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# THE ROLE OF GUIDANCES IN MODERN ADMINISTRATIVE PROCEDURE: THE CASE FOR *DE NOVO* REVIEW

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Richard A. Epstein\*

## ABSTRACT

This article examines the rise of the administrative guidance under the APA. Guidances supply information so private parties can organize their behavior in accordance with law, but also allow agencies, without notice and comment, to indiscriminately expand their power. Separating useful from dangerous guidances requires allowing review of all guidances *de novo* as questions of law, without *Chevron* and *Skidmore* deference, by any interested party, even for nonfinal agency actions. Private selection effects will limit challenges to dangerous guidances without undermining those guidances that reduce uncertainty without improperly expanding the scope of agency power.

The purpose of this article is to analyze the role that various guidance statements have played in the modern law of administrative procedure. In one sense this inquiry is an odd one, because the canonical statute of administrative law, the Administrative Procedure Act of 1946 (APA), 5 U.S.C. § 500 et seq, does not use the term “guidance” at all. Historically, the phrase only worked its way into administrative law in the mid-1990s, about 50 years after the passage of the APA

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I would also like to give an all-purpose thanks to Gary Lawson. When I last taught administrative law I used his casebook, *Federal Administrative Law* (5th Edition), which contains a powerful and straight-forward narrative on the evolution of administrative law, on which I have relied heavily throughout this article.

(Rakoff 2000, p. 159).<sup>1</sup> The first full blown administrative account of the term “guidance” came as late as 1997, when the Food and Drug Administration published its report “Development, Issuance, and Use of Guidance Documents,” 62 Federal Register 8961-01 (February 27, 1997). Major developments of this sort do not happen by chance, but are often responses to powerful changes in the larger legal environment. In this article, I trace the legal and political developments that account for these changes in the day-to-day practice of administrative law, and offer an evaluation of the benefits and disadvantages of the guidance system. The conclusion is that, contrary to current law, private parties should be allowed to bring *de novo* facial challenges to any major published guidance.

The basic argument runs as follows. Guidances in one form or another are here to stay. Administrative law determines how “organic” statutes (which set out the relevant substantive statutory scheme) actually distribute power to public officials and impose obligations on the ground. But the very complexity of the substantive commands of most modern regulatory schemes requires the creation of an intermediate system to complete the governance cycle from government command to private compliance. That intermediate function necessarily falls to government officials, who sometimes respond in formal ways and other times in informal ones. No one can force all of the needed information into formal rules, so guidances necessarily arise to fill the gaps. It is precisely here that their good and bad features become evident. On the positive side, the guidance can reduce uncertainty and offer those parties subject to the regulatory regime—ordinary individuals, private firms, and state and local governments—safe harbor for compliance. It can also smooth out inconsistencies in administration that are likely to crop up in any agency that runs separate field offices spread out across the country (Seidenfeld 2011, pp. 341–342).

On the negative side, however, the guidance can become a device through which aggressive public officials, with little or no industry consultation, push the envelope on the law beyond that which the statute, or indeed the regulations under the statute, requires. It is difficult for any private party to resist compliance with guidances, even when the guidances go beyond the language or the intention of the statute, or both. Put bluntly, it is time to update Chief Justice John Marshall’s maxim from *McCulloch v. Maryland*, “The power to tax is the power to destroy,” so that it now also reads: The power to promulgate guidances is the power to destroy. *McCulloch v. Maryland*, 17 U.S. 316, 431 (1819).

To my mind, the only way to respond to this risk is to allow all affected parties to lodge facial challenges to these guidances under a standard of *de novo*

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1 For an earlier critique of the practice, see Anthony (1992, p. 1311) (harshly critical of the practice).

review for all questions of law, so that they are not required to risk extensive investigations and major fines as the price of continuing their private activities.<sup>2</sup> Guidances traverse the same terrain as major regulations, which are often required to undergo the notice and comment process. Guidances should not be allowed to fly unexamined below the judicial radar simply because they are consciously put in inchoate form. The needed counterweight to this state of affairs is standing to challenge the government action before the harm sets in.

