

ESSAYS

DOMESTICATING GUIDANCE

BY

PETER L. STRAUSS*

This Essay, written for an occasion celebrating the scholarship of Professor William Funk of Lewis & Clark Law School, builds in good part on his analyses of soft law documents—statements of general policy and interpretive rules—that today one generally finds discussed under the rubric “guidance.” These are agency texts of less formality than hard law regulations adopted under the procedures of 5 U.S.C. § 553, that inform the public how an agency intends to administer its responsibilities, as a matter of policy or (what may seem just one instance of that) via the interpretation of its governing statutes or regulations. The APA is explicit that in adopting these texts, agencies are not required to use the notice and comment process ordinarily required for the adoption of regulations having the force of law; but it also signals that, like agency caselaw precedent, guidance may be relied upon to a private party’s disadvantage if it has been published or come to its actual notice. Guidance documents, revealing agency policy and perhaps showing the way to safe compliance, can structure the behavior of agency staff and be highly influential for the regulated; but they are not in themselves enforceable against actors in the outside world—hence, soft law. Typically, they are the product of agency staff, and do not (as regulations do) require the imprimatur of the agency’s political leadership for their adoption

Documents like these are common worldwide in regulatory contexts, much more numerous than regulations (as regulations are more numerous than statutes). In American administrative law they have often been caught up in disputes whether the notice and comment procedures engaging the agency’s political leadership needed to have been used for their adoption. Judicial concerns are that ostensible soft law has often been used to evade the

* Betts Professor of Law Emeritus, Columbia Law School.

*increasingly demanding obligations associated with notice and comment rulemaking. A common test has been whether, although nominally soft law, they are “practically binding.” The basic arguments of this Essay are, first, that this approach fails to differentiate highly desirable internal agency law (that is, policies “binding” on some agency staff) from what impermissibly “binds” the public; and, second, that soft law instruments can often be found “final” for purposes of judicial review—if they are, in effect, the agency’s internal law—and that use of the equitable standards for declaratory judgment long ago endorsed for pre-enforcement review of rulemaking will then permit dealing with the legality of soft law on its merits, and not as a matter of procedural compliance. Questions about “Auer deference” that the Supreme Court addressed in *Kisor v. Wilkie*¹ twelve weeks after the celebration of Professor Funk are also briefly addressed.*

I.	INTRODUCTION.....	766
II.	IS “GUIDANCE” A SINGULAR CONCEPT?	771
III.	THE OBJECTION THAT NOTICE AND COMMENT PROCEDURES SHOULD HAVE BEEN USED	773
IV.	REVIEWING THE MERITS OF GUIDANCE DOCUMENTS	776
	A. <i>Where an agency has relied on its guidance in formally deciding a matter subject to judicial review, what standard of review applies if the guidance embodies a statutory interpretation?</i>	776
	B. <i>Where an agency has relied on its guidance in formally deciding a matter subject to judicial review, what standard of review applies if the guidance concerns interpretation of an agency regulation?</i>	778
	C. <i>The possibility of reviewing on the merits guidance documents not relied upon in a regulation or formal adjudicatory opinion.....</i>	782

I. INTRODUCTION

Professor Funk learned much of his administrative law, as I did, through his important responsibilities in the general counsel’s office of a government agency. And that experience has significantly informed his scholarship about the soft law documents—statements of general policy and interpretive rules—that today one generally finds discussed under the rubric “guidance.”² These are agency texts of

¹ 139 S. Ct. 2400 (2019).

² William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321 (2001); William Funk, *When is a “Rule” a Regulation? Marking a Clear Line Between Nonlegislative Rules and Legislative Rules*, 54 ADMIN. L. REV. 659, 662–63 (2002) [hereinafter *When is a “Rule” a Regulation?*]; William Funk, *Legislating for Nonlegislative Rules*, 56 ADMIN. L. REV. 1023, 1033–34 (2004); William Funk, *Make My Day! Dirty Harry and Final Agency Action*, 46 ENVTL. L. 313, 330–31 (2016); William Funk, *Final Agency Action After Hawkes*, 11 N.Y.U. J.L. & LIBERTY 285, 307 (2017); see also William Funk, *Why SOPRA is Not the Answer*, 36 YALE J. ON REG.: NOTICE & COMMENT (Sept. 22, 2016), <https://perma.cc/B7N8-DEFN>.

less formality than hard law regulations adopted under the procedures of 5 U.S.C. § 553. They inform the public how an agency intends to administer its responsibilities, as a matter of policy or (what may seem just one instance of that) via the interpretation of its governing statutes or regulations. The Administrative Procedure Act (APA) is explicit that in adopting these texts, agencies are not required to use the notice and comment process ordinarily required for the adoption of regulations having the force of law; but it also signals that, like agency case law precedent, guidance may be relied upon to a private party's disadvantage if it has been published or come to its actual notice.³ Guidance documents, revealing agency policy and perhaps showing the way to safe compliance, can structure the behavior of agency staff and be highly influential for the regulated; but they are not in themselves enforceable against actors in the outside world—hence, *soft* law. The term “guidance” is sometimes used in ways that could reach an extraordinary variety of agency documents, such as staff advice given individuals concerning possible statutory applications;⁴ as used in this Essay it refers only to documents issued by central administration (although often not the agency head as such) that have the quality of “soft law” that will govern staff behavior, and are likely to influence private actions as well.

Documents like these are common worldwide in regulatory contexts. The reason is not far to seek. One can imagine a hierarchy of law-like documents, each characterized by a certain level of generality resolving questions unaddressed by its hierarchical superior, yet itself leaving unaddressed questions of greater detail.

Constitutions, and perhaps treaties, mark the top of this hierarchy; these are single instruments creating institutions and expressing their authority, but rarely indicating how that authority will be exercised and not, in themselves, binding on private individuals. Their creation and amendment are unusual events.

Statutes adopted by a representative legislature or, more rarely today, directives issued by a supreme executive authority, create legal obligations of the public. An active legislature might enact hundreds annually. The imprecisions of language and the vicissitudes of legislative politics produce statutes whose meaning is not wholly determined. Often, in circumstances rendering legislative judgment difficult, statutes state only general standards, and create subordinate institutions capable of resolving the issues they address with greater expertise and flexibility.⁵ Unable quickly to respond to the appearance of new drugs, whether promoting health or promoting addiction, the legislature may empower a Food and Drug Administration (FDA) or a

³ Administrative Procedure Act, 5 U.S.C. § 552(a)(2) (2012). This endorsement of their potential use led me to propose calling guidance instruments “publication rules.” Peter Strauss, *Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Function*, 53 ADMIN. L. REV. 803, 804 (2001). In his *A Primer on Nonlegislative Rules*, Funk, *supra* note 2, at 1349, Professor Funk convincingly suggested that this locution could be misleading, substituting “nonlegislative rules,” as others also have. Since then, “guidance” has become the accepted term for describing the universe of interpretive rules and general statements of policy. *See, e.g.*, Laura E. Dolbow, *Congressional Appropriation of Administrative Guidance*, 43 ADMIN. & REG. L. NEWS 11–12 (2018).

⁴ *See* CARY COGLIANESE, ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, PUBLIC AVAILABILITY OF AGENCY GUIDANCE DOCUMENTS (2019), available at <https://perma.cc/KQB7-2XAR>.

⁵ *See, e.g.*, Federal Water Pollution Control Act, 33 U.S.C. §§ 1251–1388 (2012).

Department of Justice to identify those that are legal (or illegal) for use, using standards and following procedures it specifies, and to enforce those judgments.

Regulations government agencies adopt using the notice and comment procedures of 5 U.S.C. § 553 are a common means of using the standard-setting authority thus conferred. U.S. agencies have adopted thousands each year, signed as required by the agency head and published first in the Federal Register and then in the Code of Federal Regulations (C.F.R.). Often they convey sufficient detail to determine the matters they address. Yet agencies, too, are incapable of perfect foresight; moreover, in many contexts there is a strong preference to have regulations expressed in terms of ends to be achieved (e.g., no more than five micrograms of sulfur dioxide per cubic meter of exhaust from a coal-fired utility's smokestack, as one means of securing the cleaner air the U.S. Environmental Protection Agency (EPA) has been directed to promote) rather than particular means that must be used to attain a desired result. The idea is to promote initiative among the regulated to find the most efficient means of securing that result. But a necessary result, then, is uncertainty just what technologies will satisfy the regulatory demand.

Guidance having the quality of soft law may be created by agency bureaus and staff (that is, it need not be issued or approved by the agency head); it takes many forms and is issued in a volume that dwarfs that of agency regulations.⁶ One frequent use is to inform the public (the regulated especially) about specific approaches agency staff has determined will meet the standards a regulation has set. Since the regulation (not the guidance) sets the obligation, this is "soft law" and one can attempt to show compliance in other ways. Guidance may also inform the public of the interpretation the agency places on a statute or regulation whose language is susceptible of more than one meaning; again, if the

⁶ In 1992,

(1) formally adopted regulations of the Internal Revenue Service occup[ie]d about a foot of library shelf space, but Revenue Rulings and other similar publications, closer to twenty feet; (2) the rules of the Federal Aviation Administration (FAA), two inches, but the corresponding technical guidance materials, well in excess of forty feet; (3) finally, Part 50 of the Nuclear Regulatory Commission's regulations on nuclear power plant safety, in the looseleaf edition, consume[d] three-sixteenths of an inch, while the supplemental technical guidance manuals and standard reactor plans in the same format stack[ed] up to nine and three-fourths inches.

Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J., 1463, 1469 (1992) (citations omitted). The complaints that the obstacles to notice and comment rulemaking are increasingly leading agencies to use guidance in situations in which regulations would be more appropriate, cf. Todd Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159 (2000), suggest that today (when electronic data bases complicate similar measurements) the contrast would, if anything, be more dramatic. Suggestions that the use of "guidance" is a product of bad faith agency behaviors seeking affirmatively to evade the requirements of rulemaking have been refuted, not only in the scholarship of Professor Funk but also in recent empirical work underlying an important set of recommendations by the Administrative Conference of the United States (ACUS). ACUS Recommendation 2017-5, *Agency Guidance Through Policy Statements*, 82 Fed. Reg. 61734 (Dec. 29, 2017); Nicholas Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 YALE J. REG. 165, 174-75 (2019); see also Daniel E. Walters, *The Self-Delegation False Alarm: Analyzing Auer Deference's Effect on Agency Rules*, 119 COLUM. L. REV. 85, 85 (2019) ("[A]gencies did not measurably increase the vagueness of their writing in response to Auer. If anything, rule writing arguably became more specific over time.").

agency is using guidance correctly, the legal obligation is that stated by the law or regulation and *not* what the guidance instrument itself may say. Guidance may also set out policy paths the agency intends to take, enforcement priorities it anticipates following, or rules of conduct it expects its staff to follow. None of this is obligatory on the public, although it may provide useful information and, if it has been included in the agency's electronic library, the agency is permitted to give it presumptive force against outside parties who might be disadvantaged by its use.⁷ Within the agency, however, the agency leadership and its staff may regard it as internal law; if a regulated party has followed guidance in its actions, then the staff will not (and should not) feel free to accuse it of non-compliance; if a member of staff does not act as agency guidance directs, she might be subject to internal discipline.

Perhaps surprisingly given how common guidance documents are, and how important they are in the world of regulation—to the regulated, to regulatory beneficiaries and, perhaps especially, to agency leadership seeking to coordinate the activities of its staff and to assure their predictability, uniformity and regularity—they are not often the subject of litigation; and when they are, their treatment is contentious and confused. Unlike some among the scholars who have written on the subject,⁸ Professor Funk⁹ and I,¹⁰ with others who frequently encountered it from inside government¹¹ believe that procedural issues should be

⁷ 5 U.S.C. § 552(a)(2) (2012) After requiring that guidance (and other matters not relevant here) be made “available for public inspection in an electronic format,” the provision ends with the statement that:

[a] final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—(i) it has been indexed and either made available or published as provided by this paragraph; or (ii) the party has actual and timely notice of the terms thereof.

⁸ Notably, Robert A. Anthony, *Three Settings In Which Nonlegislative Rules Should Not Bind*, 53 ADMIN. L. REV. 1313, 1318–19 (2001); Robert A. Anthony, *A Taxonomy Of Federal Agency Rules*, 52 ADMIN. L. REV. 1045, 1047 (2000); Robert A. Anthony & David A. Codevilla, *Pro-Ossification: A Harder Look At Agency Policy Statements*, 31 WAKE FOREST L. REV. 667 (1996); Robert A. Anthony, “Interpretive” Rules, “Legislative” Rules and “Spurious” Rules: *Lifting the Smog*, 8 ADMIN. L.J. AM. U. 1, 21–22 (1994); Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them To Bind The Public?*, 41 DUKE L.J. 1311, 1355 (1992); Robert A. Anthony, *Which Agency Interpretations Should Bind Citizens and the Courts?*, 7 YALE J. REG. 1, 4–5 (1991); Ronald M. Levin, *Rulemaking and the Guidance Exemption*, 70 ADMIN. L. REV. 263, 356–57 (2018); Ronald M. Levin, *Nonlegislative Rules and the Administrative Open Mind*, 41 DUKE L.J. 1497, 1507 (1992) [hereinafter Levin, *Open Mind*].

⁹ Funk, *Final Agency Action After Hawkes*, *supra* note 2, at 293–94; Funk, *Make My Day! Dirty Harry and Final Agency Action*, *supra* note 2, at 330–31; Funk, *Legislating for Nonlegislative Rules*, *supra* note 2, at 1027–28; *When is a “Rule” a Regulation?*, *supra* note 2, at 662–63; Funk, *A Primer on Nonlegislative Rules*, *supra* note 2, at 1352.

¹⁰ PETER L. STRAUSS, *ADMINISTRATIVE JUSTICE IN THE UNITED STATES* 303–05, 352–56, 501–02 (3d ed. 2016) [hereinafter STRAUSS, *ADMINISTRATIVE JUSTICE*]; Peter L. Strauss, *Implications of The Internet for Quasi-Legislative Instruments of Regulation*, 28 WINDSOR Y.B. ACCESS JUST. 377, 379 (2010) [hereinafter Strauss, *Implications of the Internet*]; Strauss, *supra* note 3, at 806–08; Strauss, *supra* note 6, at 1472–75.

¹¹ Cass R. Sunstein, “Practically Binding”: *General Policy Statements and Notice-and-Comment Rulemaking*, 68 ADMIN. L. REV. 491, 515–16 (2016) (formerly Administrator, Office of Information and

resolved by what Professor David Franklin characterized as “the short cut;”¹² simply asking whether notice and comment procedures had been used and, if not, refusing the guidance the legal effect a regulation would have. The paragraphs that follow were informed by that experience and scholarship, and also by the appearance on the Supreme Court’s docket, as this Essay was being written, of *Kisor v. Wilkie*,¹³ inviting the Court to address a question much disputed in recent years: if an agency has used guidance to interpret one of its regulations, must a court reviewing an application of that interpretation simply accept it so long as the regulation’s language is susceptible of that interpretation? In *Auer v. Robbins*¹⁴ the Supreme Court ruled that a court reviewing an agency’s interpretation of its own regulations should accept that interpretation so long as it is not “plainly erroneous or inconsistent with the regulation.”¹⁵ Critics¹⁶ feared that this lenient attitude would encourage agencies to write their regulations loosely, permitting future policy changes via guidance, without the inconvenience and expense of further notice and comment proceedings. Proponents argued that the ruling supports the agency’s much greater familiarity with the intricacies of its responsibilities overall and its primary incentive to regulate for the current day with as much clarity as its knowledge permits; evidence of the feared encouragement to laxity, they say, is simply missing.¹⁷ In *Kisor*, with Chief Justice Roberts casting the pivotal vote, the Court reformulated the *Auer* proposition in ways that considerably limit its application, and instruct courts independently to assess the possibility and reasonableness of agency interpretations of its soft law—in effect, applying what has long been known as “*Skidmore* deference.”¹⁸ As this occurred twelve weeks after the *Festschrift* for which this essay was written, *Kisor* will not be addressed at any length here; one may confidently expect a rich literature to flourish. Nor is this Essay a comprehensive critical review of the literature, such as others have

Regulatory Analysis); E. Donald Elliott, *Re-Inventing Rulemaking*, 41 DUKE L.J. 1490, 1492–95 (1992) (formerly General Counsel, EPA).

¹² David A. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 289–94 (2010).

¹³ *Kisor v. Shulkin*, 869 F.3d 1360 (Fed. Cir. 2017), *cert. granted in part sub nom. Kisor v. Wilkie*, 139 S.Ct. 657 (2018).

¹⁴ 519 U.S. 452 (1997).

¹⁵ *Id.* at 461.

¹⁶ Notably the late Robert A. Anthony, *supra* note 8; *see* Parrillo, *supra* note 6, at 175–76 and accompanying footnotes.

¹⁷ *See, e.g.*, Scott H. Angstreich, *Shoring Up Chevron: A Defense of Seminole Rock Deference to Agency Regulatory Interpretations*, 34 U.C. DAVIS L. REV. 49, 112–16 (2000); Richard J. Pierce, Jr. & Joshua Weiss, *An Empirical Study of Judicial Review of Agency Interpretations of Agency Rules*, 63 ADMIN. L. REV. 515, 520–21 (2011) Recent empirical work refutes the claim that *Auer* has encouraged promulgating mush. *See* Walters, *supra* note 6, at 85 (“[A]gencies did not measurably increase the vagueness of their writing in response to *Auer*. If anything, rule writing arguably became more specific over time.”); Cass Sunstein and Adrian Vermeule, *The Unbearable Rightness of Auer*, 84 U.CHI. L. REV. 297, 308 (2017) (“[W]e are unaware of, and no one has pointed to, any regulation in American history that, because of *Auer*, was designed vaguely”; *see also* Parrillo, *supra* note 6, at 271).

¹⁸ *Skidmore* is cited with approval by all nine Justices, with Chief Justice Roberts remarking in his deciding concurrence that as *Auer* and *Skidmore* now stand, the two propositions “largely overlap.” *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019) (Roberts, C. J. concurring in part).

essayed.¹⁹ While it has points of considerable tangency with other writings on the subject,²⁰ it essentially continues to develop the view of the issues my earlier writings have expressed, reflecting many points of agreement with Professor Funk's extensive writings on the subject.

II. IS "GUIDANCE" A SINGULAR CONCEPT?

The APA does not separately define "general statements of policy" and "interpretative rules"—its definition of "rule" in 5 U.S.C. § 551(4) mentions neither while readily encompassing both, but in four places²¹ the APA refers to them separately, as if there might be a difference, but in conjunction. Is there a difference between the two types?

This question is at the heart of Ronald Levin's very recent analysis in the pages of the *Administrative Law Review*,²² and he persuasively makes the case that "guidance" should be treated as a unitary concept. To be sure, sometimes it is used to convey interpretations of other documents, rules or statutes, with which the public may be concerned, and the impact of those interpretations on the meaning of the law (statute or regulation) being interpreted is a distinct question. Conveying a policy, whether about enforcement or program development, does not speak directly to a law's meaning. In that sense these two guidance types are distinct. But in no respect does the APA suggest that the procedures necessary for their development differ from one another. Both are forms of soft law that may influence but cannot in themselves properly control private behavior. For each, it is impermissible for the agency to use it as if it did embody an independent legal obligation, and the agency must be willing to reconsider each if challenged in an appropriate proceeding—showing, however summarily, some reason for maintaining its position in the face of that challenge if it does continue to adhere to it. Procedurally, then, they are identical. And Professor Levin's article strongly argues that separate treatment has been a practical failure: that no manageable standard different from the standard for assessing the procedural adequacy of "statements of general policy" has emerged for "interpretative rules."

Professor Robert A. Anthony's scholarship, of which Professor Funk has been more accepting than I, forcefully stated a contrary position, sharply distinguishing

¹⁹ E.g., Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 332–33 (2011).

²⁰ Agreeing, for example, with Professor Seidenfeld's ultimate conclusion that finding a route to substantive review of important guidance to which agencies are seriously committed is far preferable to finding procedural fault with guidance documents not the product of notice and comment rulemaking. See *id.* at 394; and agreeing with Nina Mendelson that the importance of guidance to those on whose behalf regulation occurs counsels finding means for permitting their disputing of its merits (as distinct from the procedures by which it is formulated), Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 452 (2007).

