirements. However, a regulated entity may rationally forgo this opportunity by, for example, choosing to comply with the policy so as to avoid a loss in a later enforcement action.⁶⁷ The decision between compliance and challenge will depend on the initial costs of compliance, the costs of litigating against the agency position and the size of financial and other penalties (including bad publicity), including the extent to which those penalties depend on the period of noncompliance. (These latter costs will be discounted by the probability that the agency never brings an enforcement action at all.) By comparison, a loss in a pre-enforcement challenge to a rule, though it comes with litigation costs, will not come with penalties. Further, in the enforcement setting, the particular regulated entity generally must be individually represented. In a pre-enforcement challenge, regulated entities may be willing to pool funds and share the costs of litigation by having a trade association, rather than an individual company, challenge the rule. The expected costs of litigation to an individual regulated entity consequently may be lower.⁶⁸

As noted, however, scholars generally have reacted to this state of

environmental review requirement. 116 F. Supp.2d 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.

⁶⁶ 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 a conclusion that the guidance is not ripe for review. See *Utility Air Regulatory Group v. EPA*, *supra*; *General Motors v. EPA*, *supra*.

⁶⁷ Strauss, *supra* note 29, at 817 ("in 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").

⁶⁸ This intuition is supported by the apparent preference of trade associations for pre-enforcement challenges to rules, if available. Of course, all this assumes that the regulated entity is unhappy with the agency policy. A regulated entity may be happy to have an agency issue favorable policy in a guidance or policy statement. For reasons of regulatory certainty, the regulated entity would probably prefer the favorable policy to be issued in a binding rule; nonetheless, a favorable guidance document is clearly preferable to no statement from the agency at all.

affairs with a guarded “it’s better than nothing.”⁶⁹ Although a regulated entity’s interest in certainty and in the initial opportunity to challenge agency policy may suffer, a regulated entity can nonetheless receive very valuable information about an agency’s intentions. Moreover, these sorts of documents enable agencies to manage their many employees that have contact with the public and reduce the risk of arbitrary decisions, increasing the chances that individual agency employees will treat like cases alike. They are “important encouragements to agency regularity and even-handedness.”⁷⁰

B. Regulatory Beneficiaries and Agency Accountability

While scholars have considered the interests of “citizens” in defending guidances, citizens are not all the same. Thus far, my overview—and the scholarly debate—has focused primarily upon those whom the agency directly regulates. The discussion has not adequately considered those whose behavior is not directly regulated, but who nonetheless benefit from an agency’s program.⁷¹ I turn now to discussing these indirect regulatory beneficiaries and then to analyzing how they fare when agencies develop policy through guidance documents.

Many citizens are, of course, direct regulatory beneficiaries, such as those who receive cash or services, Social Security or Medicaid. Direct beneficiaries possess the classic “new property” of Robert Reich.⁷² They are

⁶⁹ Strauss, *supra* note 29, 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.’”); Asimow, *Nonlegislative Rules*, *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.”).

⁷⁰ Strauss, *supra* note 29, at 809.

⁷¹ Sunstein challenges this distinction, arguing that agency rules often create a bundle of rights and responsibilities for all interested parties. Cass Sunstein, *What’s Standing After Lujan? Of Citizen Suits, “Injuries,” and Article III*, 91 *Mich. L. Rev.* 163, 186-88, 196-97 (1992).

⁷² See Charles A. Reich, *The New Property*, 73 *Yale L.J.* 733 (1964). Reich argued that much individual wealth now comes from benefit claims against the government; and he argued that those claims warrant similar legal status to claims to traditional property interests. Reich’s argument was accepted in significant part in *Goldberg v. Kelly*, 397 U.S. 254 (1970) (holding that Constitution requires due process before revocation of welfare benefits).

also known to the agency because they receive their benefits in a direct relationship with the agency itself or with an implementing state or local agency.

I am concerned with a different group of regulatory beneficiaries, one which lacks any focused or direct relationship with the agency.⁷³ The particular group is composed of citizens who benefit from the regulation of others.⁷⁴ Congress has passed countless statutes justified explicitly in terms of the “public interest.”⁷⁵ Among these, many statutes, such as pharmaceutical safety, workplace safety, and environmental statutes, authorize regulation with the intent of indirectly benefitting identified—but unregulated—groups. For example, Congress enacted the Safe Drinking Water Act in 1974 (and subsequently amended it), which regulates drinking water suppliers, specifically to protect tap water users and in response to reports of lead in Boston’s tap water and carcinogenic chemicals in that of Pittsburgh and New Orleans.⁷⁶ As another example, under the Federal Meat Inspection Act, the USDA has authority to assure the quality of American beef by regulating the

⁷³ 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 them here, but it is worth noting that the concerns raised in this article affect them less. Their interests are often aligned with 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 them to improve their own prospects before the agency or the courts. For example, power plants in Michigan advocating for fewer environmental regulations are also mobilizing consumers around the higher energy costs that may result.

⁷⁴ See also Richard Stewart & Cass Sunstein, *Public Programs and Private Rights*, 95 *Harv. L. Rev.* 1193, 1203 (1982) (describing class that benefits when “government 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 that benefit from government spending (say, on highways, libraries, or parkland acquisition)—are beyond the scope of this paper.

⁷⁵ These range incredibly widely. E.g., Egg Research and Consumer Information Act, “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,” Egg Research and Consumer Information Act, PL 93-428 (1974), codified at 7 U.S.C. § 2701-06; 20 U.S.C. § 3402 (finding creation of Department of Education to be in the public interest).

⁷⁶ See James L. Agee, *Protecting America’s Drinking Water: Our Responsibilities under the Safe Drinking Water Act*, March 1975 (EPA press release on SDWA adoption), available at <http://www.epa.gov/history/topics/sdwa/07.htm> (Last visited Sep. 20, 2005).

slaughter process.⁷⁷ Beef slaughterhouses, the regulated entities, must change their conduct to conform to USDA rules and are subject to USDA inspection and enforcement actions. Tap water drinkers and beef consumers, respectively, are clearly beneficiaries, but indirect ones. While they may tell the agency what they think, the statute sets up no direct interaction between tap water drinkers and the EPA or beef consumers and the USDA.

Whom we might recognize as a beneficiary of regulatory activity raises a number of doctrinal issues, including constitutional due process and standing to seek judicial review of agency action, each of which has been the subject of some significant scholarship.⁷⁸ For example, courts more or less automatically conclude that a regulated entity has standing to challenge agency action, but the recognition of standing for regulatory beneficiaries is more recent, and its breadth more debated by scholars and in the courts.⁷⁹ Regulatory beneficiaries sometimes receive a statutory right to enforce the regulatory regime, as with citizen suits and express and implied private right of actions.⁸⁰

Rather than engage the debates on standing or due process, I instead suggest that beneficiary issues should be more explicitly considered in the design of administrative processes. With respect to administrative process, it is fair to make, at a minimum, the following points: For each regulatory statute thus far mentioned, and for countless others, there is a class of people that obtains tangible benefits from the regulation of others.⁸¹ They may also obtain benefits we may see as more abstract or ideological. (For example, we might recognize as regulatory beneficiaries childless members of minority groups that want IRS enforcement of tax code provisions revoking advantages

⁷⁷ 21 U.S.C. §§ 601 *et seq.*

⁷⁸ See generally Stewart & Sunstein, *supra* note 74. For an example of a due process analysis where a regulatory beneficiary's interests are considered, see *Brock v. Roadway Express, Inc.*, 481 U.S. 252, 262 (1987) (considering interest of whistleblower in not being discharged, as well as employer's interest in not having restrictions on ability to employ at will).

⁷⁹ See Daniel Farber, *Uncertainty as a Basis for Standing*, 33 *Hofstra L. Rev.* 1123 (2005); William Fletcher, *The Structure of Standing*, 98 *Yale L.J.* 1221 (1988); Reich, *The New Property*, *supra* note 72.

⁸⁰ See Stewart & Sunstein, *supra* note 74, at 1202-1216.

⁸¹ My focus here is upon regulatory statutes, but procurement and spending statutes also have indirect beneficiaries, such as drivers on newly repaved highways and other beneficiaries of public works projects.

to discriminatory schools.⁸²) Regulatory beneficiaries may have been specifically named; they may have done battle in Congress to obtain passage of the statute; Congress may otherwise have suggested that the statute should benefit these segments of the public; or it may simply have been widely understood that the statute was meant to regulate one segment of society to indirectly benefit another group. For example, the statute governing generation of hazardous air pollution regulates largely industrial emitters to benefit neighbors and workers.⁸³

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. Accordingly, we should see the interests of regulatory beneficiaries in the way an agency carries out its mandate as “real interests,” and be sure they are included among those that can hold an agency accountable. We already recognize the interests of regulated entities as “real interests,” by recognizing constitutional standing to challenge agency action and due process rights before agencies impose sanctions. Moreover, regulated entities often receive statutory process in excess of that required by the Constitution.

In some settings, a regulatory beneficiary’s loss of expected benefits in some settings may not as serious or coercive as a loss suffered by a regulated entity on which fines or permit requirements are imposed.⁸⁴ At a minimum, however, regulatory beneficiaries should be seen as having at least as great an interest in holding the agency accountable for doing the job that Congress set before it. Why should tap water drinkers be perceived to have any less interest than water treatment plants in how EPA sets standards for drinking water? Why should neighbors of a power plant be seen as having less interest than a power plant operator in how EPA sets Clean Air Act hazardous air pollutant standards for such plants? The interests of regulatory beneficiaries in a program delegated to an agency are undeniable and significant, and we should be sure this group can hold the agency accountable. “[E]nforcement of public policy directives is a crucial task of modern

⁸² E.g., *Allen v. Wright*, 468 U.S. 737, 750 (1984). The question whether notions of standing should be expanded in this manner is, however, beyond the scope of this paper.

⁸³ Clean Air Act, 42 U.S.C. § 7412(d) (requiring “maximum” reductions in hazardous air emissions); § 7412(f)(1) (requiring investigation of “actual health effects with respect to persons living in the vicinity of sources”).