Unfortunately, two elements prevent that result today, both of which I recommend eliminating. First, no facial challenge is possible so long as the current standing rules are read, wrongly in my view, to require some discrete or pocketbook injury. Second, guidances are not currently treated as final agency actions under section 704, which are subject to immediate appeal.<sup>3</sup> There is no question that my proposed changes will require a profound reorientation of the received wisdom of administrative law, which in general allows for pre-enforcement review only in the case of duly promulgated regulations. *See, e.g., Abbott Labs. v. Gardner*, 387 U.S. 136 (1967). A powerful selection process will be at work in this idealized system. Those guidances that pose no threat will not be challenged. Those that do will be challenged. The prospect of that challenge will in turn lead government agencies to rein in their ambitions, which should therefore improve the practice of governance from top to bottom.

It is useful at the outset to note that this rejection of the standard practices of the modern administrative state addresses in emphatic terms an uneasiness felt by many full-time administrative law scholars regarding the level of discretion that is given to these guidances, or as they are often called “nonlegislative rules.”<sup>4</sup> (Terminologically, it is generally far easier to reason through use of the two classes of administrative actions—interpretative rules and policy statements—than it is from a negative term that has no explicit content at all.) Regardless of the labeling, I think that it is a mistake to try to salvage a

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2 That standard of review need not apply to the usual set of minor questions, including evidentiary determinations, which are now reviewed under an abuse of discretion standard that I have no desire to challenge here, and will not discuss further. *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136 (1997) (using an abuse of discretion standard under the Federal Rules of Evidence to determine admissibility of expert testimony).

3 However, the government does not choose to phrase it as such. APA, 5 U. S. C. § 704 (“Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration [*see* n. 1, *supra*], or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.”).

4 For some notable contributions to the literature, *see* Franklin (2010, pp. 324–25); Funk (2001, p. 1325); Gersen (2007, p. 1719); Manning (2004, p. 893); Raso (2010, p. 782); Seidenfeld (2011, pp. 341–422); Elliott (1992, p. 1491).

coherent account of administrative law by working within the current framework that celebrates judicial deference to administrative decisions on questions of law under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). While there are also serious difficulties with regard to the “hard look” doctrine for reviewing questions of fact, this issue is outside the scope of this article.<sup>5</sup>

In my view, it is only possible to attack the guidance question by first looking to the larger statutory framework of which it is a part. Accordingly, it is important first to understand why the APA created a high degree of formality for its various procedures. The shift to guidances was a move by agencies that had received substantial judicial blessing to evade the ever greater formalities engrafted onto the various procedures that were mentioned in the APA. The latest iteration of the administrative state now says: we, the agency, ignore all the requirements for the official proceedings under the Act, be it by formal rulemaking, notice and comment proceedings, or interpretative rules, and you, the regulated party, know that these announcements are for informational purposes only and are not binding on either the agency or its regulated parties. The softening of the legal force of guidances was said to function as the quid pro quo for the want of any formal process. But it is a most unequal exchange. As noted above, in all too many cases, the velvet glove conceals an iron fist that could allow an aggressive agency to get its way even when both basic constitutional guarantees and statutory provisions cut the other way.

By virtue of removing all external constraints, the guidances push the law along a more interventionist course than it would, and should, otherwise take. The irony is that by stacking the formal procedures with so many “protective” obstacles, agencies have resorted to guidances to gain more discretion than they had under the original design of the APA. This critique depends not on any particular vision of the substantive law, but rather argues primarily that the aggressive use of guidances compromises the standard rule of law values of fair notice, impartiality, consistency, clarity, neutrality, and prospectivity.<sup>6</sup> The institutional risk is that the broad contours of basic statutory commands that speak of “public interest, convenience and necessity,” or “undue hardship”

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5 *Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), which calls for a hard look doctrine, unduly restricts the discretion of administrative agencies on disputed questions of fact. In effect, modern administrative law gets it backwards: hard look on facts, and deference on law, when the reverse is needed. See Epstein (2011, pp. 159–163).

6 These values have their greatest attraction precisely because they are not formally tethered to any particular vision of the substantive law, even if they tend to work better, as I have argued elsewhere, in connection within a classical liberal system that stresses strong property and contract rights within a framework of limited government. See generally Epstein (2014).

versus “reasonable accommodations” invite rapid expansion by administrators who tilt to one side of the ideological spectrum or the other. This vice can occur not only in areas where the case for government regulation is questionable (e.g., price controls) but also in those areas where some form of government regulation is necessary (e.g., drugs and pollution), given the difficulties that markets have in dealing with network industries, pollution externalities, and intellectual property.