²¹ "[S]tatements of general policy or interpretations of general applicability," 5 U.S.C. § 552(a)(1)(D); "statements of policy and interpretations," *id.* § 552(a)(2)(B); "[a] final order, opinion, statement of policy, interpretation, or staff manual or instruction," *id.* § 552(a)(2)(E); and "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice," *id.* § 553(b)(3)(A).

²² Levin, *Rulemaking*, *supra* note 8, at 265.

interpretive rules from general statements of policy.²³ Interpretive rules, he argued, take a legal position on the meaning of a statute (his analysis dealt, almost exclusively, with the interpretation of statutes, and not agency regulations), and he saw no greater reason for the agency to entertain others' views about its interpretation than it would have to consult with them about positions taken in its briefs.²⁴ Courts might ultimately say whether its interpretation was sustainable or not, but in its own proceedings the agency was entitled to treat those who might be affected by the interpretation as bound by it.²⁵ It had no obligation, as Professor Levin observed in a contemporary critique,²⁶ to pretend to open-mindedness on the matter.

Levin's contrary view, now fully developed in his recent analysis, was that:

[w]hich label the agency uses should have little effect on the public's right to be heard, because roughly the same procedural requirement comes into play either way. That requirement consists in a duty to give fair consideration to challenges that private parties subsequently raise against the determinations contained in the rule.²⁷

And section 552's obligations of publication, and permission to give the soft law presumptive effect against persons outside the agency if published,²⁸ are identical for each.

Professor Anthony's view respecting general statements of policy—that is, soft law that does not purport to attach a particular meaning to a text creating legal obligations of possibly uncertain meaning—was in striking contrast to his acceptance of interpretive rules. Uncontroversially, he observed that for an agency to treat the view contained in its policy statement as hard law, legally binding on a private party and directly enforceable against it, would be a fundamental error; creation of a hard law obligation not itself imposed by statute or regulation, requires use of the notice and comment rulemaking procedures of 5 U.S.C. § 553. But suppose, instead, soft law documents, *not* directly enforced against private parties, but that agency staff could be expected to treat as internal administrative law constraining their actions, and/or that could strongly influence private conduct. He described such highly influential impacts, that 5 U.S.C. § 552(a) appears to endorse so long as the policy statements have been published, as being “binding in practice.”²⁹ He argued that agencies must use section 553 procedures for general statements of policy that are “binding in practice,” as well as for those it treats as creating, in themselves, legal obligations.³⁰ Only if the agency stated its general policy in terms indicating that it was not binding on itself or its employees—just a tentative position that its front-line employees need not honor and that was fully open to reconsideration—could the exemption for general policy statements be

²³ Anthony, *Interpretive Rules*, *supra* note 8, at 1315.

²⁴ *Id.* at 1313, 1375–76.

²⁵ *Id.* at 1318, 1327.

²⁶ Levin, *Open Mind*, *supra* note 8, at 1498–99.

²⁷ *Id.* at 1507.

²⁸ 5 U.S.C. § 552(a)(2).

²⁹ Anthony, *Interpretive Rules*, *supra* note 8, at 1315.

³⁰ *Id.* at 1383.

used.³¹ Expressing understandable doubt about its one-sidedness and sincerity, Professor Anthony gave as an example a boilerplate expression that had begun to appear in EPA guidance documents:

NOTICE: The policies set out in this [document] are not final agency action, but are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this [document] or to act at variance with the guidance, based on an analysis of site-specific circumstances. The Agency also reserves the right to change this guidance at any time without public notice.³²

The problems here, fully developed in my earlier writings,³³ are the subject of the following section of these materials.

III. THE OBJECTION THAT NOTICE AND COMMENT PROCEDURES SHOULD HAVE BEEN USED

The “binding in practice” idea directly implicates a tension between the world of unquestioned hard law, and the internal law of administration that many scholars credit as a major force in securing the uniformity and predictability of administration, constraining uncontrolled exercises of discretion by agency bureaucrats—in other words, making a major contribution to the rule of law.³⁴ As the following graphic and text from my earliest writing on this subject may illustrate, treating “binding in practice” as a reason notice and comment rulemaking must be used identifies as a simple binary question an issue that has not two, but four possible outcomes:

	Gov’t bound	Gov’t not bound
Regulated party bound	A) Both parties bound	B) Regulated party only bound

³¹ *Id.* at 1316.

³² *Id.* at 1361. *Appalachian Power Co. v. U.S. Envtl. Prot. Agency*, 208 F.3d 1015, 1028 (D.C. Cir. 2000), is only one of the occasions on which the D.C. Circuit declined to credit such a disclaimer—finding, instead (and questionably in the author’s view, *see infra*, note 77 and accompanying text) a hard-law action that had required notice and comment rulemaking for its adoption.

³³ *See* STRAUSS, ADMINISTRATIVE JUSTICE, *supra* note 10; Strauss, *Implications of the Internet*, *supra* note 10, at 377–80; Strauss, *Publication Rules*, *supra* note 3, at 804–11, 838–43; Strauss, *The Rulemaking Continuum*, *supra* note 6, at 1463–68.

³⁴ Gillian E. Metzger, *The Constitutional Duty to Supervise*, 124 YALE L.J. 1836, 1883–85 (2015); Gillian E. Metzger & Kevin M. Stack, *Internal Administrative Law*, 115 MICH. L. REV. 1239, 1244–48 (2017); Nicholas R. Parrillo, *Jerry L. Mashaw’s Creative Tension with the Field of Administrative Law*, in ADMINISTRATIVE LAW FROM THE INSIDE OUT: ESSAYS ON THEMES IN THE WORK OF JERRY L. MASHAW 1, 3 (Nicholas R. Parrillo ed., 2018).

**Regulated
party not
bound**

C) Gov't
only bound

D) Neither party
bound

Box A is simple—that is the situation produced by legislative rulemaking. Box D, in which there is *no* law, is of little concern. The tension reflects the possible contents of Boxes B and C.

We can imagine cases in Box C—historically perhaps not numerous in litigation, but nonetheless central to one’s sense of what it means to have a government of laws—in which citizens who are not themselves bound by a governmental policy instrument seek to hold the government to the promise that the instrument seems to contain. As the United States Court of Appeals for the District of Columbia Circuit has stated, “it is a familiar principle of federal administrative law that agencies may be bound by their own substantive and procedural rules and policies, whether or not published in the Federal Register. . . .” The private litigants in such cases are ordinarily unconcerned with procedural sufficiency; those who are subject to regulation would prefer to have the government declare its position on some controvertible issue of law or policy and then to be able to hold the government to it. Whereas reasons of public policy may sometimes counsel against too-easy acceptance of limitations on governmental discretion, the general instincts of a society that has set its face against “secret law” and encourages citizens to obtain pre-action advice from government officials is that this is, normatively, a desirable state of affairs. Procedural rules that would inhibit reliable advice-giving, are, from this point of view, to be frowned upon.

It is hard, on the other hand, to find desirable content to Box B, in which the citizen is bound but the government is not. Pronouncements like the Environmental Protection Agency (EPA) disclaimer Professor Anthony quotes seem the very antithesis of what we think of as the “rule of law.”³⁵

One can find a recent example of the Box C phenomenon in the Supreme Court’s recent decision in *Encino Motorcars, LLC v. Navarro*³⁶ (*Encino*), in which the Court held that a 1978 agency opinion letter (that is, a guidance document) had created private party reliance interests requiring an agency to give a reasoned explanation for change in it made by a subsequently adopted notice and comment regulation. Given the seriousness and consistency with which the agency had subsequently adhered to this opinion letter, that is, the agency had bound itself, had created law for itself that its insufficiently explained statement of basis and purpose in its notice and comment rulemaking had been ineffective to change.³⁷

³⁵ Strauss, *supra* note 6, at 1464–65 (footnotes omitted).

³⁶ 136 S. Ct. 2117, 2126 (2016).

³⁷ *Id.* at 2126–27. *See also* Anastasoff v. United States, 253 F.3d 1054, 1054–56 (8th Cir. 2000) (en banc) (stating that a government statement of acquiescence in a taxpayer-favoring ruling by one circuit required the same outcome in another—the government had bound itself). Professor Parrillo’s influential empirical study, NICHOLAS R. PARRILLO, FEDERAL AGENCY GUIDANCE: AN INSTITUTIONAL PERSPECTIVE 27 (2017) (report to the Admin. Conf. of the U.S.), and the ACUS Recommendations resulting from it, ACUS Recommendation 2017-5, *supra* note 6, recognize both the fact and the

Encino did *not* hold that the notice and comment rulemaking the agency had in fact used would have been necessary to effect the desired policy change. Just a year earlier, in *Perez v. Mortgage Bankers*³⁸ (*Perez*), the Court had sharply repudiated a D.C. Circuit holding that change in an agency’s interpretation of an existing regulation could only be effected by notice and comment rulemaking.³⁹ The procedures required for the adoption of general statements of policy and interpretive rules are those stated by the APA—only publication, if soft law effects on private parties are in view.⁴⁰ In *Encino*, then, the change of interpretation could have been effected by a new interpretive rule; but that change, too, would have required the kind of explanation the Court found missing, one that sufficiently and persuasively explained the basis for the change. The failure of adequate explanation for a change in the policy by which the agency had effectively bound itself was the fatal flaw in *Encino*; its use of notice and comment rulemaking to effect the change made judicial review uncontroversially available, but was not a necessary element of change. One could say that *Encino* and *Perez*, taken together, confirm Professor Funk’s view that guidance documents and non-legislative rules are never procedurally deficient, although they may be ineffective if not properly anchored in the hard law documents to which they relate.