⁸⁴ This will depend on the setting, of course. The asthmatic neighbors of the power plant may suffer severe health costs from an agency’s failure to require air pollution controls, and perhaps we might see those losses as more serious than the power plant’s pollution control costs.

government,”⁸⁵ 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 proper 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 are not mentioned in the Constitution and whose employees are not directly elected. One prospect is to see the agency as an agent of the major “democratic” branches of government, either Congress or the President or both. The “transmission-belt” model, with its assumption that Congress has made all relevant value choices in the authorizing statute, and that the agency is merely a technocratic implementing machine, has long been out of favor given the reality that agencies are permitted to and regularly do make value-laden policy choices.⁸⁶ Instead, in view of the discretion Congress typically grants agencies (rendering 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.⁸⁷ As I have discussed elsewhere, presidential control can supply legitimacy even for executive branch agencies only to a certain extent: presidential resources to monitor agencies are limited, and presidential elections can serve to communicate the public’s preferences on particular agency policies only very imperfectly.⁸⁸ Finally, some civic republican scholars have argued that agency deliberations themselves are democratic in nature, legitimate because they supply an opportunity for truly deliberative decision making where all viewpoints are effectively represented.⁸⁹ A critical part of ensuring that these deliberations

⁸⁵ Edward Rubin, *The Myth of Accountability and the Anti-Administrative Impulse*, 103 Mich. L. Rev. 2073, 2105 (2005).

⁸⁶ See Richard B. Stewart, *Reformation of American Administrative Law*, 88 Harv. L. Rev. 1667, 1676 (1975).

⁸⁷ See Mendelson, *Agency Burrowing*, *supra* note 3, at 580-81; Elena Kagan, *Presidential Administration*, 114 Harv. L. Rev. 2245 (2001); Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J. L., Econ. & Org. 81 (1985).

⁸⁸ Mendelson, *Agency Burrowing*, *supra* note 3, at 617-19 (arguing that presidential election generally very poor method of discerning public preferences on particular agency policy).

⁸⁹ Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 Harv. L. Rev. 1511, 1515 (1992); Mendelson, *Agency Burrowing*, *supra* note 3, at 585.

are legitimate, however, is making sure that agency deliberations are not skewed and the agency officiates over a genuinely participatory decision making process.⁹⁰ Similarly, neopluralist visions of the administrative state see its outcomes as legitimate because the agency can aggregate information and preferences received from a wide variety of interest groups.⁹¹

An important component of legitimacy under any of these theories of the administrative state is undoubtedly accountability. 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.⁹² Suppose we adopt one of the "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 be able to invoke the authority of Congress or the President to ensure that the agency's actions are constrained and that it is properly implementing the relevant statute and 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 its various governing statutes and with the requirements (including the arbitrary and capricious standard) of the Administrative Procedure Act.

Due to serious resource demands (both for the relevant branch and, possibly, for the entity that wishes to invoke its supervision), however, access to genuine presidential oversight or congressional oversight seems difficult to assure for any regulatory beneficiary or regulated entity. Judicial oversight is surely deferential as well, as courts apply a relatively weak "arbitrary or "capricious" APA review standard and defer to agency legal interpretations

⁹⁰ Id. Matt Adler has thoroughly and formally critiqued these "proceduralist" civic republican and pluralist theories on the ground that they are either instrumental (justified only on the ground that the procedure assists them in getting to some sort of "best result," and hence the process itself has no independent value) or unjustified on the theory that participation cannot render preferred a non-optimal result from the welfare perspective. See Matthew D. Adler, *Beyond Efficiency and Procedure: A Welfarist Theory of Regulation* 28 Fla St. U. L. Rev. 241, 284-85 (2000). Adler's account suffers, however, from a failure to recognize critical practical uncertainties in the process and to recognize the prospect that preferences may not exist *ex ante* but may be formed in a dialogic process. See also 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, "procedural forms are more likely correlated with efficient regulation").

⁹¹ See Stewart, *supra* note 86, at 1712 (detailing administrative process similarities to legislative process); Ian Ayres & John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* 83 (1992).

⁹² Mendelson, *Agency Burrowing*, *supra* note 3, at 577.

under *Chevron* (or, less strongly, under *Skidmore/Mead*). Nonetheless, judicial review continues to represent an important external check on agency action not only because judges can demand some amount of transparency and rationality from an agency, but also because (assuming they meet threshold conditions for obtaining review) individuals can more easily invoke judicial review than they can, say, congressional oversight.

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

Consequently, to assess whether regulatory beneficiaries can effectively hold agencies accountable for implementing a statutory program meant to aid them, the "agency" theories suggest that we must look at the extent to which regulatory beneficiaries can invoke external mechanisms of control, primarily from courts. The civic republican and neopluralist models suggest that we must also look at the extent to which regulatory beneficiaries can effectively participate in the agency decision making process, including both access to that process and ensuring that their perspectives are directly engaged by agencies. As the next section describes, however, when agencies use guidance documents to set policy rather than rulemaking, regulatory beneficiaries suffer important losses to these means of accountability.

C. Regulatory Beneficiaries, Guidance Documents, and Agency Accountability

So, back to the original question: When an agency chooses to issue a policy in the form of a guidance, rather than a rule, what are the consequences to regulatory beneficiaries? Close analysis suggests that this agency decision interferes with critical tools that regulatory beneficiaries can use to hold agencies accountable for the policy choices they make—and hence with the likelihood that regulatory beneficiaries will view agency choices as legitimate. Regulatory beneficiaries lose significant access both to the courts and to their ability to participate in agency decision making.

1. Loss of Judicial Review Opportunities

First, and most significantly, when an agency enunciates its approach in a guidance rather than a rule, a regulatory beneficiary will likely never have the opportunity for judicial review that (eventually) is afforded to a regulated entity. Initially, neither regulatory beneficiaries nor regulated entities have

easy access to judicial review. Even assuming standing to sue can be shown,⁹³ guidance documents may not be considered final agency action or ripe for review.⁹⁴

The regulated entity, however, has an opportunity to challenge the agency policy if it is enforced. The scholarly defense of guidance documents has turned in large part on this ultimate access to judicial review. In the widely-quoted words of E. Don Elliott defending letting agencies 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...."⁹⁵ 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, by comparison, may never have that opportunity at all. 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 Headquarters.⁹⁶ It is fair to say that this policy, until its rescission at the end of 2003, was welcomed by the "objects of regulation," who could look forward to saving the costs of a discharge permit or effluent control or of mitigation requirements prior to filling a wetland. Similarly, assume FDA's choice of a tolerable patulin level in apple juice, while welcomed by juicers, is one that consumer groups believe to be inadequately protective of public health. In both cases, the part of the policy that concerns consumers—or environmental users—will be realized

⁹³ While many have argued that standing for regulatory beneficiaries is insufficiently broad, e.g., Fletcher, *supra* note 79, a regulatory beneficiary's standing to challenge a policy statement is likely to be little different than 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.

⁹⁴ E.g., *National Automatic Laundry & Cleaning Council v. Schultz*, 443 F.2d 689 (D.C. Cir. 1971); *Abbott Labs v. Gardner*, 387 U.S. 136 (1967).

⁹⁵ E. Donald Elliott, *Reinventing 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.").

⁹⁶ 68 Fed. Reg. at 1997. The memorandum also was coupled with 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. 68 Fed. Reg. at 1991.

primarily through agency inaction. The agency will simply not bring enforcement actions. To the extent a policy is realized through nonenforcement of a statutory scheme, the regulatory beneficiary generally may not challenge that.⁹⁷

Moreover, in a situation such as the patulin case, a choice by regulated entities to comply with the guidance the agency has issued will also foreclose any enforcement actions, and with that, the prospect of any judicial oversight at all. In a case where a regulated entity commits a violation (in the agency's view) and litigation ensues, a regulatory beneficiary's ability to get a hearing on its arguments will still be far from guaranteed. Suppose, for example, that in the case of the EPA guidance on intrastate waters, a regulated entity places "fill" within traditionally navigable intrastate waters without seeking a permit. The Army Corps of Engineers (which implements this part of the Clean Water Act) brings an enforcement action. A regulatory beneficiary, such as a neighbor who boats on the waters, would be hard pressed to use this as a vehicle for challenging the guidance's policy on intrastate waters. The boater would face several obstacles: First, under Fed. R. Civ. P. 24(a), the boater might not be entitled to intervention as of right.⁹⁸ The boater would first be faced with an argument that the agency was adequately representing its interests, since both the boater and the Corps would presumably take the position that the defendant was violating the statute. The boater might be able to argue under some circumstances that it would not be effectively represented by the government and that its interests would be impaired to the extent the court upheld the agency's policy overall as a valid, nonarbitrary position under the statute. On the other hand, the boater would also face strong arguments that the court could readily resolve the enforcement action without reaching arguments about the overall legality of the policy, any resolution of those arguments would be dicta, and the boater's interests would therefore not

⁹⁷ Heckler v. Chaney, 470 U.S. 821 (1985). If a beneficiary possessed a private right of action, such as a citizen suit, the beneficiary could litigate the policy issue in that setting. But see *infra* text accompanying notes 183-185 (discussing availability of citizen suits). Of course, an agency can always simply decline to address an issue altogether. Under some circumstances a regulatory beneficiary will prefer an inadequate agency guidance to none at all. Consistent failure to implement a statute, however, is more likely to lead to congressional and presidential oversight.

⁹⁸ Fed. R. Civ. P. 24(a) provides in relevant part: "Upon timely application anyone shall be permitted to intervene in an action: . . . (2) 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."

be impaired.⁹⁹ The boater might also face difficulty in asserting the “interest” that might be practically impaired by a judicial ruling, as required by Rule 24(a), since judicial holdings have varied on whether a substantial interest, including an economic stake, will suffice, or whether a party must show a “legally protected interest,” something an indirect regulatory beneficiary may have a hard time doing.¹⁰⁰

Admittedly, the case for intervention might be closer with a guidance such as that issued by the FDA on patulin in apple juice. Take the enforcement action where the FDA is arguing that an apple juice maker sold adulterated apple juice containing 60 ppb patulin (and that under the statute, any level above 50 ppb is “adulterated”). The position of consumers is that the statute (or the record) requires the FDA to treat juice with 30 ppb patulin as “adulterated.” The consumer conceivably could more successfully argue that its interests could be impaired by a judicial ruling upholding the FDA position that anything above 50 ppb is “adulterated.”¹⁰¹ Even here the case may be close, to the extent the court holds that it can resolve the enforcement action without reaching the issue raised by consumers.