In order to see how this process unfolds, Section 1 traces the rise of administrative guidances and Section 2 discusses guidances in the modern era. Section 1 first delves into the historical evolution that turned the modest requirements of the APA as drafted into an onerous code that imposes heavy burdens on any administrative agency that wants to operate either by rule or adjudication. In my own view, these transformations were wrong as a matter of statutory construction, and, more to the point, their hydraulic force created an incentive for agencies to avoid the whole system by relying heavily on the guidance mechanism over which the APA places no controls. Next, it examines the evolution of the key devices that are used to deal with administrative rules—the formal hearing and the notice and comment proceeding. Finally, Section 1 discusses the role of interpretive rules and policy statements, and critiques the level of deference on matters of statutory interpretation that is afforded to administrative agencies under the protean decision in *Chevron*.

Section 2 illustrates the impact of modern guidances in areas such as drug regulation and civil rights, and then conducts a closer examination of the rules that govern guidances today. The point here is to show that it is a mistake to think of binding and nonbinding as dichotomous categories with little or no overlap. In many cases the guidances in question have powerful implications for internal governance within an agency, which thus ensures that it acts with a uniform face to the external world. The implicit threat of sanctions in the case of noncompliance is never far from the surface, for even though the guidance may be pulled at will, the *probability* of that happening is often quite low, as these guidances have, with at most modest modifications, useful lives of many years.

Section 3 then takes a closer look at the standing and ripeness issues. The first of these is often tied to the constitutional requirements of a case or controversy under Article III, and thus applies to all sorts of government actions, not just guidances. The finality requirement under the APA is more narrowly focused on administrative actions in which the veiled threat remains strong even if the government may in principle change its view at any time. The difficulties here are often similar to that associated with preliminary notices that precede enforcement actions, which often share the same coercive effect. This section explores the close relationship between these two forms of government action

in urging that *de novo* review of these various orders need not await the issuance of the final regulation or the initiation of an enforcement action.

## 1. THE RISE OF ADMINISTRATIVE GUIDANCES

### 1.1. History

In order to understand why a method of cabining administrative guidances makes sense, it is necessary to go over in some detail the elaborate administrative system that was adopted in the aftermath of World War II, within which these modern developments took place. That APA structure was articulated as a quasi-constitutional framework that harmonized the far-reaching legal changes needed to implement the vastly larger federal government authorized by the New Deal's constitutional revolution in the October 1936 Supreme Court term. Those now distant decisions in 1937 vastly expanded the power of the federal government. More concretely, they removed the last major obstacles that stood in the path of massive federal regulatory power over the economy, namely, the protection of economic liberties, the limitations on the federal commerce power, and the constraints of the nondelegation doctrine as it applied to administrative agencies.<sup>7</sup> In dealing with the technical issues under the APA, this bigger picture is not directly relevant, so I will not revisit those battles to express yet again my uneasiness with the eclipse of these doctrines.<sup>8</sup>

What is important is the legislative reaction to these changes. Congress and the courts struggled to find the proper response to the vast new powers that had been granted in the first instance on the federal government, but also (as is sometimes forgotten) on the states when the federal government had ceded them authority over a particular field.

The reform venture was sidelined during the Second World War, but it gained new urgency, especially in labor law, when the huge "strike wave" broke out in American industry.<sup>9</sup> The chaotic conditions led among other things to the passage of both the APA in 1946, which was signed by President Harry Truman, and the Taft-Hartley Act of 1947, which was enacted over his veto, after the Republicans took control of both Houses of Congress in the 1946 elections. The APA is best understood as the consolidation and

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7 With respect to the economic liberties, *see, e.g., West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937) (upholding minimum wage law for women). On commerce power, *see, e.g., Wickard v. Filburn*, 317 U.S. 111 (1942); *United States v. Darby*, 312 U.S. 100 (1941); *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1 (1937). On delegation, *see, e.g., Yakus v. United States*, 321 U.S. 414 (1944).

8 For that discussion, *see* Epstein (2006).

9 For the numbers, *see Strike Wave of 1945–1946*, WIKIPEDIA, [http://en.wikipedia.org/wiki/Strike\\_wave\\_of\\_1945-1946](http://en.wikipedia.org/wiki/Strike_wave_of_1945-1946).

rationalization of the administrative state, not as its repudiation. The initial intellectual impetus of the APA was James Landis, who wrote the immensely influential book *The Administrative Process* in 1938.<sup>10</sup>

## 1.2 The Structure of the APA

The APA governs how administrative agencies propose and establish regulations. The primary processes discussed are formal hearings on the record and notice and comment proceedings.