Nonetheless, at least in part as a consequence of the obstacles to review on the merits of guidance documents that are addressed in the next section of this Essay, courts sustaining challenges to guidance documents under the “binding in practice” rubric have generally done so by finding a procedural fault, holding that notice and comment procedures had been necessary. But then, as has been noted, agencies have the choice not to issue guidance, or to pretend to its unreliability, as in the EPA boilerplate Professor Anthony quoted. One readily agrees that statements that are “binding in practice” on the outside world, but ineffective internally—Box B in the graphic above—are undesirable, insupportable. Yet forbidding actions fitting Box C in the graphic above—internally hard law, but externally only the soft law evoked by “binding in practice”—would leave to staff discretion (and consequent variation in administration) outcomes that could have been made predictable and uniform. Frequent actual use of notice and comment rulemaking for the ends now served by guidance is unlikely, given its significant resource and time costs. Agencies could act through adjudication—again at the considerable cost of abjuring timely notice to the regulated of agency views, since interpretations emerging through agency adjudication, like those emerging through judges’ statutory interpretations, are (if linguistically proper) applied retrospectively, to behavior that has already occurred.

If the agency has not made the fundamental error of treating its guidance as hard law for the outside world, then, discouraging its use of soft law would be unfortunate indeed. Requiring the relatively formal procedures of notice and comment rulemaking for advice that is intended to control staff actions and to be reliable for the public creates perverse incentives—either not to give such advice,

desirability of internal agency law of this nature, that operating staff will treat as binding for them, albeit open to waiver or alteration by their superiors on a demonstration of the need for that.

³⁸ 135 S. Ct. 1199 (2015).

³⁹ *Id.* at 1203–04.

⁴⁰ *Id.*

or to accompany any advice given with prominent notices that it is *not* intended to bind agency personnel and may *not* be relied on by the public. Such notices now do appear frequently. Why one should wish such outcomes is beyond the author's ready understanding. Whether publicized instructions to staff take the form of enforcement policies, indications of behaviors the agency will accept as compliance with its regulations, or other "soft law," it is much better if guidance seriously given and intended is treated as open to reconsideration within the agency,⁴¹ and can be reviewed on the merits by those whose behavior may be seriously affected by it.

IV. REVIEWING THE MERITS OF GUIDANCE DOCUMENTS

Agency use of guidance is readily reviewed, whether for procedural sufficiency or for its substantive acceptability, when reliance on the guidance has been an element of decision in a matter undeniably final, such as a notice and comment rulemaking or an on-the-record adjudication.⁴² The issues then concern the force the agency has given the guidance in that proceeding, and the extent (if any) to which courts should respect the judgments it embodies in determining its acceptability. But parties may also seek review of the guidance itself, before any such embodiment, asserting that it is an improper influence on their conduct, or fails responsibly to protect their interests, as the agency's statutes require. If the consequence of the guidance will be non-enforcement or an agency action in which they are unable to participate, pre-enforcement review may be all that could possibly be available for members of the general public who fear being harmed by resulting private behaviors.⁴³ Here, the absence of a decision creating or formally enforcing hard law raises questions whether the guidance, in itself, has the "finality" and "ripeness" of decision that are requisite for securing review. The paragraphs following treat these issues in turn.

A. Where an agency has relied on its guidance in formally deciding a matter subject to judicial review, what standard of review applies if the guidance embodies a statutory interpretation?

Agency interpretations of their constitutive statutes that are first voiced in "interpretive rule" guidance, and then relied upon in a notice and comment regulation or a formal adjudicatory decision are, on judicial review, entitled to review under the two-step process known as *Chevron* deference.⁴⁴ That entails, first, an independent judicial determination whether the statute is susceptible of the meaning the agency has given it, and, second, a further decision (such as animates

⁴¹ See Parrillo, *supra* note 6, at 182. Professor Parrillo's study and the ACUS recommendation resulting from it suggest both the importance of and appropriate structures for this.

⁴² *Perez*, 135 S.Ct. at 1209.

⁴³ See Parrillo, *supra* note 6, at 183.

⁴⁴ *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 842-43 (1984). Note that on this hypothesis the guidance's interpretation has effectively been adopted by the agency and given the force of law for itself as well as for the outside world. The guidance itself would not be reviewed in the *Chevron* framework. *United States v. Mead Corp.*, 533 U.S. 218, 237-38 (2001).

review under 5 U.S.C. § 706(2)(A)) whether the agency appropriately reasoned to the choice it made, in relation both to the facts before it and to policies it may appropriately pursue.⁴⁵ As *Chevron* itself illustrates, and was more recently confirmed by *Perez*,⁴⁶ an agency is not permanently wedded to the first interpretation it may adopt; but its reasoning in adopting any interpretation it may make, within the space statutory language permits,⁴⁷ is an element of the judicial review of that interpretation.⁴⁸

It is a separate question, one Professor Anthony elided: may an agency treat an interpretive rule, issued informally, as binding upon disadvantaged private parties who later protest it in a subsequent, more formal proceeding? It is impossible to square that position with the language of 5 U.S.C. § 552(a), which permits interpretive rules, as well as general statements of policy, to be “relied on, used, or cited as precedent by an agency against a party other than an agency” if they have been published. “Precedent” is inherently subject to reexamination in the proceeding in which it might be relied on, used or cited;⁴⁹ it does not constitute “hard law” as constitution, treaty, statute and regulation do, and treating soft law as hard law—whether it is an interpretive rule or a general statement of policy—is a categorical error. Professor Anthony never turned his attention to this element of the APA. Professor Funk saw this clearly eighteen years ago, when he wrote these words:

There is, I believe, a simple test for whether a rule is legislative rule or a nonlegislative rule: simply whether it has gone through notice and comment rulemaking. Thus, any substantive rule adopted without notice and comment and without a finding of good cause for avoiding notice and comment must of necessity be a nonlegislative rule. It may still be an invalid nonlegislative rule on the merits, such as by interpreting the law erroneously, but it is not invalid procedurally. Moreover, if an agency gives a nonlegislative rule binding, legal effect, then the agency has acted unlawfully, not because the nonlegislative rule was an invalid legislative rule, but because the nonlegislative rule cannot have the legal effect the agency accorded it.⁵⁰

What it means to “give[] a nonlegislative rule binding, legal effect” is a separate question, already addressed. Here, too, there can be a “simple test”—whether the agency has treated a nonlegislative rule as, in itself, the direct source of

⁴⁵ Peter L. Strauss, *A Softer, Simpler View of Chevron*, 43 ADMIN. & REG. L. NEWS 7, 7–8 (2018).

⁴⁶ See *Perez*, 135 S.Ct. at 1206.

⁴⁷ Peter L. Strauss, “*Deference*” is Too Confusing—Let’s Call Them “Chevron Space” and “Skidmore Weight,” 112 COLUM. L. REV. 1143, 1162–63 (2012).

⁴⁸ Note in passing the tension between this flexibility and the increasing tendency of the Supreme Court, when itself engaging in statutory interpretation, to treat statutory meaning as a static matter, determined by the language and expectations of the enacting legislature, and not subject to subsequent variation within the possibilities of contemporary meaning that language (and contemporary legal understandings) may suggest. See, e.g., *Epic Systems Corp. v. Lewis*, 138 S.Ct. 1612, 1629 (2018); See Peter L. Strauss, *Resegregating the Worlds of Statute and Common Law*, 1994 SUP. CT. REV. 429, 498 (1995).

⁴⁹ After *x* repetitions of reliance, and in the absence of any indication that it is weakening, an adjudicator might impatiently refuse to reexamine a precedent. See, e.g., *Cooper v. Aaron*, 358 U.S. 1, 19 (1958). But the general obligation is reflected in the very premises of common law development.

⁵⁰ Funk, *A Primer on Nonlegislative Rules*, *supra* note 2, at 1324–25.

the legal obligation it is enforcing. My view that this is the appropriate test (essentially excluding the idea of “binding in practice” for the outside world), would not prevail in the D.C. Circuit or for many scholars. But on the quoted proposition I believe we all agree.

It follows that when an interpretive rule addressing statutory meaning becomes relevant in a formal agency proceeding, rulemaking or adjudication, the agency *must* be open to its reconsideration if that is sought in the proceeding, and the findings in that proceeding should then explain the agency’s conclusion to adhere to, or to change, its interpretation. Should the agency treat the interpretation as not open to re-examination, because it has already been expressed in the interpretive rule, a reviewing court might find that interpretation to have been beyond the agency’s authority to adopt: *Chevron*’s step one. But if it finds the interpretation within the agency’s authority to adopt, it should *not* then reach the *Chevron* step two question about its reasonableness; rather, it should remand the matter to the agency for the reconsideration the agency improperly denied its interpretive rule, which is soft law, when it treated it as if it were hard law.

B. Where an agency has relied on its guidance in formally deciding a matter subject to judicial review, what standard of review applies if the guidance concerns interpretation of an agency regulation?

Readers will quickly recognize that the question here concerns the controversy over so-called *Auer* deference; highly controversial in recent years and recently addressed by the Supreme Court in *Kisor v. Wilkie*.⁵¹ *Auer* had been taken by many to limit judicial inquiry on the merits of an agency’s interpretation not of a statute, but of its own regulation, to the equivalent of *Chevron*’s first step—to the question whether the agency’s regulation could possibly bear the interpretation the agency had given it. And the Supreme Court’s recent decision in *Perez*⁵² (which featured several separate opinions questioning *Auer*) made clear that agencies are not bound by the first interpretation they may give to their regulations, but are free to change those interpretations, within the possibilities that regulatory language permits (and, as *Encino* holds, with demonstrable reasons for the change).⁵³ Unsurprisingly, the range of scholarship on *Auer* and its predecessor *Bowles v. Seminole Rock & Sand Co.*⁵⁴ (*Seminole Rock*) was great,⁵⁵ and the treatment of *Kisor* in this Essay should be summary, given its decision after the celebration of Professor Funk’s scholarship at which this Essay was presented.

Supporters of *Auer* have pointed to an agency’s vastly superior and integral knowledge of its regulations and their bearing on its continuing responsibilities; to

⁵¹ *Kisor v. Shulkin*, 869 F.3d 1360 (Fed. Cir. 2017), *cert. granted sub nom. Kisor v. Wilkie* 139 S. Ct. 657 (2018).

⁵² *Perez*, 135 S. Ct. 1199, 1206 (2015).

⁵³ *Encino*, 136 S. Ct. 2117, 2127 (2016).

⁵⁴ 345 U.S. 410 (1945).