In either case, the regulatory beneficiary could also seek permissive intervention. Not only are permissive intervention decisions highly discretionary with the district court,¹⁰² however, but to obtain intervention on

⁹⁹ The exception might be the following: suppose the agency argued that the defendant’s apple juice contained 60 ppb patulin, and the defendant responded in part by asserting that the marketed apple juice contained only 40 ppb patulin. At this point, the consumer could respond that despite the agency’s position, the statute still required the court to conclude that the defendant was in violation. However, this is likely to be the rare case.

¹⁰⁰ Compare *Ranchers’ Cattlemen Action Legal Fund Stock Growers of America v. U.S. Department of Agriculture*, 143 Fed.Appx. 751 (9th Cir. 2005) (2005 WL 1719211, *5) (rejecting “economic expectancy” as insufficient to justify intervention as of right); 223 F.R.D. 407, 433 (E.D. La. 2004) (rejecting interest in having children attend neighborhood school as sufficiently protected interest to warrant intervention) with *Liberte Capital Group v. Capwill*, 126 Fed.App.X 214, 220 (6th Cir. 2005) (finding banks’ “vested financial interest” sufficient to justify permissive intervention). See generally Wright, Miller & Kane, 7C Federal Practice & Proc. § 1908 at 271-300 (1986 & supp. 2005); *The Fund for Animals v. Norton*, 322 F.3d 728 (D.C. Cir. 2003) (finding Mongolian ministry could intervene as of right in Interior Department’s listing of certain sheep as threatened rather than endangered).

¹⁰¹ See Wright, Miller & Kane, 7C Federal Prac. & Proc. § 1908, at 302 (“several 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)”) (1986 & Supp. 2005).

¹⁰² See Wright, Miller & Kane, 7C Federal Prac. & Proc. § 1913, at 378.

this basis the regulatory beneficiary would have to show that it could have maintained the claim as a separate lawsuit—in other words, independent grounds for jurisdiction.¹⁰³ While there would surely be common issues of law and fact, 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 standing and ripeness that would have impeded obtaining review of the guidance in the first place. Moreover, courts may be reluctant to grant intervention to the extent they see beneficiaries as trying to “creat[e] whole new lawsuits” by intervening.¹⁰⁴ In short, even if the agency files enforcement litigation, a regulatory beneficiary’s ability to use the suit as a vehicle to litigate the rationality and legality of the policy stated in the guidance is uncertain at best.

Finally, even if enforcement actions could sometimes serve as a vehicle for regulatory beneficiaries to attack a statute, regulatory beneficiaries are likely to have a hard time learning about these actions, and they are thus unlikely to be able to participate in settlement negotiations.¹⁰⁵ When a regulated entity receives notice of an agency enforcement action, it may well invite support by a trade association.¹⁰⁶ However, it is highly unlikely to invite intervention by consumers that wish to see the agency more aggressively

¹⁰³ See *Rancher’s Cattlemen Action Legal Fund United Stockgrowers of America v. U.S. Dept. of Agric.*, 2005 WL 1719211 (9th Cir. 2005) (interpreting Rule 24 to require showing of “independent grounds for jurisdiction”); *Jones v. Prince George’s Cty, Md.*, 348 F.3d 1014, 1017 (D.C. Cir. 2003) (requiring party seeking permissive intervention to show standing to assert claim); *EEOC v. National Children’s Ctr., Inc.*, 146 F.3d 1042, 1045-46 (D.C.Cir.1998) (recounting that Rule 24(b) requires would-be intervenors to have “an independent ground for subject matter jurisdiction” on a claim or defense that shares a common question with the claims of the original parties); *Diamond v. Charles*, 476 U.S. 54, 76, 106 S.Ct. 1697, 90 L.Ed.2d 48 (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 lawsuit”). But see *EEOC v. National Children’s Ctr.*, 146 F.3d 1042, 1045-46 (D.C. Cir. 1998) (noting that circuit precedent seems to “allowing intervention even in ‘situations where the existence of any nominate ‘claim’ or ‘defense’ is difficult to find.”).

¹⁰⁴ See *Southern California Edison v. Lynch*, 307 F.3d 794, 804 (9th Cir. 2004).

¹⁰⁵ On the other hand, consent decrees entered under some statutes are reviewed for consistency with “the public interest.” In theory, then, regulatory beneficiaries could intervene before a settlement is entered in court to complain that the government is seeking inadequate damages or penalties.

¹⁰⁶ Cf. *National Petroleum Refiners’ Ass’n v. FTC*, 482 F.2d 672 (D.C. Cir. 1973) (trade association challenge to FTC issuance of octane ratings rule as beyond FTC’s rulemaking authority).

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 regulated entities are on the same footing. Neither has a particular entitlement to disclosure of agency data related to the guidance document or to an agency response to comments. These are, of course, entitlements that any member of the public would possess if the agency used notice-and-comment rulemaking to issue its policy.¹⁰⁷ As a practical matter, however, a number of features of the agency process suggest that regulatory beneficiaries generally will have less access.

First, it is worth noting the wide range of practices among the agencies. Agencies are not, of course, generally required to seek outside views upon their guidance materials, and some agencies indeed seek none. This is the practice with opinion letters, even ones taking a broad, prospective position, that are issued by the Wage and Hours Division of the Department of Labor.¹⁰⁸

Treating opinion letters as more akin to individual adjudications, the Labor Department has decided to forgo the information and views it might have received had it decided to seek public comment or hold public meetings. In these circumstances, regulated entities and regulatory beneficiaries are on the same footing.

However, other agencies, including other divisions of the Labor Department, regularly do seek input on significant guidances or policy documents.¹⁰⁹ An agency may hope to gather new information or identify any significant problems in how a guidance's policy will work. The agency may also hope to flush out any controversy or political opposition, especially from groups that can evoke oversight from Congress, the White House, or both. By

¹⁰⁷ This is not to say that such a regulatory beneficiary automatically could obtain judicial review of the agency's failure to respond to the beneficiary's comment in the notice and comment process.

¹⁰⁸ These opinion letters represent an unusual case, since by statute, if they are relied upon, the opinion letters afford a "safe harbor" to regulated entities. See 29 U.S.C. § 658 (Portal-to-Portal Act). Thus, although they are generally phrased in a broad, prospective manner, like guidance documents issued by other agencies, they are binding in a way that other guidance-type documents are not. Nonetheless, the Labor Department procedures are instructive.

¹⁰⁹ See Cornelius Kerwin, *Rulemaking: How Government Agencies Write Law and Make Policy* 189 (3d ed. 2003) (reporting that over 50% of surveyed interest groups reported receiving contacts from agencies).

responding to those sorts of concerns in advance, the agency may hope to avoid such oversight altogether. Indeed, agencies often claim greater legitimacy for these policies as a consequence of seeking public input.

At one end of the spectrum, some agencies—for some guidance documents—will solicit public input in a manner very similar to notice-and-comment rulemaking. Congress has instructed the FDA to develop procedures for guidance documents,¹¹⁰ and for so-called “Level 1 Guidances,” FDA has bound itself to publish notice of the draft guidance and invite comment either in the Federal Register or on the web.¹¹¹ The National Organic Program of the Department of Agriculture seems on the verge of issuing a similar binding rule.¹¹² Further, agencies have expressed a public commitment (nonbinding, of course) to reach out to a wide array of interested groups. The Coast Guard has publicly stated that it will circulate draft guidance documents known as “Navigation and Vehicle Inspection Circulars” to “all affected and interested parties” for “technical and policy comments” but supplies no explanation of how those parties will be identified.¹¹³ EPA’s 2003 Public Involvement Policy states that EPA’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.”¹¹⁴ The policy lists numerous methods by which EPA officials are encouraged to reach out, such as by including all citizens that request involvement, developing a contact list based on a group’s expression of past interest in writing or in person, and a host of other methods. (On the other hand, EPA has not clearly defined a set of actions outside rulemaking to which the policy will apply, noting only that it will seek such input when the Administrator or other top officials determine that a particular action “warrants public

¹¹⁰ See supra note 24.

¹¹¹ See Food & Drug Administration, Final Rule: Administrative Practices and Procedures: Good Guidance Practices, 65 FR 56468 (Sep. 19, 2000).

¹¹² National Organic Program: Development, Issuance, and Use of Guidance Documents, 70 Fed. Reg. 5129, 5131 (Feb. 1, 2005).

¹¹³ Department of Transportation, US Coast Guard, “Navigation and Vehicle Inspection Circulars,” www.uscg.mil/hq/g%2Dm/nvic/ (Last visited 8/3/05) (quoting linked graphic entitled “NVIC Clearance Process”).

¹¹⁴ See Office of Policy, Economics, Environmental and Innovation, US EPA, “Public Involvement Policy of the U.S. EPA,” May 2003, at 1 (Doc. EPA 233-B-03-002), available at www.epa.gov/policy2003/policy2003.pdf.

participation.”¹¹⁵). This is not identical to notice-and-comment rulemaking. None of these agencies, for example, have bound themselves to respond to comments in the way the APA requires for notice-and-comment rulemaking. Nonetheless, these procedures suggest agencies making a real effort to elicit a public response.

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.”¹¹⁶ Those that are “frequent communicators” with the agency generally tend to be included. 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. In the words of another agency employee that sometimes was responsible for public input on guidance documents, “I had a list of people I’d already met at other meetings.” An employee from another agency stated that after attending meetings on a particular issue, he would “become aware of which [national, Washington-DC-based] organizations were focused on issues.” Again, however, this process is often highly arbitrary. In the words of a former employee, “Some groups might have greater access to meetings than others based on connections to those in positions of authority.”