### 1.2.1. Formal Hearings on the Record

Under the APA, the first and most complex system of review involves “formal” or “on the record” determinations that seek to incorporate into the administrative framework the formal procedures often associated with complex litigation, such as the class action rules that were only fully developed in the 1966 revisions to the Federal Rules of Civil Procedure (*see* Rule 23). These formal hearings cover both rulemaking determinations (APA section 553) and adjudications—a line that proves difficult to maintain in many situations, but which does not loom large in this discussion since general guidances are intended to short-circuit case-by-case adjudication.<sup>11</sup> A rule, roughly speaking, is intended to articulate general principles that guide future decisions, while adjudication is intended to resolve particular disputes, leading to some administrative sanction that either requires or prohibits some person from doing something. As the APA states:

“[R]ule” means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency. . . . (APA section 551(4)).

During the course of a formal hearing on the record, all of the parties who appear before the agency will have the power to present evidence and to engage in cross-examination, much as in a full-fledged trial, which is why these cases are sometimes called “trial-type proceedings.” Typically, they are presided over

10 His book set out the template for the administrative procedure just after the consolidation of the administrative state. It is no accident that the Federal Rules of Civil Procedure, which did the same thing for litigation, was published in the same year, both published as modest reform activities. In time, Landis became disenchanted with the direction of administrative law and came to stress the importance of personnel relative to doctrine. For a discussion of his evolution see Koch (1996, pp. 431–32).

11 APA § 554 sets out special rules for adjudication.

by an administrative officer who allows the parties to present or conduct cross-examination. These proceedings are often marked by liberal rules of admissibility of evidence. In effect, all parties involved in these proceedings generally have a right to some kind of hearing. It takes little imagination to see how these cumbersome and time-consuming procedures have little significance in the fast-paced and complex operation of the modern law. They tend to be systematically avoided unless some explicit statutory requirement outside the APA requires their adoption, one that is often imposed in ratemaking cases where what is at issue is the rates of a single public utility, where only a few outsiders generally participate in the hearings.<sup>12</sup>

### 1.2.2 Notice and Comment Proceedings

Far more common are APA notice and comment proceedings. Under the basic statutory framework, the agency posts under section 553(b) a “general notice” of the proposed rulemaking in a prominent place, and then seeks private parties to comment on it. The statutory requirements are contained in two short paragraphs:

Section 553(b) The notice shall include -

- (1) a statement of the time, place, and nature of public rule making proceedings;
- (2) reference to the legal authority under which the rule is proposed; and
- (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose.

There is no requirement of a formal hearing, oral testimony or cross-examination. To examine the three requirements of section 553(b) in a historical void is to think that the formalities involved are relatively modest and straightforward. The statement of the time, place and nature of a public rule proceeding could often take just a short paragraph to state; “this proceeding is to set standards for fire suppression in nuclear power plants” seems to suffice.

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12 For a case denying that a statutory requirement for “a hearing” does not, without more, include an “on the record” hearing, see *United States v. Florida E. Coast Ry. Co.*, 410 U.S. 224 (1973), a dubious decision that takes the term “hearing” and excludes any requirement that the parties be heard, which seems to preclude a simple notice and comment proceeding.

The reference to legal authority looks as though one need only state the statute under which the proceedings take place, and the last requirement, which allows for one of three ways to attack the subject matter, also seems relatively forgiving. The option to give “either the terms or the substance”—note the “or”—of the proposed rule looks as though the emphasis is upon getting the basic ideas out. The option to use a “description of the subject and issues involved” is again stated in very broad terms. The entire section begins with the words “general notice,” so it seems quite unlikely that any level of specificity was required to set this process in motion, and the conclusion found in section 553(c) that the agency “shall incorporate in the rules adopted a concise general statement of their basis and purpose” only reinforces the notion that the agency does not have to reveal every zig and zag along the path of rule formation.