⁵⁵ See generally Parillo, *supra* note 6; Walters *supra* note 6; Sunstein, *supra* note 11; Sunstein & Vermeule, *supra* note 17. Interested readers can get a start into it in an online symposium with thirty contributors. See Online Symposium, *Reflections on Seminole Rock: The Past, Present, and Future of Deference to Agency Regulatory Interpretations*, YALE J. ON REG.: NOTICE & COMMENT Sept. 2016, at 1, <https://perma.cc/CJ3B-X6U8>.

the consequence of preferring to have regulations stated as standards to be attained rather than rules to be rigidly adhered to in inviting changes in policy within the framework they establish as social and technical understandings alter; to an agency's incentives to be as clear as possible to those it regulates in the current day; and to the sluggishness of the rulemaking process. Critics have expressed concern that *Auer's* strong deference invited the outcomes Professor Anthony so feared—vacuous regulations structured to permit future interpretations that effectively change governing law without the need for notice and comment rulemaking—and also that it effectively and unconstitutionally conveys inherent judicial authority on executive branch actors.⁵⁶ As Professor John Manning argued at the inception of the disputes over *Auer*, at least when Congress drafts imprecise language it is aware that under *Chevron* it is transferring lawmaking authority to a body it can at best imperfectly control,⁵⁷ giving it an incentive to be as precise as it can be in drafting; agencies drafting regulations that leave their staff room for future maneuver experience no similar incentive, and for *Auer's* critics the temptation to avoid the considerable costs of notice and comment rulemaking will be high.⁵⁸

The *Kisor* opinions essentially steered a middle course. Justice Kagan, for the four Justices consistently identified as more liberal, made the case for deference while noting initial judicial inquiries that significantly limit the constraints on independent judicial judgment many had attributed to the doctrine. Strikingly, her opinion directly engaged with the commands of the Administrative Procedure Act respecting judicial review, that had been remarkably absent from *Chevron*, the Supreme Court's influential and now contested opinion on agency statutory interpretation.⁵⁹ Justice Gorsuch, for the four most conservative Justices, strongly argued for overruling *Auer*, while appearing, however, to accept the appropriateness of judicially centered deference on the *Skidmore* model. Chief Justice Roberts found overruling inappropriate, invoking the importance of *stare decisis*, but—importantly, and accurately in the author's judgment—he noted that between the constraints acknowledged by the four liberals and the appropriateness of judicial respect for agency judgment acknowledged by the dissents, there were in fact few areas of practical disagreement.

⁵⁶ See *supra* note 6 and accompanying text. As noted above, recent empirical work refutes this claim. See Walters, *supra* note 6, at 85 (“[A]gencies did not measurably increase the vagueness of their writing in response to *Auer*. If anything, rule writing arguably became more specific over time.”); see also Nicholas Parrillo, *Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries*, 36 YALE J. REG. 165, 271 (2019).

⁵⁷ Lisa Schultz Bressman & Abbe R. Gluck, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons: Part I*, 65 STAN. L. REV. 901, 992 (2013); Lisa Schultz Bressman & Abbe R. Gluck, *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation and the Canons: Part II*, 66 STAN. L. REV. 725, 765–71 (2014).

⁵⁸ John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612, 680–81 (1996); John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 928–44 (2004).

⁵⁹ This Essay is hardly the place for a discussion of *Chevron*, which all opinions indicated was not at issue; but the author takes a certain satisfaction from observing that Justice Kagan's way of describing the independent judicial role in relation to agency regulatory interpretations strongly resembles the softer and more constrained view of that case that he has long urged. See *supra* note 48 and accompanying text. See also Walters, *supra* note 17; Sunstein & Vermeule, *supra* note 17.

It seems likely this outcome has pleased Professor Funk, since his experience at the Department of Energy (DOE) led him to see reality in both sides of this dispute, as more recently has Professor Parrillo.⁶⁰ When DOE drafted regulations, providing clarity of obligation for the regulated was its major incentive; but if unforeseen issues subsequently arose that permitted a choice between interpreting an existing regulation and engaging in new rulemaking, the high costs and time dimensions of notice and comment rulemaking encouraged interpretation.⁶¹

Daniel Walters's recent empirical study published in the *Columbia Law Review*,⁶² measuring regulatory slack in a variety of ways, concluded that *Auer* deference has had no measurable impact on the extent to which agencies are less precise in regulatory drafting than arguably they could be. Although the argument that *Auer* might provide an incentive for capacious drafting has theoretical legs, careful linguistic analysis revealed no such effect. One might, as he briefly recognizes, think his findings compromised by the data set he relies on for his analysis, the genuinely important (Office of Information and Regulatory Affairs (OIRA) "significant") rules that face both the most demanding scrutiny within government, under the Executive Order process, and the highest prospect of intense ("hard look") judicial review. This is a setting in which effort and precision are likely to be maximized. Yet other elements of his analysis point in the same direction—that agencies, like other human institutions, will value immediate, short-term outcomes over creating longer-term uncertainties (uncertainties that might fall into the hands of political opponents). Achieving present regulatory ends will ordinarily conduce to achievable precision.

Nonetheless, as Professor Funk reported experiencing at DOE, resource constraints (and the impossibility of foreseeing all possible future situations) will limit today's rule-drafting efforts in ways that might permit responding with new interpretations, in lieu of fresh rulemaking, in the future.⁶³ So too, when agencies draft regulations with the often preferred end of setting standards to be achieved rather than specifying particulars in rules. In the statutory context, inquiries into excessive delegation are frustrated by the absence of judicially manageable

⁶⁰ See generally Parrillo, *supra* note 6, at 165–69 (discussing how agencies often follow guidance rigidly, rather than flexibly).

⁶¹ William Funk, *Why SOPRA is Not the Answer*, *supra* note 2, at 68–69, <https://perma.cc/42UB-PX7M>.

Professors Sunstein and Vermeule have in their blog here and in their Chicago Law Review article [Sunstein & Vermeule, *supra* note 17] provided their policy reasons for why they believe *Auer* should be retained. I will not add to that debate except to second, on the basis of my experience as a government lawyer writing regulations, their belief that *Auer* does not in fact result in agencies writing vaguer regulations than they otherwise would. . . . Unlike the incentive to write ambiguous regulations in order to retain flexibility for later interpretation, for which there is no empirical support for agencies acting on that basis, the incentive to avoid notice-and-comment rulemaking is strong, and there is a wealth of empirical support for the fact that agencies indeed try to cut corners, especially given the number of cases challenging agency interpretive rules as improperly adopted legislative rules.

Id. at 68.

⁶² Walters, *supra* note 6, at 164. See also Cass R. Sunstein & Adrian Vermeule, *Auer, Now and Forever*, *YALE J. ON REG.: NOTICE & COMMENT*, Sept. 2016, at 41, <https://perma.cc/RVC7-G3XQ>.

⁶³ Funk, *Why SOPRA is Not the Answer*, *supra* note 2, at 68–69.

standards for assessing the adequacy of legislative effort.⁶⁴ Yet one might think courts more capable of measuring the adequacy of the regulatory effort that created the potential for subsequent guidance than they are of measuring the adequacy of statutory effort creating the potential for regulations. Courts asking such a question would not face the political issues associated with telling Congress how well or poorly it has done its job; and the intensity of rulemaking review—well known to agencies and a strong incentive to careful drafting—is itself a signal of that. The extensive agency explanations of their reasoning now commonplace in adopting regulations, no longer “concise, general statements of basis and purpose,” in themselves can provide a framework for constraining the range of possible future interpretations, a framework that is simply unavailable in the statutory context.⁶⁵

The extent of overall agency effort was important to the decision in *Shalala v. Guernsey Memorial Hospital*,⁶⁶ briefly mentioned in Professor Walters’s analysis. There, the Court remarked that the revised interpretation challenged in that case had addressed only one element of a highly complex set of rules, in the formulation of which considerable administrative energy had been spent.⁶⁷ Similarly, one could view the controversy involved in *Hocor v. U.S. Dept. Agriculture*⁶⁸ (*Hocor*), frequently invoked in Professor Funk’s discussions of guidance questions, as having been one element of a highly complex set of rules about structural integrity in animal breeding—reaching many species, and for common ones (cattle, cats, hamsters) in considerable detail; that issues about raising lions, tigers and leopards were less precisely dealt with, in that context, was hardly surprising.⁶⁹ The Department, moreover, had made the fundamental mistake of accusing Hocor of violating its eight-foot standard rather than the regulatory requirement to provide a structurally sound containment, thus treating its guidance as if it were hard law. The Department’s regulatory requirement could properly have been informed by

⁶⁴ See, e.g., *Mistretta v. United States*, 488 U.S. 361, 416 (1989) (Scalia, J., dissenting); *Whitman v. Am. Trucking Ass’ns, Inc.*, 531 U.S. 457, 472–74 (2001).

⁶⁵ Kevin Stack, *Interpreting Regulations*, 111 MICH. L. REV. 355, 360–61 (2012).

⁶⁶ 514 U.S. 87, 101 (1995).

⁶⁷ *Id.*

⁶⁸ 82 F.3d 165, 167 (7th Cir. 1996).

⁶⁹ *Id.* at 167–68. Judge Posner’s concluding paragraph in his *Hocor* opinion notes that

The Department’s position might seem further undermined by the fact that it has used the notice and comment procedure to promulgate rules prescribing perimeter fences for dogs and monkeys. 9 C.F.R. §§ 3.6(c)(2)(ii), 3.77(f). Why it proceeded differently for dangerous animals is unexplained. But we attach no weight to the Department’s inconsistency, not only because it would be unwise to penalize the Department for having at least partially complied with the requirements of the Administrative Procedure Act, but also because there is nothing in the Act to forbid an agency to use the notice and comment procedure in cases in which it is not required to do so.