Even among regulated entities affected by a proposed agency policy, there may be wide variance in involvement. Seiguer and Smith interviewed industry representatives as part of a study of FDA guidance document development and found that some representatives felt closed out of the process, finding it “opaque.” Meanwhile, others found FDA staff to be “very responsive” and felt that merely picking up the phone would afford them easy access.¹¹⁷

Agency participation decisions sometimes formally and overtly advantage regulated entities, compared with other members of the public. For example, the Federal Aviation Administration has explicitly adopted an exclusionary approach in its development of “advisory circulars,” which represent a major category of guidance documents concerning aviation safety. The FAA has posted on the Internet an exclusive list of 17 associations of regulated entities and related businesses from which it welcomes comments on

¹¹⁵ Id. at 3.

¹¹⁶ Strauss, *supra* note 29, at 805.

¹¹⁷ See Seiguer & Smith, *supra* note 8, at 30.

draft advisory circulars. 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."¹¹⁸ The list includes no airplane passenger or consumer safety organizations.¹¹⁹ Similarly, despite the policy document cited earlier, EPA's document describing its procedures for issuing guides to small entities for compliance with new rules suggests that it will circulate those guidance documents only to representatives of small businesses, not others.¹²⁰

The FDA's "Good Guidance Practices" rule also documents this asymmetry. The FDA has formally committed to seek public input in advance of issuing so-called "Level 1" guidances, which are directed primarily to regulated industry and that "set forth first interpretations of statutory or regulatory requirements, changes in interpretation or policy that are of more than a minor nature, unusually complex scientific issues, or highly controversial issues." In general, the FDA will publish draft guidances of this sort in advance of finalizing them, **except** where those documents are "presenting a less burdensome policy that is consistent with public health."¹²¹

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 National Organic Program of the Department of Agriculture has followed the FDA's lead, both by systematizing public participation in

¹¹⁸ See "How do I comment on a Draft Advisory Circular?" posted at www.faa.gov/arp/publications/acs/draftacs.cfm#comment (Last visited Aug. 11, 2005).

¹¹⁹ One such group, not included on the FAA list, is the International Aviation Safety Association, whose website can be found at: <http://www.iasa.com.au/folders/menu/index.htm> (Last visited Aug. 11, 2005).

¹²⁰ Revised Interim Guidance for EPA Rulewriters: Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act (March 29, 1999), at 61 ("Small entity representatives should typically be involved in reviewing the draft compliance guide after the rule is promulgated so 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."), available at <http://www.epa.gov/sbrefa/documents/iguid99.pdf> (Last visited Sep. 8, 2005).

¹²¹ See 62 Fed. Reg. 8968 (Feb. 27, 1997) (noting that FDA will seek public input after issuance of these guidances); 65 Fed. Reg. 7321, 7324 (Feb. 14, 2000) (confirming same position). But see Kay Lehman Schlozman & John Tierney, *Organized Interests and American Democracy* 344 (1986) (reporting study documenting "hostility toward business among the occupational safety and health professionals at the Occupational Safety and Health Administration").

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.”¹²²

Even without being as overt or consciously exclusive as the FAA appears to be, agencies that consult ad hoc on draft guidance documents likely will deemphasize participation by regulatory beneficiaries. This is for straightforward reasons wholly unrelated to agency “capture.” (Of course, capture, if present, could also lead an agency to favor a regulated entity). First, because of the direct relationship with regulated entities, the agency is more likely to know and to have more regular relationships with those groups. Given time and resource constraints upon the agency, it is comparatively convenient and inexpensive to reach out to these same entities as a sounding board for policy development.¹²³ Second, the agency may have a greater interest in maintaining a good long-term relationship with these entities, since it must constantly deal with them and is interested in procuring their compliance with the statutory regime. Meanwhile, the agency will lack a direct relationship with regulatory beneficiaries. An agency official thus may have greater difficulty identifying the appropriate people to contact and less interest in maintaining a long term relationship. Third, regulated entities, in particular, are likely to have valuable information – often superior to that of the agency – regarding the policy’s cost and feasibility.¹²⁴ Regulatory beneficiaries, while they may have valuable information on a policy’s effects, are likely to have less information on feasibility. Consequently, regulators may especially emphasize informal interaction with regulated entities.¹²⁵

¹²² See National Organic Program: Development, Issuance, and Use of Guidance Documents, 70 Fed. Reg. 5129, 5131 (Feb. 1, 2005).

¹²³ See also William F. West, Formal Procedures, Informal Processes, Accountability, and Responsiveness in Bureaucratic Policy Making: An Institutional Policy Analysis, 64 Pub. Admin. Rev. 66, 70 (Jan./Feb. 2004) (“[Public p]articipation [in pre-rulemaking agency discussions] was bounded by administrators’ past experience and by their sense of who the significant players were.”).

¹²⁴ E.g. Kerwin, Rulemaking, *supra* note 109, at 189 (noting that agencies may seek information from interest groups “especially when dealing . . . with production processes and technology or business practices”).

¹²⁵ See Cary Coglianese, Richard Zeckhauser, Edward Parson, Seeking Truth for Power: Informational Strategy and Regulatory Policymaking, 89 Minn. L. Rev. 277, 327-28 (2004) (noting that advisory committees give “regulators and industry representatives opportunities to . . . build relationships that can lead to productive informal interaction” and arguing that “informal interaction” provides superior opportunities for regulators to gather information from regulated entities); see generally Schlozman &

Further, characteristics of regulatory beneficiaries also may lead them to be less involved in policy development. First, finding about these guidances before they are finalized can be difficult and expensive unless the agency itself either chooses to give public notice or else initiates contact. Regulatory beneficiary groups may have fewer resources to devote to this sort of information gathering.¹²⁶

Second, to the extent 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 that is passed for 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 represent an extraordinarily large and diffuse group, both those who presently benefit and those (such as future asthma sufferers in the case of air quality regulation or fetuses in the case of toxics and food safety regulation) who cannot yet self-identify. There is an enormous literature on the organizational difficulties faced by groups of this type, beginning with Mancur Olson.¹²⁷ I will not engage that literature here, but suffice it to say that these groups will have a more difficult time - given the level of their interest - obtaining information about agency actions and participating fully in the agency decisionmaking process.¹²⁸

Regulatory beneficiaries also may lack the political clout that might otherwise motivate an agency to seek their blessing.¹²⁹ They may be less able

Tiemey, *supra* note 121, at 331 (discussing 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] over time to the development of mutual trust”).

¹²⁶ Schlozman and Tierney, *supra* note 121.

¹²⁷ E.g., *id.*; Mancur Olson, *The Logic of Collective Action Public Goods and the Theory of Groups* 5-65 (1971); James Q. Wilson, *The Politics of Regulation* 366, 70 (1980) (describing circumstances under which groups are likely to organize); James Q. Wilson, *Political Organizations* 33-35 (1976) (describing variety of incentives, including solidary and purposive, that may cause individuals to join groups), Schlozman & Tierney, *supra* note 121.

¹²⁸ Moreover, even when formed, these groups may not represent the wide range of views present in the public. 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.”).

¹²⁹ See Schlozman & Tierney, *supra* note 121, at 357 (“Organized interests enjoy influence in bureaucratic decision making not because agencies are captive to

to call upon political oversight mechanisms such as Office of Management and Budget review or congressional oversight.¹³⁰

When Congress considered proposals to reform the environmental statute relating to hazardous waste cleanup in the 1990s, for example, companies lobbying to weaken the law “outnumber[ed] environmental groups by 30 to 1.”¹³¹ This is not to say 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 interest in a particular agency action. Finally, regulated entities may have “more to lose” than others, giving them greater motivation than regulatory beneficiaries to participate in the process.¹³² Schlozman and Tierney’s systematic study of organized interest groups documents earlier insights 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.”¹³³ Kerwin has summarized subsequent studies suggesting that businesses and trade associations dominate contacts with agencies on rulemaking on environmental and transportation issues.¹³⁴

Similarly, while EPA officials are careful to include “the enviros” whenever they contemplate a significant change in guidance, that may mean calling the representatives only of a Washington, D.C.-based organization that

organized 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.”).

¹³⁰ Admittedly, this same problem may exist with respect to notice-and-comment rulemaking, but there the agency has the legal obligation to respond to any significant comment submitted during the rulemaking process, whether or not the commenter possesses political clout.

¹³¹ See Bill McAllister, *Guns for Hire*, *Washington Post*, June 18, 1998, at A23 (quoting US PIRG 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 99 companies).

¹³² See Kerwin, *Rulemaking*, *supra* note 109, 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.”).

¹³³ See Kay Lehman Schlozman & John Tierney, *Organized Interests and American Democracy* 68 (1986).

¹³⁴ See Kerwin, *Rulemaking*, *supra* note 109, at 182-183 (summarizing relevant studies, though also noting reasons that groups representing other interests may now be finding a foothold); *id.* at 184 (summarizing study finding participation by “ultimate consumers” in product safety standard setting “nominal at best”).

has previously expressed interest, rather than posting the guidance publicly or contacting a wide range of environmental groups.¹³⁵ Again, the decision appears to be made on an ad hoc basis. In addition, the lack of advance public notice is likely to particularly disadvantage highly interested individuals or very small organizations representing a subset of regulatory beneficiaries.¹³⁶

These concerns may well affect the content of an agency guidance document. If the agency heard from a wider variety of regulatory beneficiaries, the agency might respond to the intensity of views held by regulatory beneficiaries or might receive new information. Without outside involvement, the agency's value choices might be less responsive to public values or not engage them at all.¹³⁷ For example, in 2003, EPA proposed guidance that would permit wastewater treatment plants to "blend" partially treated sewage with fully treated sewage in "wet weather," a measure that would save the plants and the cities that owned them many millions of dollars and would not result in violation of permit limits for wastewater. However, EPA did not simply "float" the guidance informally, but instead published the draft guidance for comment. After receiving 98,000 comments, including a strong response from environmental public interest groups, expressing concern that discharged water would have higher levels of viruses and parasites, EPA decided in 2005 not to finalize the guidance.¹³⁸

Similarly, when a rule is published for notice and comment, an agency may find that it is receiving comments from "interested individuals in the hinterland" who also happen to know a lot about the subject matter, but whom

¹³⁵ The public involvement policy described supra text accompanying note 114 is not to the contrary. It leaves it to staff to "exercise judgment" in designing public involvement, including identify[ing] the "interested and affected public." See Public Involvement Policy of the U.S. EPA, May 2003, at (posted at <http://www.epa.gov/stakeholders/pdf/policy2003.pdf> (Last visited Aug. 12, 2005)).