This plain-meaning rendering also animated the original understandings inside the Justice Department’s 1947 *Manual on the Administrative Procedure Act*, which announced a general policy, written in a highly permissive fashion.<sup>13</sup> The question of statutory construction here is not difficult, so long as the construer does not have a rooting interest in the outcome. The basic point is that the 1947 Guidelines gave agencies a lot of discretion on how they publicize their actions and evaluate the information that they receive. It is telling that while the agency has to consider all the evidence that the public presents, it may do so in a pro forma way, so long as it announces that it has done just that. In addition, it is equally clear that the agency can make its decision on information that it already has in its own files or acquires thereafter, even if that information

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13 See Attorney General’s Manual on the Administrative Procedure Act (1947):

Under section 4(b) each agency . . . may conduct its rule making by affording interested persons opportunity to submit written data only, or by receiving a combination of written and oral evidence, or by adopting any other method it finds most appropriate for public participation in the rule making process. . . (*id.* at § 4(a)).

Either the terms or substance of the proposed rule or a description of the subjects and issues involved.”

Where able to do so, an agency may state the proposed rule itself or the substance of the rule in the notice required by section 4(a). On the other hand, the agency, if it desires, may issue a more general “description of the subjects and issues involved” (*id.*). It is suggested that each agency consider the desirability of using the latter method if publication of a proposed rule in full would unduly burden the Federal Register or would in fact be less informative to the public. . . .

Each agency is affirmatively required to consider “all relevant matter presented” in the proceeding; it is recommended that all rules issued after such informal proceedings be accompanied by an express recital that such material has been considered. It is entirely clear, however, that section 4(b) does not require the formulation of rules upon the exclusive basis of any “record” made in informal rule making proceedings (*id.*).

is unknown to the public. It is less than clear whether the agency has to disclose the basis of its decision at the time that it issues its rule. The emphasis here is on a fluid procedure to expedite matters, not to facilitate a probing form of judicial review of what has transpired within the agency. As a matter of first principle, it is easy to conclude that these APA requirements give a bit too much play to agency discretion.

Yet this approach was typical for the time. By way of analogy, it is instructive to look to the approach for presenting a case found in the Federal Rules of Civil Procedure. First, Rule 8 talks about “a short and plain statement of the claim showing that the pleader is entitled to relief,” which is then illustrated by a compendium of short and simple complaints that read the terms quite literally.<sup>14</sup> The words “concise” and “general” in section 553(c) carry with them the same general point of view. The basic logic of the APA, as it applies to both initial proceedings and judicial review, is that it takes very little to get the process going. At all key stages, the party in charge of the overall process has extensive discretion in case management. The heavy lifting is done within the agency. The collection of information is within its discretion and the judicial review of the record is generally done with a light touch. See *Connecticut Light & Power Co. v. Nuclear Regulatory Commission*, 673 F.2d 525 (D.C. Cir. 1982) (dealing with fire suppression techniques).

In effect, this understanding presumes, much as is the case with title searches, that the filing in question gives the parties enough information to formulate their own strategy, including the specific inquiries that they want to make of the agency, which it of course ignores at its peril. At this point, the main burden is sifting through the number of comments given, which can range into the thousands (as was indeed the case with the proposed rules of gender equality in intercollegiate sports under Title IX).<sup>15</sup> This convoluted procedure in turn raises the question of just how much attention it is possible for the relevant agency to give to each individual comment in formulating its own rule, and in offering rationales for its adoption.

If the formal hearing is not used, notice and comment rulemaking becomes the next best option to exercise independent rulemaking. However, this system has become vastly more complex as modern courts require agencies to beef up

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14 See F.R.C.P., Appendix of Forms. Form 8, complaint for money had and received, is a single sentence. Form 9, claim for negligence, is three paragraphs: the first for the general allegation of negligence, the second to describe the injuries, and the third a prayer for damages.