Id. at 171–72. Appropriately in the author’s judgment, *Shalala* suggests that the important consideration here is the extent of the agency’s overall effort. *Shalala*, 514 U.S. at 108. Dogs and monkeys are extensively bred commercially, and the court should have accepted the regulations’ lacunae for species much less commonly bred. From this perspective, the Department’s use of its guidance would have been acceptable, *if* it had used it as soft, and not hard, law. *Hocor*, 82 F.3d at 171–72.

the guidance, 5 U.S.C. § 552(a)(2), but it was an elementary error to rely on the guidance as if it stated a legal obligation.⁷⁰

The majority's reformulation of *Auer* in *Kisor* strongly suggests that future courts presented with an agency's interpretations of its own regulation, informed by *Perez*,⁷¹ will avoid any suggestion that the meaning of regulations, once adopted, is necessarily static,⁷² or that their own interpretation of regulations' meaning may be wholly independent of agency views. Rather, they will understand that the possibilities of interpretation are limned in the many ways the majority opinion outlines, and informed not only by the regulation's language, but also by the explanations given in its accompanying statement of basis and purpose.⁷³ That is, the agency's responsibilities and awareness of the universe of its governing law entitles it to the respect the Court has accorded administrative views over the whole course of its history⁷⁴—now encapsulated in the formulation Justice Jackson famously stated in *Skidmore v. Swift & Co.*;⁷⁵ and, finally, that the reasonableness and acceptability of the present interpretation is to be assessed in relation to the explanation the agency has contemporaneously given for having changed its view of the regulation's meaning and application.⁷⁶

C. The possibility of reviewing on the merits guidance documents not relied upon in a regulation or formal adjudicatory opinion

Given the requirement of “finality” for merits review of agency action, courts facing challenges to seriously intended guidance have often used “binding in practice” formulations to hold that its adoption had required notice and comment rulemaking. This passage from *Appalachian Power Co. v. Environmental Protection Agency*⁷⁷ (*Appalachian Power*) reflects reasoning often used:

If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes “binding.”⁷⁸

The understood implication is that notice and comment procedures are then required.

⁷⁰ Professor Gersen stresses this aspect in his illuminating discussion of *Hocror*. Jacob E. Gersen, *Legislative Rules Revisited*, 74 U. CHI. L. REV. 1705, 1719 (2007).

⁷¹ *Perez*, 135 U.S. 1199, 1206–07 (2015).

⁷² See Strauss, *Resegregating the Worlds of Statute and Common Law*, *supra* note 48, at 436–37; cf. Jeffrey A. Pojanowski, *Revisiting Seminole Rock*, 16 GEO. J.L. & PUB. POL'Y 87, 87–88 (2018).

⁷³ See Stack, *supra* note 65, at 355.

⁷⁴ Peter L. Strauss, *In Search of Skidmore*, 83 FORDHAM L. REV. 789, 789 (2014).

⁷⁵ 323 U.S. 134, 139–40 (1944).

⁷⁶ *Encino*, 136 S.Ct. 2117, 2125 (2016); cf. JERRY L. MASHAW, REASONED ADMINISTRATION AND DEMOCRATIC LEGITIMACY 71 (2018).

⁷⁷ 208 F.3d 1015, 1021 (D.C. Cir 2000); see also *supra* note 32 and accompanying text.

⁷⁸ *Appalachian Power*, 208 F.3d at 1021.

Yet in the context of Judge Randolph's opinion, this passage was merely dictum. In subsequent passages he properly found both that the EPA guidance at issue in the case had been final agency action⁷⁹—hence reviewable on its merits—and that because, on the merits, the guidance did not reflect a reasonable meaning of the regulation it purported to interpret, it was improper as an interpretive rule.⁸⁰ Finding, on the merits, that a regulation cannot support the interpretation given it is wholly appropriate and, as already indicated, insufficient agency effort when adopting the interpreted regulation might be one basis for such a finding. One can understand the quoted passage simply as a means of rejecting the EPA's boilerplate denial of finality,⁸¹ that had been prompted by earlier judicial holdings requiring notice and comment rulemaking in lieu of interpretive rules or general policy statements courts concluded were "binding in practice."

The difficulties arise when, unlike Judge Randolph, courts use the criteria he stated to support finding guidance documents *not* to be final but *nonetheless* "binding in practice," and then conclude that notice and comment rulemaking had been required, vacating the agency action without ever reaching the merits.⁸² The result is to discourage an agency's formulation of the internal administrative law to be found in Box C of the graphic above. To be sure, an agency that "treats the document in the same manner as it treats a legislative rule" clearly errs; soft law cannot be used as hard law.⁸³ Yet an agency acting "as if a document issued at headquarters is controlling in the field" is revealing its internal administrative law.⁸⁴ So too, is an agency that "bases enforcement actions on the policies or interpretations formulated in the document," or that indicates particular courses of conduct it has determined will satisfy a standard created by a regulation that intentionally defined parameters to be achieved, rather than the manner of achieving them, in order to permit the regulated to create their own means of satisfying the standards if so moved.⁸⁵

Having internal administrative law effective and known to all conduces to regularity and predictability in agency action, essential elements of the "rule of

⁷⁹ *Id.* at 1023.

The short of the matter is that the Guidance, insofar as relevant here, is final agency action, reflecting a settled agency position which has legal consequences both for State agencies administering their permit programs and for companies like those represented by petitioners who must obtain Title V permits in order to continue operating.

⁸⁰ *Id.* at 1028.

⁸¹ Anthony, *supra* note 8, at 1318.

⁸² *Appalachian Power*, 208 F.3d at 1021. One can identify a similar difficulty in Professor Franklin's account of *Appalachian Power*. See Franklin, *supra* note 12, at 302 (recognizing that Judge Randolph had indeed found the guidance document in that case to have been final, he fails to see this as opening the possibility of review on the *substantive* merits, as Judge Randolph did see it, and like others treats the quoted language as having been us as a test for required procedure rather than finality).

⁸³ *Appalachian Power*, 208 F.3d at 1021.

⁸⁴ *Id.* "An agency could properly hope that 'a document issued at headquarters [would be regarded by its staff as] controlling in the field'—that is perhaps the most important reason why guidance documents are issued." STRAUSS, ADMINISTRATIVE JUSTICE, *supra* note 10, at 354 (remarking that the Supreme Court has recognized this beneficial effect) (citing *United States v. Mead*, 533 U.S. 218 (2001)).

⁸⁵ *Appalachian Power*, 208 F.3d at 1021.

law.” Knowing an agency’s internal administrative law has great value to those it regulates, to those it is responsible to protect, and to both the public and the agency’s political overseers, Congress and President. Given their limited resources, agencies cannot be expected often to engage in notice and comment rulemaking to adopt their internal administrative law, and the APA is clear that they are not required to. Thus, the realistic alternatives to having seriously intended guidance documents is leaving discretion unstructured—permitting field agents to reach their own, varying and probably secret understandings of the agency’s regulatory requirements; enforcing those requirements for reasons that may be secret and unpredictable; and leaving the regulated on their own to find the means of complying with regulatory standards. All of these impacts reflect departures from the rule of law.

Is lack of finality in guidance documents, whether proclaimed by them or simply inferred as a characteristic of soft law, an insuperable obstacle to merits review? *Appalachian Power* properly discredited that claim in a context in which it was demonstrable that a soft law document represented a firm agency judgment having substantial impacts on the actions of the regulated and of state agencies. And that soft law measures *inherently* lack finality was famously repudiated in Judge Harold Leventhal’s decision in *National Automatic Laundry & Cleaning Council v. Schultz*.⁸⁶ Here, the Department of Labor’s bureau responsible for administration of the Fair Labor Standards Act, controlling employers’ obligations respecting working hours and overtime pay for certain classes of employees, had responded to a request for advice about the Act’s application with an opinion letter. The bureau wrote about 750,000 opinion letters annually, but fewer than 1.5% of them, including the one challenged, were issued over the Administrator’s signature.⁸⁷ That usage made the letter likely to be profoundly influential on employers’ conduct (i.e., binding in practice, but not binding as a matter of law), “presumptively final.”⁸⁸ The absence from the letter of any indication that the views it expressed were tentative persuaded Judge Leventhal that it was reviewable final action; addressing the merits, he upheld the agency’s action.⁸⁹

Professor Funk’s very recent scholarship⁹⁰ addresses the issues of finality in soft law guidance documents and, like my own,⁹¹ concludes that finding finality in soft law meeting Judge Randolph’s *Appalachian Power* tests, followed by review on the merits, is far preferable to the alternative too often used—denying finality in the guidance but, without reaching the merits, finding that notice and comment rulemaking had been required.⁹² The D.C. Circuit has regularly found an obstacle to “finality” in the second leg of a two-part test articulated in the Supreme Court’s

⁸⁶ 443 F.2d 689, 698 (D.C. Cir. 1971).

⁸⁷ *Id.* at 699–701. Similar considerations may underlie *Kisor* on remand. As Justice Kagan noted towards the end of her opinion, the regulatory interpretation in the case had been formulated by only one of the “100 or so members of the VA Board,” whose “roughly 80,000 annual decisions have no ‘precedential value.’” *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019).

⁸⁸ *Nat’l Automatic Laundry & Cleaning Council*, 443 F.2d at 701.

⁸⁹ *Id.* at 701, 707.

⁹⁰ Funk, *Final Agency Action After Hawkes*, *supra* note 2, at 285; Funk, *Make My Day! Dirty Harry and Final Agency Action*, *supra* note 2, at 317–25.

⁹¹ See *supra* note 10 and accompanying text.

⁹² See Funk, *Final Agency Action After Hawkes*, *supra* note 2, at 304–05.

decision in *Bennett v. Spear*,⁹³ that agency action must be both “the consummation of the agency’s decision-making process” and a decision by which “rights or obligations have been determined” or from which “legal consequences will flow.”⁹⁴ But as Professor Funk’s analysis⁹⁵ of the Supreme Court’s 2016 decision in *U.S. Army Corps of Engineers v. Hawkes*⁹⁶ persuasively shows, *Bennett*’s test is a sufficient, but not a necessary test of finality. The Corps judgment sought to be reviewed in *Hawkes* would, if favorable to him, have created a safe harbor from EPA enforcement under the Clean Water Act (CWA); denied, as it was in an informal proceeding, it signified only that if Hawkes pursued the course of action he wanted to, EPA might seek to enforce the CWA against it, in a proceeding in which the Act’s proper application would have been an issue. Treating the Corps’ “denial of the safe harbor” as final, the Court said, “tracks the ‘pragmatic’ approach we have long taken to finality.”⁹⁷ Government actions fitting Box C in the preceding graphic, then, as the culmination of an agency’s decision-making process, binding the government but not private parties, may be found to be “final.” In effect, Judge Leventhal’s approach in *National Automatic Laundry & Cleaning Council*⁹⁸ has been sustained.