¹³⁶ See, e.g., text accompanying note 138 (describing individual who filed public comment on water treatment rule and then became intrinsically involved in agency decision making process).

¹³⁷ Mendelson, *Agency Burrowing*, supra note 3, at 586 (discussing agency-centered conceptions of political legitimacy).

¹³⁸ Another interpretation could simply be that the agency correctly identified a policy with great potential for controversy—hence one in which public comment could be expected to make a difference—and for a less controversial guidance document, public comment would have made little difference. This is one reason why I advocate permitting citizens to initiate a dialogue with the agency through a petition process, see *infra* Sec. III, rather than requiring an agency to have a comment process for every significant statement of policy.

the agency would not otherwise know to contact. For example, when EPA published a recent (different) 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 them more specific feedback on small systems needs. These are opportunities the agency may forgo when it embodies a policy in a guidance document, rather than a rule.

Lack of involvement creates other costs for regulatory beneficiaries. To the extent one sees the administrative process as a civic republican substitute for other forms of democratic dialogue, such as deliberation at the polls, regulatory beneficiaries may feel excluded from that community of debate. Because of their inability to have their views heard in the decision making process, regulatory beneficiaries may view a particular policy decision as lacking legitimacy.¹³⁹

This is not to say that guidance documents never benefit regulatory beneficiaries. There are undoubtedly cases where guidance documents are, for regulatory beneficiaries, “better than nothing.” For example, if patulin levels for apple juice are set at a reasonable level – even if not ideal, from the consumer’s perspective – an apple juice consumer might prefer such a guidance to no apple juice regulation at all. On the other hand, some guidance documents may be worse than nothing. In this category might fall the FDA guidance documents on “direct-to-consumer” pharmaceutical advertising, which has spurred a dramatic increase in advertising. That advertising has been criticized as creating demand for advertised medications that may be inferior in particular cases to other drugs, or that may be medically unnecessary. Similarly, the EPA guidance documents signalling a pull-back of its jurisdiction over the condition of isolated waters undoubtedly encouraged environmentally damaging activity.

Whether guidance documents can be “better than nothing” for regulatory beneficiaries is ultimately an empirical question. However, the characteristics of agency procedures already discussed strongly suggest that they will not be. Regulatory beneficiaries lose opportunities to participate in agency decision making and to invoke judicial review. In addition, they are likely to be relatively lacking in political clout. Although agency civil servants and their political leadership may be ideologically committed to the interests of regulatory beneficiaries, these other factors make it much less likely that guidance documents will tend to favor beneficiaries.

In short, then, when agencies issue their policies in the form of guidance documents rather than notice and comment rulemaking, regulatory

¹³⁹ E.g., Frank Michelman, *Formal and Associational Aims in Procedural Due Process*, in *Nomos: Due Process 126* (J. Pennock & J. Chapman eds. 1977); Lawrence Tribe, *Structural Due Process*, 10 *Harv. C.R.-C.L.L. Rev.* 269 (1975).

beneficiaries lose some of their most valuable tools for holding an agency accountable. Accordingly, some reform of agency process is warranted.

III. Some Solutions

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

Rather than advocate for a single “best” solution, I now examine two prevailing proposals, and then turn to overviews of a few alternatives likely to offer more promise to a regulatory beneficiary. The two dominant proposals are to forgo regulation of guidance document issuance altogether or to subject all guidance documents to notice-and-comment rulemaking. Each seems clearly unsatisfactory. The former is unsatisfactory because it incorrectly assumes the alternative is a world of “secret law;” the latter because of the disadvantages of reducing every feature of agency implementation to a rule.

Which of the alternatives is best may depend upon how some empirical issues are resolved. Among them are proposals to permit citizens to petition an agency to revise or repeal a guidance document, along the lines of APA Section 553(e); to require guidance documents to be treated as precedent; and to require agencies to develop “good guidance practices,” currently the subject of an OMB Draft Bulletin.

A. No Action

A number of commentators have advocated against further procedural regulation of guidance document issuance. Although the use of guidance documents clearly has costs for both regulated entities and regulatory beneficiaries, the concern is that the sheer cost of notice-and-comment proceedings will deter agencies from publishing anything on implementation and will thus deprive the public of valuable information. As the argument goes, a world without 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 in some cases, adjudication.¹⁴⁰

¹⁴⁰ Strauss, *supra* note 29; Manning, *Nonlegislative Rules*, *supra* note 11, at 930. See also *American Mining Cong. v. Mine Safety and Health Admin.*, 995 F.3d 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] the agencies into pure ad hocery—an ad hocery, moreover, that affords less notice, or less convenient notice, to

This risk of losses from agency policymaking-in-secret is almost certainly overstated. With respect to regulated entities, it is surely correct that if the FDA has de facto adopted a policy with respect to patulin in apple juice, or the Education Department has de facto adopted a policy on Title IX compliance, that an apple juice producer or university would rather find out about it before the enforcement action has actually been filed. This may have been Congress's view when it enacted 5 U.S.C. § 552(a)(3) as part of the Freedom of Information Act, barring an agency from relying upon an unpublished document in dealing with a private party.¹⁴¹

Even if guidances and policy statements were somehow off-limits or agencies were required to use notice-and-comment rulemaking to issue them, however, the result is highly unlikely to be a world of "secret law." Despite the cost of enhanced procedures, agencies face other very significant incentives to go public with their policies rather than to leave them secret.

First, simple good government concerns may motivate an agency to make its positions public. An agency head may well wish to treat regulated entities fairly—or 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 require) agency employees to make positions public.¹⁴² Even the purely rational, cost-minimizing agency will face significant incentives to issue policies publicly if the cheapest mechanism, such as a guidance document, is unavailable. Possibly more important, not disclosing agency policy positions or interpretations is likely to undermine relations with regulated entities, who strongly prefer to operate in an atmosphere of greater certainty.¹⁴³ Agency officials typically like relations with regulated entities to remain cordial, not only because they frequently interact with regulated entities, but because regulated entities can be a critical source of information or, if well-organized,

affected parties.") (Williams, J.).

¹⁴¹ Strauss, *supra* note 29, at 806 (when Congress enacted 552(a)(3), "it 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.").

¹⁴² E.g., Small Business Regulatory Enforcement Fairness Act, 5 U.S.C. § 601.

¹⁴³ See Manning, *supra* note 11, at 930 (suggesting that in settings such as nuclear power plant licensing "the demand for advance technical specifications is urgent," making the agency feel "obliged" to publicly disclose licensing criteria).

may be able to invoke political discipline.¹⁴⁴ Even in less urgent settings, failing to disclose policy positions in advance may alienate members of Congress concerned with compliance assistance.

Finally, there may be a price to pay in court. Under some circumstances, a failure to disclose a particular interpretation of a statute or regulation can interfere with an agency's ability to penalize statutory or regulatory violations.¹⁴⁵ A number of appellate 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 has had clear notice of the conduct required.¹⁴⁶ Under these precedents, the regulated entity must know with "ascertainable certainty" based on **public** agency statements that its conduct was regulated.¹⁴⁷ To this point, 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. However, if guidance documents become unattractive to agencies for other reasons, due process will still serve as a powerful incentive for agencies not simply to hide their enforcement approaches.

In short, agencies are unlikely to relegate all their policies to secrecy. This intuition is confirmed by the fact that agencies issue guidance documents, even when they are not required to do so. While it is surely less expensive than issuing notice-and-comment rules, guidance development also can require significant agency resources. An agency may have to develop the data on

¹⁴⁴ Stewart, *supra* note 86, at 1712; Steven Croley, White House Review of Agency Rulemaking, 70 U. Chi. L. Rev. 821 (2003) (describing informational capture hypotheses).

¹⁴⁵ See generally Kieran Ringgenberg, *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 doctrine permitting retroactive effects of adjudications).

¹⁴⁶ E.g., *Excel Corp. v. United States Dept. of Agriculture*, 397 F.3d 1285, 1298 (10th Cir. 2005) (discussing fair notice defense requirements, but finding cease and desist order did not amount to penalty to which fair notice requirements applied); *SBC Communications, Inc. v. FCC*, 373 F.3d 140 (D.C. Cir. 2004); *WHX Corp. v. SEC*, 362 F.3d 854, 858 (D.C. Cir. 2004) (invalidating cease-and-desist order because of lack of fair warning of FCC interpretation of rule); *Trinity Broad. 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 particular seat belt anchor); *General Electric v. EPA*, 53 F.3d 1324, 1332 (D.C. Cir. 1995).

¹⁴⁷ Preenforcement efforts to obtain compliance can also satisfy the requirement. See Ringgenberg, *supra* note 145, at 925; *General Elec.*, 53 F.3d at 1329.

which the guidance depends—for example, how much patulin is harmful to human health—or conduct a significant internal dialogue before arriving at a final position. Yet, an agency does so 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 also likely drive them to issue rules if the 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 admittedly not cheap. If guidance documents are unavailable to the agency, rulemaking's costs, combined with the loss of flexibility to the agency, may well lead an agency to state its policies publicly somewhat less often or in less detail. An agency also might bypass issuing helpful information if members of Congress are uninterested, relations with regulated entities are strained anyway, or due process does not require an agency to publicly state its position on a statutory or regulatory standard before enforcing it. Where an agency does not focus on law enforcement, but instead, say, spends money on highway building, the agency may also face fewer incentives to use rulemaking to set policy.

At bottom, however, the answer: “Policies/guidances/interpretive rules are better than nothing,” hardly resolves 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 is highly unlikely to completely hide its policy positions. Given the significance of the interests of regulated entities and regulatory beneficiaries, some effort should be made to reform guidance document development.