15 See Proposed Sex Discrimination Regulations, 39 Fed. Reg. 22,228 (June 20, 1974) (where the U.S. Department of Health, Education, and Welfare (“HEW”) issued draft Title IX regulations). HEW published proposed Title IX regulations in Federal Register for notice and comment. HEW received more than 10,000 comments (most on athletics). <http://www.titleix.info/history/the-living-law.aspx>.

the information that they put in the public record before making a decision, so that, as is often the case today, the agency must literally disclose all the sources on which it has relied. The justification for this onerous practice is that full information allows first all the interested commenting parties, and then the reviewing court, to develop a sufficient basis on which to evaluate the soundness of the rule. When a court finds that soundness lacking, it can remand for further proceedings, at which point there is a duty not only to correct any earlier errors, but also to update the record to take into account further developments. The cycle is capable of constant repetition that should warn courts against taking this aggressive reading of the APA requirement. Yet over the 30 years following the passage of the APA, just this drama played out in the D.C. Circuit in multiple decisions by judges of all political persuasions, even though, as Judge Kavanaugh remarked in *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 246 (D.C. Cir. 2008), this received judicial wisdom “cannot be squared with the text of section 553 of the APA.” See, e.g., *Automotive Parts and Accessories Association v. Boyd*, 407 F.2d 330 (D.C. Cir. 1968) (McGowan, J.); *Natural Resources Defense Council v. Nuclear Regulatory Commission*, 547 F.2d 633, 653–54 (1976) (Bazelon, J., rev’d in *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519 (1978)); *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977).

Under these decisions, the ease of judicial review trumped flexibility inside the administrative process. But there was a strong response. In *Vermont Yankee Nuclear Power Corp. v. National Resources Defense Council*, 435 U.S. 519 (1978), Justice Rehnquist slapped down the D.C. Circuit in unusually harsh terms because it “had seriously. . .misapplied this statutory and decisional law,” and the Court ruled that once the minimum requirements of the statute were met, it was for the agency and not the courts to decide if any additional procedural protections should be given. *Vermont Yankee* did limit the ability of lower courts to craft new procedures under the APA. But the decision did not deal with either the issue of the proposed notice of rulemaking or with the issuance of the final rule. In these areas, it became quickly clear that the circuit court law on these two parts of the APA “read—and cite cases—as though they could have been written in 1977” (Lawson 2012, p. 279).<sup>16</sup> The philosophical rear-guard action against the textualism of *Vermont Yankee* went a long way to ensure that notice and comment procedures became far more complicated and prolonged than anyone would expect—which gave agencies all the incentives they needed to set up shop outside the notice and comment framework

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16 Relevant cases that support this trope include *Connecticut Light and Power Co. v. NRC*, 673 F.2d 525 (D.C. Cir. 1982).

through interpretative rules and policy statements that let agencies operate free of judicial oversight.

### 1.3 Interpretative Rules and Policy Statements

#### 1. 3. 1 *The Chevron Diversion*

The transformation of administrative law on matters of law is evident from a quick look at section 706 of the APA. The APA structure treats the administrative agency more or less like a court of first instance, with extensive power over matters of fact, and weak powers over questions of law, which are subject to *de novo* oversight in the Court of Appeal.

Section 706: To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
  - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . . .

To be sure, a plain meaning approach to this statute will not answer every question, but it does confirm that the basic pattern treats, by way of imperfect analogy, the administrative agency as though it were a trial court. Ordinarily trial courts do not have final say on any question of law, and introductory text notes that “the reviewing court shall decide all relevant questions of law.” There are no express or implied limits on the power of the reviewing court to decide, so that the term has the same meaning here as it does in ordinary civil procedure contexts, where all questions of law are decided *de novo*, without any deference to the decision of the court below.

That division of power, moreover, makes as much sense here as it does in ordinary litigation, because there is no particular agency expertise on matters of statutory construction or constitutional complication, so that leaving these decisions to reviewing courts imposes a sensible check on agency action on matters where an appellate court labors under no particular disadvantage. But, in its *Chevron* surprise, the Supreme Court started a sustained revolution in administrative law when it introduced a two-part test in which the agency was required to follow the meaning of the text when plain, but gave the agency deference to its own interpretive views when the text was not. *Chevron* was something of an interpretive marvel because it was rendered without any

citation to section 706, and without noting explicitly that the proceeding below was a notice and comment procedure. This rule and its omissions have gone on to create serious intellectual difficulties.