An independent judicial inquiry into the finality of soft law—which, as has not been clearly seen, was in fact Judge Randolph’s approach—would greatly reduce the incentives agencies otherwise may have to hide or be disingenuous about their seriously intended soft law. The model for review is not far to find, in the well-established action for declaratory judgment that Justice Harlan drew upon in his opinion establishing the possibility of pre-enforcement review of agency regulations, *Abbott Laboratories v. Gardner*⁹⁹ (*Abbott Laboratories*). To be sure, the “finality” question was easily disposed of in *Abbott Laboratories*, since no one could doubt that promulgation of an agency regulation after notice and comment rulemaking, binding on the whole world, if valid, is “final.”¹⁰⁰ But, as *Encino* makes clear, guidance constituting internal administrative law—fitting Box C of the graphic above—is binding on and within the agency.¹⁰¹ That, indeed, is the essence of *National Automatic Laundry & Cleaning Council*; agency staff will take the decision to use the Administrator’s signature on a letter lacking any sign of tentativeness of opinion, as setting the terms by which they must respond to other inquiries raising the same question.¹⁰² Where guidance has a strong potential to structure agency behavior in ways that demonstrably fail to meet its regulatory obligations toward the public, or effectively compel serious and disadvantageous behavior by the regulated—the kind of showing that would warrant declaratory judgment in the context of pre-enforcement review of the validity of a statute or

⁹³ 520 U.S. 154, 177–78 (1997).

⁹⁴ See, e.g., *Ctr. for Auto Safety v. Nat’l Highway Traffic Safety Admin.*, 452 F.3d 798, 807–11 (D.C. Cir. 2006); *Nat’l Mining Ass’n v. McCarthy*, 758 F.3d 243, 250–51 (D.C. Cir. 2014).

⁹⁵ Funk, *Make My Day! Dirty Harry and Final Agency Action*, *supra* note 2, at 331.

⁹⁶ 136 S. Ct. 1807, 1813 (2016).

⁹⁷ *Id.* at 1815.

⁹⁸ 443 F.2d 689, 695 (D.C. Cir. 1971).

⁹⁹ 387 U.S. 136, 139, 156 (1967).

¹⁰⁰ *Id.* at 150.

¹⁰¹ See *Encino*, 136 S. Ct. 2117, 2124 (2016); see also Box C, *infra* Part III.

¹⁰² See *Nat’l Automatic Laundry & Cleaning Council*, 443 F.2d at 697.

regulation—judicial review of its substantive merits, if achievable, would be preferable to requiring procedures that the APA explicitly states giving influential (and valuable, desirable) public notice of agency interpretations and policies does not require.

As in *Abbott Laboratories*, and indeed as in the declaratory judgment model, permitting what amounts to pre-enforcement review of guidance leaves open the kinds of questions addressed by “ripeness.”¹⁰³ How severe is the threat to the regulated? Are alternative means available to resolve the merits issues? If, for example, staff has issued guidance indicating one view how a regulatory standard could be satisfied, have those who are subject to it a realistic opportunity to demonstrate alternative means of doing so? But if in fact the requisites for declaratory judgment are satisfied, then the merits of the action found to have been “binding in practice” can be reached, and procedural requirements indifferent to the merits will have been avoided.¹⁰⁴

One of the signal advantages of pre-enforcement review is that it permits review by regulatory beneficiaries claiming that the agency has erred in failing adequately to protect their interest. Consider, for example, the sharply criticized¹⁰⁵ D.C. Circuit opinion in *Community Nutrition Institute v. Young*,¹⁰⁶ that found notice and comment rulemaking required for enforcement guidance the FDA had issued to its staff, setting a concentration level of aflatoxin in shipped grain that should lead them to seize the shipment. Aflatoxin is a naturally occurring carcinogen inevitably present to some degree in dried grain; like many such substances, no absolutely safe level of presence is known, but its health effects vary with concentration and at very slight levels those costs are overcome by the benefits of having a supply of grain. The Community Nutrition Institute (CNI) thought the declared level was too high, excessively threatening human health—and perhaps also that having a level declared would encourage shippers to mix the bad with the good, to create a level of contamination FDA inspectors would tolerate. Ordinarily, one might think, review of agency enforcement choices would be precluded;¹⁰⁷ and one might also believe public administration the better, not the worse, for letting both the regulated and the public health community know what levels of an unavoidable carcinogen constituent of grain the FDA had told its staff warranted regulatory action. For the D.C. Circuit, this guidance, “binding in practice” given its impact on staff actions, required notice and comment rulemaking. FDA could publicly give its staff this guidance only at that significant cost.¹⁰⁸ How much better it would have been to

¹⁰³ *Abbott Laboratories*, 387 U.S. at 148.

¹⁰⁴ *Nat'l Park Hosp. Ass'n v. Dep't of the Interior*, 538 U.S. 803 (2003).

¹⁰⁵ See Richard M. Thomas, *Prosecutorial Discretion and Agency Self-Regulation: CNI v. Young and the Aflatoxin Dance*, 44 ADMIN. L. REV. 131, 132 (1992) (illustrating the “tension between two conflicting administrative law paradigms”).

¹⁰⁶ *Cnty. Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987).

¹⁰⁷ *Heckler v. Chaney*, 470 U.S. 821, 837 (1985).

¹⁰⁸ In a concurrence and partial dissent, Judge Kenneth Starr made what many see as the first statement of Professor Funk's (and others') argument that the agency procedural choice controls the force its pronouncement may legally be given in other proceedings. According to Judge Starr, “the correct measure of a pronouncement's force in subsequent proceedings is a practical one: must the agency merely show that the pronouncement has been violated or must the agency, if its hand is called, show that the pronouncement itself is justified in light of the underlying statute and the facts.” *Id.* at 952.

treat its character as internal administrative law as sufficient to make the action “final,” permitting merits review if declaratory judgment standards had been met—as for CNI one could believe they had been.¹⁰⁹

This is also applicable to the enforcement directions involved in the challenge to the Department of Homeland Security’s guidance respecting the treatment of illegally present immigrants whose lengthy presence in the United States had otherwise been innocent, challenged by Texas in *Texas v. United States*.¹¹⁰ The lower courts found notice and comment rulemaking to have been required, a result affirmed without opinion by an equally divided Supreme Court. Standing was no issue for Texas, and the circumstances readily met the *Abbott Laboratories* declaratory judgment standards of ripeness. Clearly the program amounted to internal administrative law—and if it had been accepted as “final” for that reason, the merits could have been reached on judicial review, without casting unwarranted procedural doubt on an important tool of administrative action, explicitly recognized in the APA.

Meeting those standards is easier when the regulated have complaints about guidance documents that put them directly in the path of enforcement actions. *Alaska Professional Hunters’ Ass’n v. Federal Aviation Administration*¹¹¹ was a case perhaps involving the “one bite” doctrine disapproved in *Perez*. Under interpretations given by the local Federal Aviation Administration (FAA) office, Alaskan bush pilots had for years been free of FAA regulations applicable to commercial flights. FAA’s central office, after considerable discussion with those affected (in effect, a kind of informal notice and comment procedure not unlike the FDA’s Good Guidance practices), concluded that the regulations (that needed no change in their terms to be so interpreted) did apply. Undoubtedly this constituted internal administrative law, and was final in that perspective; the bush pilots might then have had judicial review of the merits of the change, as in *Encino*. Notice, too, that here FAA’s central Washington office was correcting what it had determined, after consultation with those affected, to have been an error of judgment in the field; to have required notice and comment procedures to do so amounted to finding a measure of estoppel created by subordinates’ judgments, a result generally avoided.¹¹² *Hocor* presented similar problems; Hocor was advised by a local Department of Agriculture official that a 6-foot fence would suffice to meet the Department’s rule about structural integrity for his large cat “farm” (doubtless,

¹⁰⁹ Franklin, *supra* note 12, at 310–11. Treating the guidance as final would have permitted CNI to put the reasonableness of the twenty-parts-per-billion enforcement guidance to the test on pre-enforcement review, and as Professor Franklin remarks, Judge Starr failed to see this consequence, reasoning only that a shipper against whom the FDA had brought an enforcement action could do so. *Id.* at 309.

¹¹⁰ 809 F.3d 134, 149 (5th Cir. 2015), *aff’d*, 136 S. Ct. 2271 (2016).

¹¹¹ 177 F.3d 1030 (D.C. Cir. 1999).

¹¹² See *Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 383–85 (1947) (denying plaintiff’s claim for recovery from the government because the regulations were binding, even though they were ignorant of the regulations partially due to a local federal agent who led them to reasonably believe their crop was insured); see also *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 419–20, 434 (1990) (stating that erroneous advice given by a government employee to a benefits claimant cannot stop the government from denying benefits not otherwise permitted by law, especially because payments of money from the Federal Treasury are limited to authorization by statute).

in the circumstances, more a protection for local livestock and children outside the fencing than for animals within it).¹¹³ The 8-foot guidance from Washington, then, impugned that advice; one would not ordinarily think the Department estopped in his case, albeit it was not entitled to treat “8 feet” rather than “structural integrity” as defining the issue on actual enforcement.

Consider also *U.S. Chamber of Commerce v. Department of Labor*.¹¹⁴ There, the D.C. Circuit found notice and comment rulemaking required for the Department’s announcement of a program addressed to a significant number of employers having demonstrably hazardous workplaces. Any of these employers who agreed to cooperate with safety guidance provided to them, could be assured of freedom from rigorous Occupational Safety and Health Administration (OSHA) inspections and significant administrative fines absent some unusual reason (say, an accident in which regulatory violations led to a worker’s death). OSHA, notoriously lacking in enforcement resources adequate to its statutory enforcement tasks, could not credibly threaten thorough inspections of all. But if many of the identified employers elected to participate in the program, the consequence could be enhanced workplace safety for their employees—and more certain inspections and enforcement actions for those who did not rise to this bait. The state of Maine’s OSHA had earlier adopted such a program, reaching out to the state’s 200 most hazardous workplaces; 198 of them subscribed, and the consequences were a dramatically reduced accident rate, a more cooperative regulatory endeavor, and much more efficient and effective use of the agency’s enforcement resources, where that was required. OSHA anticipated similar participation levels and benefits from nationalizing this approach. Perhaps the Chamber of Commerce, on behalf of its supporters, wished to avoid the expense of recommended safety practices to some of its members and a more efficient and effective use of OSHA’s enforcement resources against those not participating. The D.C. Circuit, finding the guidance announcing this program coercively “binding in practice,” concluded that notice and comment rulemaking would be required to adopt it. If coercive, then declaratory judgment standards were satisfied; nor could it be doubted that, from an internal administrative law perspective, this action was final. Had the court reached the merits, given both the force of the Maine experience and OSHA’s responsibility to promote workplace safety, it is hard to imagine the program to have been found wanting.