2. Full Notice-and-Comment Rulemaking

So, should the other major proposal be the solution? Should an agency be required to issue every significant aspect of its policies, as Anthony has advocated, in the form of a notice-and-comment rule?¹⁴⁸ Although this would give regulatory beneficiaries full participation rights in agency decisionmaking, and also make agency positions legally binding, the answer, in my view, is also no. An agency cannot, and probably should not attempt to, fully specify its policies. As already noted, the high cost of rulemaking may lead to less *ex ante* information from the agency about its policies (though, as I argue, not leave us with a world of secret law and ad hoc adjudication). Moreover, an agency cannot be reasonably expected to foresee every possible instance in which its policy may be applied. Finally, for the unforeseen or

¹⁴⁸ See Anthony, Interpretive Rules, *supra* note 2. Anthony's position does include an exception for agency interpretations that do not add any substantive terms to an underlying rule or statute, though distinguishing a “nonsubstantive” interpretation from one that has a substantive effect would be difficult at best.

unforeseeable case, it may be desirable for an agency to retain flexibility to design “just” results.¹⁴⁹

Further, an approach of this type, as others have observed, would raise issues of judicial competence. 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 publicly issued by an agency regarding the programs it implements should be subjected to notice-and-comment rulemaking. However, this presents judges with a very 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.”¹⁵⁰ Manning argues, moreover, 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.”¹⁵¹ This is because the inquiry “turns on distinguishing interpretation from policymaking,” a most difficult question of degree because the two are typically so intertwined.¹⁵²

C. More Palatable Proposals

1. Citizens’ Right to Petition

An intermediate, process-focused solution might offer another option. Along the lines of APA 553(e), citizens could be entitled to notice of the guidance document and entitled to petition the agency to revise or repeal any guidance document not already been issued in conformity with Section 553's notice and comment procedures. The agency would have a limited time to

¹⁴⁹ E.g., Mashaw, *Prodelegation*, supra note 87, at 86; Mark Seidenfeld, *Bending the Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 *Admin. L. Rev.* 429, 440 (1999); see also Strauss, *Publication Rules*, supra note 29, 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 Cornelius Kerwin, *Rulemaking: How Government Agencies Write Law and Make Policy* 174 (3d ed. 2003) (“any clarification 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”);

¹⁵⁰ Manning, *Nonlegislative Rules*, supra note 11, at 896.

¹⁵¹ Manning, *Nonlegislative Rules*, supra note 11, at 914.

¹⁵² Manning, *Nonlegislative Rules*, supra note 11, at 916.

respond to the petition on the merits, say, 180 days. In response, the agency could modify the guidance document or give reasons in response to the petition why the document should not be changed.¹⁵³ To avoid the spectre of multiple successive petitions on a single document, the statute could require the agency to publish a notice inviting all related petitions to be filed within a limited period.¹⁵⁴ The statute should also bar pro forma petitions by making clear that a citizen would have to submit significant facts or arguments supporting the petition. On judicial review, an agency could defend by arguing that the submission did not require a substantive response. Finally, the agency could respond by publishing the guidance (or its revision) for a full notice and comment proceeding, which would have the advantage of more fully flushing any other guidance detractors out of the woodwork.¹⁵⁵ As with other similar petitions, the agency's response (or failure to respond by the statutory deadline) would be subject to judicial review.

No similar right appears to exist under current law.¹⁵⁶ Despite

¹⁵³ The proposal would 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 Professional Hunters Ass'n v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999) and *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 587 (D.C. Cir. 1997). These holdings have been subject to considerable criticism. See Richard Pierce, Distinguishing Legislative Rules from Interpretive Rules, 42 Admin. L. Rev 547, 563-66 (2000); Strauss, supra note 29, at 809, 811 (advocating "free revision" of publication rules); Michael Asimov & Robert A. Anthony, A Second Opinion? Inconsistent Interpretive Rules, 25 Admin. & Reg. L. News 16 (2000).

¹⁵⁴ I am grateful to Jonathan Molot for proposing this solution to the problem of successive petitioning. Of course, a citizen should not be barred from petitioning on later-arising grounds. The statute could include a bar on later petitions if the arguments could have been raised during the initial petitioning period.

¹⁵⁵ The D.C. Circuit generally will decline to consider an argument raised in opposition to a rule unless it has been raised during the rulemaking proceeding. E.g., *Advocates for Highway and Auto Safety v. Federal Motor Carrier Safety Administration*, ___ F.3d ___, 2005 WL 3242383 (Dec. 2, 2005), *National Wildlife Federation v. Environmental Protection Agency*, 286 F.3d 554 (D.C. Cir. 2002).

¹⁵⁶ APA 553's language exempting guidance documents from 553's requirements is sloppily drafted, but does not seem to entitle a citizen to file a petition for revision of a guidance document. The relevant language from subsection 553(b) containing the notice-and-comment rulemaking exemption states:

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

(A) to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice . . ."

Read plainly, that might suggest that guidance documents are not exempt from the

statements by some commentators that the APA supplies an obvious right to file such a petition under Section 553,¹⁵⁷ the few courts to have opined on the issue have unanimously and flatly disagreed, finding no right to petition to revise or repeal an interpretative rule or policy statement.¹⁵⁸

A petition process would confer several advantages on regulatory beneficiaries. First, it would enable a regulatory beneficiary—or any citizen—to directly 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 would parallel its obligations to respond to significant comments in rulemaking,¹⁵⁹ and, in an enforcement action, to

petition procedures of 553(e), since 553(e) is a different subsection. On the other hand, the exempting language has been read uniformly to exempt guidance documents not only from the notice requirements of subsection 553(b), but the comment and “concise general statement” requirements of a different subsection 553(c). In that case, perhaps, “subsection” should be read as a scrivener’s error, and the correct reference should be “section.” In that case, 553(e) would not apply.

¹⁵⁷ See William V. Luneberg, *Petitioning Federal Agencies for Rulemaking: An Overview of Administrative and Judicial Practice and Some Recommendations for Improvement*, 1988 *Wis. L. Rev.* 1, 13-14; William Asimow, *California Underground Regulations*, 44 *Admin. L. Rev.* 43, 44 n.5 (1992); Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 *Duke L.J.* 381, 424 & n. 225 (suggesting that the public can petition for repeal or amendment of a nonlegislative rule under 5 U.S.C. 553(e)).

¹⁵⁸ See *National Wrestling Coaches Ass’n v. U.S. Department of Education*, 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.”), affirmed on different grounds in relevant part, 366 F.3d 930, 948 (D.C. Cir. 2004) (“Leaving aside any difficulties as to whether the Three-Part Test is the type of policy subject to the APA’s petition requirements, NWCA’s 1995 letters simply cannot be construed as a petition for repeal or amendment.”); *Atchison, Topeka, and Santa Fe Rwy Co. v. Pena*, 44 F.3d 437, 441 (7th Cir. 1994) (en banc) (“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. 5 U.S.C. 553(e).”) (dicta); *United Transportation Union v. Delaware and Hudson Rwy Co.*, 970 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.”)

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

¹⁵⁹ See *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 252 (2d Cir. 1977).

defend its position against a regulated entity's challenges.¹⁶⁰ By requiring an agency to supply crystallized reasons for its decision, this process would in turn make judicial review more effective.

Such a process might prompt agencies to identify more significant and controversial policies earlier on and to use a more thorough, participatory process. The agency might consult with a wider array of interest groups in order to forestall later petitions or, on the most significant issues, simply choose notice-and-comment rulemaking. As argued above, broader consultation may affect the substance of an agency policy. Moreover, regulatory beneficiaries (like regulated entities) are likely to value significantly the entitlement to express views to the agency and to participate in the policy making process.¹⁶¹

Compared with a requirement to use notice and comment rulemaking for all nontrivial matters of policy, a petition process would raise fewer issues of judicial competence. The inquiry on judicial review would be one with which it is very familiar: is the agency's decision arbitrary and capricious? Has it considered the relevant factors, including any relevant information or arguments presented by petitioners? Is it authorized by the statute? Does the agency's decision represent a clear error of judgment?¹⁶²

The proposal could raise some significant concerns. Most important is undoubtedly cost, especially if costs were high enough that agencies cut back significantly on issuing policies, whether in the form of guidance documents or rules. How significant the costs of a petition process would be, is, of course, an empirical question. It is a function of both the number of likely petitions and the amount of agency resources required to resolve a petition, including any later litigation over the agency's response. The worst case scenario would be the prospect of a revision petition regarding each of the vast number of agency guidance documents on the books - or endless successive petitions on a single guidance document - followed by significant litigation. If any of this were to occur, the costs of such a process would be

¹⁶⁰ See Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 *Duke L.J.* 1497, 1501 (1992) (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").

¹⁶¹ Kerwin, *Rulemaking*, supra note 109 (noting that interest groups value highly the opportunity to participate in notice-and-comment rulemaking); see generally Adler, supra note 90.

¹⁶² E.g., *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402 (1971); *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 464 U.S. 29 (1983); *Skidmore v. Swift*.

substantial and even overwhelming.¹⁶³

Costs are surely lower than across-the-board rulemaking, however. Petitions would seem unlikely for the very large number of truly routine guidance documents, 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 also are likely to cut down on costs. Perhaps an attorneys' fee award for truly unfounded petitions could further reduce costs.

Moreover, it might be argued that because agency decision making will be finished by the time a petition is filed, an agency might not be truly open-minded and willing to revisit its earlier decision. As a consequence, a regulatory beneficiary (or regulated entity) might not be able to engage the agency in a meaningful dialogue about the substance of its policy.¹⁶⁴ The petition process is likely to represent an improvement over the status quo for a couple of reasons, however. First, the right to petition will encourage an agency to consult and consider a wider range of views in advance of issuing the guidance. Second, the prospect of judicial review of the quality of the

¹⁶³ Reportedly, agencies already spend a considerable portion of their rulemaking budgets to meet statutory deadlines, often under court order. E.g. Natalie M. Henry, Resources Panel to Review FWS, NOAA Budget Requests, *Environment & Energy Daily*, Apr. 30, 2001 (reporting that the F.Y. 2001 budget for listing and critical habitat was depleted after only two months due to litigation-driven deadlines). "Water Quality and Wetlands," 2001 ABA *Env't, Energy, & Resources L.: Year in Rev.* 356, 370 ("In practice, [Clean Water Act effluent limitation guidelines] review occurs much less frequently, and in recent years, the agency's priorities and schedules for reviewing effluent limitation guidelines have been driven largely by court-imposed consent decrees.") 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, 798 (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."); National Academy of Public Administration, *Setting Priorities, Getting Results: A New Direction for the Environmental Protection Agency* 8, 131 (1995).