First, the basic logic of the APA was turned upside down, especially since it is, to coin a phrase, never clear when a statute should be regarded as ambiguous. What is critical about this decision is that on matters of law, the cumbersome review procedures outlined above for notice and comment proceedings no longer apply, so that the deference trope empowers any agency to make whatever doctrinal flip-flop it wants, so long as either rendering of the text is to some extent plausible. The differences can be very large. The “waters of the United States” could be defined to cover either only navigable lakes and rivers or to also embrace uplands from which it is possible for water to make itself into navigable waters. See *Rapanos v. United States*, 547 U.S. 715 (2006).<sup>17</sup> At this point, an unfortunate but pervasive linguistic skepticism works its way into the legal system, because agency lawyers have a constant incentive to manufacture welcome ambiguities in order to increase their power. That point was made very clear to me years ago when I visited the Federal Communications Commission (FCC) as a consultant for the then Bell Atlantic Company to talk about the distribution of authority between the FCC and the state regulatory bodies in administering the then recently passed 1996 Telecommunications Act, 47 U.S.C. §§ 251–52. When I made my points about why it was that the state agencies had more authority than the FCC was prepared to recognize, I was met with a tart and conclusive response: so what, the FCC had *Chevron* deference. At that point, it was clear to me that the FCC no longer had the incentive to seek out the best reading of the statutory provisions. Rather, its main objective was to try to reach the outer limits of its authority by taking positions that, even if wrong, were plausibly defensible, which is the surest way to plunge legal systems into intellectual disrepair. It is one thing for a court to rescue an honest effort to stay within the law by giving deference to an agency in a close case. It is quite another for the agency to count on that extra margin of safety time after time when it formulates its basic rules. The lack of oversight on statutory interpretation does not operate all that differently from the same lack of control over the guidance.

There are many illustrations of how this works, but it should be sufficient here to point out one case that reveals these tendencies, in which the peculiar non-ideological nature of these administrative law disputes is highlighted by the simple fact that Justice Clarence Thomas wrote the opinion for the Court from which Justice Scalia, taking the role of the smart textualist, dissented. In the 2005 decision *National Cable and Telecommunications Association v. Brand X*

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17 The divided decision in *Rapanos* has led to enormous rulemaking through notice and comment.

*Internet Services*, 545 U.S. 967, the question was whether a dial-up cable modem service provided over local telephone should be classified as “a telecommunications service” that was subject to heavy FCC regulation or, alternatively, as an “information service” that was not. Under the basic statutory set-up, “[t]elecommunications” is “the transmission, between or among points specified by the user, of information of the user’s choosing, without change in the form or content of the information as sent and received.” 47 U.S.C. § 153(46). This definition covers dial-up, which has no transformative power. In contrast, “information service” is “the offering of a capability for generating, acquiring, storing, transforming, processing, retrieving, utilizing, or making available information via telecommunications . . .” 47 U.S.C. § 153(20). Dial-up does not seek to organize information even if the information that is so transferred may thereafter be organized separately. Creating ambiguity here is cut out of whole cloth.

Difficult questions arise from *Chevron* deference. The first question is exactly how far the deference extends. The point is especially acute with respect to decisions that construe the scope of agency jurisdiction where the bureaucratic imperatives of aggrandizement will often make the agency less than a disinterested broker in its own affairs. Nonetheless, as late as 2013, Justice Scalia wrote in *City of Arlington v. FCC*, 133 S. Ct. 1863, that the deference on these jurisdictional issues was “rooted in a background presumption of congressional intent” that under *Chevron* “provides a stable background rule against which Congress can legislate” (*id.* at 1868). He also noted that departing from *Chevron* could create major difficulties in deciding whether a question went to jurisdiction or the merits.

None of these defenses bears the weight placed on it. It is hard to see why only the *Chevron* rule can create stable expectations for adjudication that reflects the intention of Congress. Congress has not expressed any such intention, and the use of *Chevron* always opens up the gate to huge debates as to whether the statutory provision is or is not clear. In addition, the line between jurisdictional issues and decisions on the merits (which does work tolerably well on matters of *res judicata*) disappears if the usual rule of *de novo* review applies to *all* determinations, whether on the merits or not.

A unified approach, moreover, gets rid of the second question under *Chevron*, which is how much deference extends to determinations that various administrators make in settings where there are no notice and comment procedures, such as opinion letters in *Christensen v. Harris County*, 529 U.S. 576 (2000), which don’t merit judicial deference, and tariff classifications in *United States v. Mead Corp.*, 533 U.S. 218 (2001), which get some deference, but not as much as *Chevron* would require for notice and comment procedures. The simple point here is that if there is no deference afforded in *Chevron* on

questions of law, all these other variations fall into line; there is no deference in any less formal procedure either. At this point, the system that followed the original APA directives would have modest restraints on questions of fact, and stronger ones on questions of law in the form of *de novo* review in all cases. Once again, the jerry-built judicial scheme marks a clear step backwards from the original intention.