Finally, consider in this light a pair of D.C. Circuit opinions, *General Electric Co. v. Environmental Protection Agency (General Electric)* and *Center for Auto Safety v. National Highway Traffic Safety Administration (NHTSA)*. In seeming tension with one another, they can animate an administrative law casebook.¹¹⁵ In the first, EPA developed detailed regulations for remedying contamination by polychlorinated biphenyls (PCBs), a potent carcinogen widely used before discovery of its toxicity; its manufacture in the United States is now forbidden, and

¹¹³ *Hoctor*, 82 F.3d 165, 168 (7th Cir. 1996).

¹¹⁴ 174 F.3d 206 (1999).

¹¹⁵ *E.g.*, PETER L. STRAUSS ET AL., *GELLHORN & BYSE’S ADMINISTRATIVE LAW CASES AND COMMENTS* 365–71 (12th ed. 2018).

its continued use is heavily regulated by the Toxic Substances Control Act.¹¹⁶ The extensiveness of PCB use, for example in capacitors and electric power transformers, has made contamination of buildings, soil and water common,¹¹⁷ and the regulations, in general, prescribed acceptable methods for cleanup and disposal both of PCB bulk product waste,¹¹⁸ and PCB remediation waste.¹¹⁹ General Electric's (GE) extensive use of PCBs in its manufacturing processes and consequent disposal of them as waste had resulted in extensive contamination of the Hudson¹²⁰ and Housatonic¹²¹ Rivers, creating expensive clean-up obligations and actions that endured long past this litigation.¹²² For GE (and other large industrial users), it could be anticipated that the generic methods prescribed by the regulations would be unsatisfactory, and so a separate section invited applications to use different methods that would demonstrably avoid "unreasonable risk of injury to health or the environment."¹²³ Taken as a whole, note, this approach fully reflected the now-conventional preference for setting standards permitting alternative means of compliance that could be demonstrated to meet them over precise specification of a required course of action. EPA then published an extensive guidance document indicating its views how such a showing could be made, and alternative measures that in its judgment would permit granting such an application.¹²⁴ This was unquestionably a final agency action, in the sense that the Agency had bound itself to accept the showings its guidance indicated; GE did not attempt an application, but challenged the guidance as being "binding in practice." That the Agency had indicated acceptable means of compliance, and bound itself to accept a demonstration that they had been met, the court held without fully reaching the merits, required notice and comment rulemaking. Confronting final action, why could the merits not be reached?

In *Center for Auto Safety*, NHTSA had issued policy guidelines indicating when it would accept regional recalls for manufacturing defects where the issues prompting the recalls were most likely to be presented in some but not all parts of the United States.¹²⁵ Examples might be corrosion defects unlikely to occur in

¹¹⁶ *Gen. Elec. Co. v. U.S. Env'tl. Prot. Agency*, 53 F.3d 1324, 1326 (D.C. Cir. 1995); 15 U.S.C. §§ 2601–2692 (2012).

¹¹⁷ *Learn About Polychlorinated Biphenyls*, U.S. ENVTL. PROTECTION AGENCY, <https://perma.cc/RDP6-E3ZU> (last visited July 13, 2019); Heidelore Fiedler, *Global and Local Disposition of PCBs*, in *PCBs: RECENT ADVANCES IN ENVIRONMENTAL TOXICOLOGY AND HEALTH EFFECTS* 11 (Larry W. Robertson & Larry G. Hansen eds., 2001).

¹¹⁸ 40 C.F.R. § 761.62 (2018).

¹¹⁹ *Id.* § 761.61.

¹²⁰ *Hudson River PCBs Superfund Site Hudson River Cleanup*, U.S. ENVTL. PROTECTION AGENCY, <https://perma.cc/M7J4-YJ2D> (last visited July 13, 2019); *Hudson River PCBs Site New York Record of Decision* 1–3, U.S. ENVTL. PROTECTION AGENCY, <https://perma.cc/B44E-ZL6M> (last visited July 13, 2019).

¹²¹ *Cleaning up the Housatonic: Why Cleanup the GE Site and the Housatonic River?*, U.S. ENVTL. PROT. AGENCY, <https://perma.cc/YM33-L5BY> (last visited July 13, 2019).

¹²² *See, e.g.*, Lauren Stanforth, *Decades of Contamination at General Electric's Main Plant*, ALBANY TIMES UNION (Jul. 7, 2016), <https://perma.cc/P9MV-2HG9>; Jesse McKinley, *G.E. Spent Years Cleaning Up the Hudson. Was It Enough?*, N.Y. TIMES (Sep. 8, 2016), <https://perma.cc/DGK5-9EN8>.

¹²³ 40 C.F.R. § 761.60(e) (2018).

¹²⁴ *General Electric*, 290 F.3d 377, 379 (D.C. Cir. 2002).

¹²⁵ *Ctr. for Auto. Safety*, 452 F.3d 798, 800 (D.C. Cir. 2006).

states not using road salt to de-ice roads during winter weather, or in states where sustained high humidity encouraging corrosion would not be present. Its administrators encouraged automakers to comply with the guidelines and brought no enforcement actions requiring wider recalls if they had been followed.¹²⁶ The Center challenged the guidelines as having to be adopted by notice and comment rulemaking.¹²⁷ Reasoning from *Bennett*, the court concluded that while the guidelines did mark the end of the agency's decision-making process, they neither determined rights or obligations nor resulted in legal consequences. This led to a holding that the guidelines were not final and for that reason review of them could not be had.¹²⁸ But in this case too, as Professor Funk's *Final Agency Action After Hawkes*¹²⁹ strongly suggests, the high level and importance of the agency's action should have permitted the conclusion that it *was* final. There would perhaps remain questions about the Center's standing and the ripeness of its claims—but if satisfactorily answered, the result would be a judgment on the merits, not procedural requisites.¹³⁰

The two cases, then, reflect a binary judicial approach in which, if review is available, it is only available to determine what procedures were requisite. There is no review at all for guidance that is not "binding in practice," and required procedural rigor if it is. The consequence, again, is to invite the boilerplate EPA used in *Appalachian Power*, that either rewards agency disingenuousness or results in procedural requirements the APA denies. Judge Leventhal's approach, apparently sustained in *Hawkes*, would treat demonstrably serious, high-level guidance as final because of its effects on agency function. And that would then permit merits judgments in cases suitable for declaratory judgment—aka "ripeness." Such an outcome would validate the APA's acceptance of published guidance as permissibly influential on private conduct, and it would avoid discouraging the use of an administrative technique valuable for its contribution to agency regularity and predictability, and to public knowledge of its policies.

Were this done, agencies might find in the outcome a reason to invite the public participation in guidance formulation already instinct in FDA Good Guidance practices, OIRA oversight of significant guidance, Administrative Conference of the United States (ACUS) recommendations, and thoughtful writing about it.¹³¹ *Hocot*'s eight-foot fence, *CNI*'s 20 parts per billion threshold for aflatoxin contamination, and EPA's definitions of alternative toxicity factors for PCB contamination all set possibly arbitrary cut-off lines between the tolerable and the intolerable—the kinds of lines legislatures set by votes and courts are incapable of themselves providing,¹³² relying instead upon demonstrated agency expertise and rationalization to sustain. Each of these lines, note, could be complained of from

¹²⁶ See *id.* at 809.

¹²⁷ *Id.* at 804.

¹²⁸ *Id.* at 800.

¹²⁹ Funk, *Final Agency Action After Hawkes*, *supra* note 2.

¹³⁰ See generally *Ctr. for Auto Safety*, 452 F.3d at 798–811.

¹³¹ *E.g.*, Sunstein, *supra* note 11, at 498–99, 515–16; Franklin, *supra* note 12, at 294–95. Neither author, however, associates the possibility of pre-enforcement review with merits review, as this Essay attempts.

¹³² *Cf.* Gersen, *supra* note 70, at 1715; *Am. Trucking Ass'ns.*, 175 F.3d 1027, 1034, 1035–36 (D.C. Cir. 1999), *rev'd sub nom.*, *Whitman*, 531 U.S. 457, 486 (2001).

either side—area residents might think 8 feet too low to protect their children; shippers, 20 parts per billion too high to permit shipments of healthy, nutritious grains; residents of Pittsfield, Massachusetts, the permissible toxicity factors too generous to protect their health. Given finality and pre-enforcement review, agencies would understand they might need to defend those judgments on their merits from either side—encouraging, at the least, the development of supporting internal data-bases and explanations based upon them (as well as the necessary willingness to consider alternative showings in the event of resisted enforcement). Where the stakes are high enough, consultation with those affected is to be expected, and one’s sense is that, as in *Alaska Professional Hunters’ Ass’n*¹³³ and as since urged by the White House and ACUS, it often occurs. And the agency that has set such levels without using the APA’s procedures to do so, absent a clear explanation of its basis for doing so grounded in the information it possesses, might find itself facing an appropriately high level of judicial skepticism.¹³⁴

What ought not be faced, however, absent the actual legal effect that can be associated only with regulations, is a demand for notice and comment procedures. “There is a reasonable . . . argument that the balance of considerations usually argues in favor of allowing a period for notice-and-comment, certainly for significant guidance documents. But as a matter of law, things are much more straightforward. The practically binding test is an unacceptable departure from any plausible reading of the APA.”¹³⁵

¹³³ *Alaska Prof’l Hunters’ Ass’n*, 177 F.3d 1030, 1032, 1036 (D.C. Cir. 1999).

¹³⁴ Consider the impact of the failure to make and explain findings in the highly informal administrative processes involved in *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 420–21 (1971), a 27-day trial on remand, testing the basis for the decision under review.

¹³⁵ Sunstein, *supra* note 11, at 516.