¹⁶⁴ With regard to notice-and-comment rulemaking, some have made similar arguments that the agency may already be committed to a limited set of options by the time the notice of proposed rulemaking is published. See Marissa Martino Golden, *Interest Groups in the Rule-Making Process: Who Participates? Whose Voices Get Heard*, *J. Pub. Admin. Res. & Th.*, Apr. 1998, at 261 (noting that in most rulemakings analyzed, "agencies ignored the often impassioned pleas of their clientele and stuck with their initial proposals, albeit with some modifications"); West, *supra* note 123, at 69 (summarizing data suggesting that vast majority of notices of proposed rulemaking articulated tentative conclusions to policy problems rather than containing "open-ended solicitations of policy recommendations").

agency's response is likely to encourage it to consider the petition carefully. Ultimately, how effective regulatory beneficiaries will find this opportunity to engage the agency is an empirical question. It is worth noting, however, that when an agency publishes a proposed rule for comment in the rulemaking process, it generally has already committed to a limited set of policy alternatives. The petition process thus does not seem substantially worse than notice-and-comment rulemaking. The ideal opportunity to engage agency officials would be when the agency is devising its initial list of solutions to a policy problem, as long as the beneficiary would continue to have participatory opportunities as the agency develops a particular solution in more detail. While the timing of a petition process is thus not perfect, an agency would at least have to show evidence of having directly engaged the regulatory beneficiary's position.

Thirdly, a petition process could, in theory, further increase the influence of not only regulatory beneficiaries, but regulated entities as well. Filing a petition takes time and resources. Regulatory beneficiary organizations are disadvantaged on both counts relative to regulated entities. Consequently, the petition process might, as with informal consultation, political access, and even judicial review,¹⁶⁵ unevenly benefit regulated entities compared with regulatory beneficiaries.¹⁶⁶

Conceivably, an agency could spend more time responding to regulated entity petitions than those of regulatory beneficiaries.¹⁶⁷ That might encourage the agency to seek out even more regulated entity feedback earlier in the process. However, the creation of a formal opportunity to petition the agency would clearly still help regulatory beneficiaries. Beneficiaries would still be entitled to engage the agency with their (significant) arguments. A petition process would prompt an agency to seek input earlier from a broader

¹⁶⁵ E.g., Amy Sinden, In Defense of Absolutes: 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.”).

¹⁶⁶ E.g., Marissa Martino Golden, Interest Groups in the Rule-Making Process: Who Participates? Whose Voices Get Heard, J. Pub. Admin. Res. & Th., Apr. 1998, at 245, 255 (noting that of Clinton-era rulemakings randomly selected, EPA and NHTSA rulemakings had “extremely limited participation by public interest or citizen advocacy groups,” while HUD commenters included citizen advocacy groups, individual citizens, and others).

¹⁶⁷ Some regulated entities are likely to moderate their petitions in order to maintain a good long term relationship with the agency.

array of groups. If an agency tried to forestall extensive regulated entity petitions on a controversial issue by using notice-and-comment rulemaking, this too would have substantial benefits for regulatory beneficiaries.

That a process open to all might be used more by better-funded, better-organized parties is hardly surprising. Others, such as Ayres and Braithwaite, have proposed ways to rectify this resource imbalance.¹⁶⁸ Whether this is a serious indictment of the proposal depends on how we understand the agency decisionmaking 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 expressed “interests” in deciding which policies to select, and if all regulated entities already had an adequate opportunity to participate absent a petition process—both dubious assumptions—then creating yet another opportunity for regulated entities might worsen the existing imbalance with little benefit for regulatory beneficiaries.

On the other hand, if the agency decision making process is seen as at least partly deliberative, a petition right would help regulatory beneficiaries by requiring an agency to include, and engage, new substantive viewpoints in its policy decisions.¹⁶⁹

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

This proposal is a more palatable variant of the one discussed earlier. It would not require notice-and-comment rulemaking for every new policy decision, but only those of great significance. For that category, an agency would be obligated to use rulemaking instead of a guidance document, with the accompanying obligations to make the policy binding, to disclose data, to respond to comments, and to be subject to judicial review.

This proposal would be less costly and cumbersome than a more expansive rulemaking requirement. For the policies subject to the requirement, regulatory beneficiaries could engage the agency more effectively and obtain judicial review. Such a requirement would undoubtedly prompt the agency to reason through the policy more carefully.

Such a policy would, however, place a difficult burden on judges to

¹⁶⁸ See Ian Ayres & John Braithwaite, *Responsive Regulation* 82 (1992).

¹⁶⁹ Another concern about a petition process might be that citizens without a broad view of the public interest will somehow drive policy making priorities, rather than an agency subject to democratically accountable oversight. Much the same concern has been leveled against 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). Here, however, no petition can be filed unless the agency has already selected an issue for its agenda by issuing a guidance document.

distinguish the “important” policies that should be issued through rulemaking from other ones.¹⁷⁰ In deciding that a guidance is “really” a rule, courts currently focus in large part upon whether a particular policy is effectively binding.¹⁷¹ That surely misses policies that most would agree should have been issued by rule, because they evoke a significant change in behavior among regulated entities and meet some level of “significance.” However, it is a standard judges can administer. By comparison, determining whether a policy is “important” not only requires distinguishing interpretation from policy making, but must be done in the context of the particular program. The risk is that judges will be unwilling to apply the standard with any stringency.¹⁷²

In this respect, this proposal compares unfavorably to, say, a petition process. On review of a petition, a judge would not have to decide which agency decisions receive full-blown notice-and-comment rulemaking and which require no participation or response from the agency. Instead, an affected party could engage the agency with a non-frivolous argument on any guidance or policy the affected party perceives to be of significance. 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. Guidance as Precedent

Strauss and Manning have both discussed an intermediate solution—having courts treat published agency guidance documents as “precedent.”¹⁷³ An agency would have to supply a reason for departing from

¹⁷⁰ E.g., Strauss, *supra* note 29, at 812 (suggesting that court could be tasked with deciding that a particular rule is “insufficiently specific,” and “fail[s] to articulate important policy conclusions it could reasonably have been expected to reach”).

¹⁷¹ See *Community Nutrition Inst. v. Young* (discussing cases).

¹⁷² See *supra* text accompanying note 150 (discussing Manning’s argument that judicial hesitation to apply even mild rulemaking requirement reflects doubts about judicial competence).

¹⁷³ See Manning, *Nonlegislative Rules*, *supra* note 11; Strauss, *supra* note 29. Strauss more clearly specifies that guidance documents will have precedential effect in the sense that agencies will be required to justify any departure from them, but not greater effect in the courts. 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 instead that the agency must focus on violation of the underlying legally binding statute or regulation. Strauss, *Publication Rules*, *supra* note 29. Manning suggests that agencies could indeed rely directly on a guidance document if the document contained

a position taken in a guidance document. This approach is surely easier for courts to administer compared with having to identify “significant” or “important” agency policies requiring rulemaking. From the perspective of regulatory beneficiaries, however, this proposal is largely unhelpful.

The primary benefit of treating guidance as precedent is in an enforcement action against a regulated entity. To return to the patulin guidance, suppose an apple juice maker ships juice with 45 ppb patulin in interstate commerce, relying on the 50 ppb patulin guidance. The FDA brings an enforcement action, arguing – more aggressively than the position taken in the guidance – that this level should be viewed as “adulterated.” Rather than treat the guidance document as completely non-binding (according to its terms), Strauss and Manning would permit the producer to argue that the agency can only depart from the terms of the guidance document in a reasoned way. The FDA would have to explain why 45 ppb can reasonably be seen as “adulterated,” given its earlier, presumably reasoned position that 50 ppb and up is “adulterated.”

This proposal would increase the consistency of agency behavior and allow regulated entities to rely more upon agency statements. However, the approach implicitly presumes that the guidance itself is valid and has properly implemented the social policy embodied in the statute. It thus does comparatively little for regulatory beneficiaries, because it affords no opportunity to argue, say, that the choice of 50 ppb is not legal or not adequately justified or that the agency should be more aggressively interpreting the statute.¹⁷⁴

The beneficiaries receive no new opportunity to challenge the guidance’s underlying reasoning if the agency adheres to it. The approach presumably would not increase the ripeness or reviewability of these

“reasoning adequate to support the adjudicative decision.” Manning, *Nonlegislative Rules*, supra note 11, at 933-34. While a court could 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 does not increase the chances that agencies will consult widely on their policies. On the other hand, because of the increased chances a court will follow the guidance, regulated entities are more likely to follow its terms, reducing the judicial review opportunities for regulatory beneficiaries.

¹⁷⁴ John Manning does argue in *Nonlegislative Rules*, 72 *Geo. W. L. Rev.* 893 (1994), that if an agency guidance document is “reasoned,” that an agency should be permitted to rely upon it in an adjudication. A party would be permitted to raise arguments that the agency position is unreasoned, and the agency would have to respond to any arguments that are sufficiently material. *Id.* at 934. This does not resolve whether a court would be willing to let a regulatory beneficiary intervene, however, and of course, if the guidance document meant that the agency would file no enforcement action at all, then the beneficiary is without recourse.

documents on direct review, since the document remains formally not binding.¹⁷⁵ Indeed, it could result in courts granting such agency statements even greater deference than under current law. Even if beneficiaries agreed with the position taken in the guidance document, the beneficiary could not, say, require an agency to bring an enforcement action in accordance with its (nonbinding) guidance. A lawsuit to compel enforcement has traditionally been found unreviewable.¹⁷⁶ There is one exception where according a guidance document precedential effect would generally serve the interests of regulatory beneficiaries. This is where the primary mode of agency implementation is not program enforcement against a third party, but instead agency actions to manage a resource on the public's behalf, for which judicial review is typically more available. These might include public lands management decisions, for example. Beneficiaries might be able to obtain review of a final agency action (or some limited categories of inaction), and argue that the agency action should be vacated because the agency has failed to explain reasonably why it is acting at variance with the position taken in the guidance document.

4. Agency Self-Regulation and “Good Guidance Practices”

Another moderate proposal would require agencies to develop more inclusive procedures, such as those developed by the FDA in its “Good Guidance Practices” or EPA’s Public Involvement Policy. However, regulatory beneficiaries would receive no new access to judicial review or other external control upon agency conduct. The Office of Management and Budget’s “Proposed Bulletin for Good Guidance Practices” posted on the Internet on November 23, 2005, represents a variant of this proposal.¹⁷⁷ For a significant or controversial policy decision, an agency would conduct some

¹⁷⁵ Strauss does suggest 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 29, at 811. However, this does not seem a significant change from current law. See text accompanying notes 64-65; Strauss, *supra* note 29, at 819 (suggesting that staff level guidances could not be considered “final”).

¹⁷⁶ See *supra* note 97.

¹⁷⁷ See Office of Management and Budget, Proposed Bulletin for Good Guidance Practices, http://www.whitehouse.gov/omb/inforeg/regpol/good_guidance_preamble.pdf (last visited Nov. 30, 2005); see also Office of Management and Budget, Notice: Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 76333 (Dec. 23, 2005) (extending comment period to Jan. 9, 2006).

sort of notice and comment proceeding. The current proposals, however, generally include no obligation to publicly respond to significant comments.¹⁷⁸ Without any binding legal commitment, they also do not increase the extent to which an agency is subject to judicial review. Like the “guidance as precedent” approach, the Good Guidance Practices and the OMB proposal also include a conformity norm. Agency employees are expected to conform to the terms of a guidance unless there is “adequate justification” and supervisory review.¹⁷⁹

“Good guidance practices” clearly would give a regulatory beneficiary a greater opportunity to submit comments to the agency, in turn increasing the information available to the agency about both the technical issues faced by the agency and public preferences relevant to the decision. Further, a beneficiary could comment when the guidance document is still in draft form, rather than after the agency has already issued the guidance document.

What is unclear from these proposals for “improved self-government,” however, is whether the agency will meaningfully engage the comments it receives. Comments from an entity with the ability to mobilize political oversight will, of course, receive attention, as they would have in any event. Further, well-intentioned civil servants will undoubtedly endeavor to read comments. However, resources and time are tight, and it is unclear what new incentive an agency will face to engage comments from a broader segment of the public. Thus far, research has uncovered no information regarding the effects of the FDA’s “good guidance practices” upon public participation and the ultimate content of FDA decisions. Further, although the FDA Good Guidances Practices are codified as a binding legislative rule, no reported judicial opinions address the FDA’s compliance with those procedures.

Regulatory beneficiaries would have no greater ability to invoke external measures of control, and the agency issuing the guidance would have no greater incentive than presently to respond meaningfully to regulatory beneficiary comments.

Going a step beyond the FDA’s “Good Guidance Practices,” the OMB Draft Bulletin would require an agency to respond to comments on “economically significant” guidances. However, because the OMB proposal

¹⁷⁸ See Proposed Bulletin, *supra* note 177, at III.2.b. (No response to comments required); *supra* note 177, at sec. V (bulletin creates no enforceable rights). Section IV, which would require an agency to take public comment on a significant guidance document prior to issuance, does also require a response to comments. However, the bulletin provides neither for OMB review of particular agency guidance documents nor for creation of a binding rule that might raise the prospect of judicial review.

¹⁷⁹ The OMB proposal also requires an agency to accept comment on a guidance at any time, including comments suggesting revision or repeal. See Proposed Bulletin, *supra* note 177, at III.2.a.

would create no enforceable rights, a regulatory beneficiary's recourse presumably would be to OMB itself. It is unclear how effective that recourse might be.¹⁸⁰

Rakoff has suggested that placing agency response to public comment (and compliance with policy documents) outside the courts may not be significant in the mind of the agency and possibly not for regulated industry either, since at FDA, the industry participated extensively in the development of the "good guidance practices," and since the relationships in this "highly regulated industry" all involve "repeat players."¹⁸¹ As I suggest above, however, for regulatory programs where regulatory beneficiaries lack a direct relationship with the agency, they may lack the "repeat player" relationship that prompts the agency to seek their views or engage their comments.¹⁸² In that case, a regulatory beneficiary likely would benefit substantially from the opportunity to invoke outside oversight.

5. Expanding Citizen Suits

In a citizen suit or other private enforcement suit, a regulatory beneficiary could obtain judicial review of an agency's policy choice. While common in the environmental laws governing pollution, citizen suit provisions are generally relatively rare.¹⁸³ Even in the environmental laws, citizen suits are significantly limited by statutory and constitutional requirements.¹⁸⁴

¹⁸⁰ OMB is perceived generally to influence rules to reduce their costs and burdens upon regulated entities. Further, the disadvantages regulatory beneficiaries face in the agency setting also may reduce their ability to gain assistance from OMB as agencies develop guidances. See *supra* text accompanying notes 127-128. But see Steven Croley, *White House Review of Federal Agency Rulemaking: An Empirical Investigation*, 70 *U. Chi. L. Rev.* 821 (2003) (arguing that regulated entities and regulatory beneficiaries had equivalent access to OMB).

¹⁸¹ See Rakoff, *supra* note 3, at 169-170; but see Golden, *supra* note 144, at 263 (noting absence of "repeat players" in eleven randomly selected NHTSA, EPA, and HUD rulemakings).

¹⁸² See *supra* text accompanying note 124.

¹⁸³ A November, 2005, Westlaw search of the United States Code for "citizen suits" or "citizen enforcement" turned up 12 provisions, only 11 of which authorized suit against private parties. All concerned environmental or energy use issues.

¹⁸⁴ See *Gwaltney of Smithfield Ltd. v. Chesapeake Bay Foundation*, 484 U.S. 49 (1987) (requiring under Clean Water Act that citizen suits allege continuing or repeated violations); *Steel Co. v. Citizens v. a Better Environment; Friends of the Earth, Inc., v. Laidlaw Environmental Services, Inc.*, 528 U.S. 167 (2000) (applying standing

Outside the securities and civil rights contexts, private rights of action are infrequently implied.¹⁸⁵

Expanding citizen enforcement provisions to encompass obligations under a broader array of health, safety, and environmental laws would surely address regulatory beneficiary concerns regarding inadequate agency enforcement of statutory provisions. Moreover, broadening citizen suits would increase the ability of regulatory beneficiaries to hold agencies externally accountable for their implementation of a statute. Regulatory beneficiaries could use these enforcement actions as a vehicle for litigating their preferred interpretation of the underlying statute or regulation. To the extent a different agency interpretation or position is raised by other parties, the regulatory beneficiary could obtain judicial review of it without first having to go to the agency.¹⁸⁶ The agency would have to present its position to the court either indirectly, through its guidance document, or through an amicus brief.

Admittedly, a regulatory beneficiary could obtain judicial review only in the context of an enforcement action against a third party, requiring a statutory or regulatory violation that the regulatory beneficiary could detect and document. Further, regulatory beneficiary lawsuits would be subject to resource constraints; filing a lawsuit is considerably more expensive than submitting comments, or a petition, to receptive agency officials.

The proposal has some significant shortcomings, however. Aside from the fact that expanding citizen enforcement is not likely to be politically viable in a climate where high priority is placed on discouraging litigation, current citizen suit provisions appear to raise significant issues under both Article III

doctrine to citizen suits).

¹⁸⁵ See Bradford Mank, Can Administrative Regulations Interpret Rights Enforceable Under Section 1983?: Why Chevron Deference Survives *Sandoval* and *Gonzaga*, 32 Fla. St. U. L. Rev. 843, 896 n. 63 (2005) (listing examples of private rights of action implied by courts); Michael A. Mazzuchi, Note, Section 1983 and Implied Rights of Action: Rights, Remedies, and Realism, 90 Mich. L. Rev. 1062, 1073-74 (1992) (suggesting courts willing to expand private rights of action prior to 1975); see 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 securities area, courts reluctant to imply private rights of action even before *Cort v. Ash*); Stewart & Sunstein, *supra* note 74, at 1206.

¹⁸⁶ Even in direct review of, say, an agency rule, courts are now requiring the issue first to be presented to the agency. See *National Wildlife Federation v. Environmental Protection Agency*, 286 F.3d 554 (D.C. Cir. 2002). Further, the court would likely apply *Skidmore* deference to review of an agency interpretation not contained in a notice-and-comment rule or formal adjudication. See *Mead v. United States*; *Christensen v. Harris County*. If it does not contain an interpretation, a court hearing a citizen suit might not review an agency position in a guidance document at all.

and Article II.¹⁸⁷ They could also be criticized as interfering with an enforcement agency's legitimate weighing of a "wide variety of . . . managerial, political, and substantive considerations" in deciding whether to bring a claim.¹⁸⁸

IV. Conclusion

The debate over agency guidance documents has been incomplete because scholars have failed to adequately consider the interests of regulatory beneficiaries. When an agency chooses to issue a policy in a guidance document rather than a rule, regulatory beneficiaries lose critical ability to participate in the agency decision and to obtain judicial review of it. This takes place although the agency may be implementing statutes that were enacted to help the beneficiaries. Consequently, regulatory beneficiaries should have greater procedural rights with respect to agency policy making. Further empirical research is surely warranted, including on the extent to which agencies, as a practical matter, make an effort to include regulatory beneficiaries in their decision making, and the difference that comments from outsiders make, if any, in agency decision making.

Clearly, however, some reform, such as a right to petition, greater notice-and-comment rulemaking opportunities, good guidance practices, should be adopted. Reform is necessary to enable a regulatory beneficiary to engage an agency directly on the substance of an issued policy, ideally with the ultimate prospect of judicial review. It would also represent a significant step toward ensuring that agency procedures better recognize and incorporate the legitimate, immediate interests of regulatory beneficiaries in agency policy.

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¹⁸⁷ See supra note 184 (listing standing cases); *Vermont Agency of Natural Resources v. US ex rel Stevens*, 529 U.S. 765 (2000) (bounty cannot solve standing problem; identifying Article II issues with citizen enforcement).

¹⁸⁸ Stewart & Sunstein, supra note 74, at 1209.