### 1.3.2 *Interpretive Rules, Policy Decisions, and the Transition to Guidances*

The very tough standards that the courts have imposed on notice and comment proceedings have induced administrative agencies to take further evasive steps. Historically, they moved one step closer to the guidance by seeking to take advantage of section 553(b), which holds: “Except when notice or hearing is required by statute, this subsection does not apply—(A) to interpretative rules, general statements of policy, or rules of agency organization procedure, or practice.” The opportunities in this area have proved fertile because of the deep difficulty in giving a coherent account of these three exceptions, all of which have been subject to extensive litigation.

Textually the problems start with the phrase “interpretative rule.” These rules are subsets of the definition of “rule,” which covers “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy.” It is clear from this definition that interpretation is a proper subject of rules. What is not clear is how this is at all possible. Rule 706(a) makes “interpretation” of constitutional and statutory provisions a proper judicial function for *de novo* review. How then does an interpretative term, which reads like an ungrammatical form of the more common word “interpretive,” come to be a matter lodged exclusively in the agency? Some hint of its possible scope comes from section 553(d), which does refer to “substantive rules,” the flip side of the coin from interpretative. The difficulty with this opposition is that it offers no clear path for beating back a potential oxymoron, because an interpretation as normally understood does not create a rule of any sort, but only explains, clarifies, or reveals the meaning of particular terms that are found in a constitution, statute, regulation, or contract, which is why it is treated elsewhere in the APA as a question of law. One way to put the issue is captured in the view that “the emphasis for evaluating an interpretive rule is whether the binding obligation is created by the rule rather than reflecting a preexisting obligation imposed by the statute or regulation the rule purports to interpret” (Seidenfeld 2011, p. 350). Or as was recently stated in *National Mining Assn. v. McCarthy*, 758 F.3d 243 (D.C. Cir. 2014), a legislative rule is any “agency action that purports to impose legally binding obligations or prohibitions on regulated parties” (*id.* at 251).

In contrast, an interpretative rule is any “agency action that merely interprets a prior statute or regulation, and does not itself purport to impose new obligations or prohibitions or requirements on regulated parties” (*id.* at 252). Clarification of prior law, rather than the creation of new law, is the focal point here. On this view, interpretative rules should play only a tiny role in the overall picture of administrative law, by which the content of rules is restated or paraphrased in ways that spell out some of the textual implications or ambiguities with the terms. Even the term “minor rule” does not quite capture the sense of the distinction, because even minor rules (which could have major effects) are intended to be binding on the parties whose conduct they control. In the end, any effort to articulate a set of substantive commands directed to any group of individuals looks like an effort to craft a substantive rule to which under current law the notice and comment sections should apply.

Nonetheless, it has proved difficult to cabin these interpretative rules into a subordinate role. Not surprisingly, the uneasiness about the subsequent evolution of the subject has spawned an extensive academic literature that has sought to domesticate the practice within the current legal framework (Seidenfeld 2011, p. 331). One oft-expressed view is that the use of notice and comment proceedings becomes a litmus test as to whether the rules issued should be legally binding: yes, if the proceedings have been otherwise taken, but no, if they have not. The substance of the rule now does little to determine its effect, which depends on the procedural path for its articulation. Professor Jacob Gersen puts the point as follows:

Rather than asking whether a rule is legislative to answer whether notice and comment procedures should have been used, courts should simply ask whether notice and comment procedures were used. If they were, the rule should be deemed legislative and binding if otherwise lawful. If they were not, the rule is nonlegislative. If the rule is nonlegislative, a party may challenge the validity of the rule in any subsequent enforcement proceeding; if the rule is legislative, the agency may rely on the rule in a subsequent enforcement proceeding without defending it (2007, p. 1719).<sup>18</sup>

That view is in turn attacked by Professor David Franklin, who rightly points out that any emphasis solely on the formal aspects of the process could short-change the interests of the various parties that should be protected under the Act, and who uses his insight to explain why the courts have in general refused

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18 See also Elliott (1992, p. 1491); (Manning 2004, p. 931) (urging that reviewing courts should handle the distinction between legislative and nonlegislative rules solely “by assigning different legal effects to an agency’s application of rules that are adopted without notice and comment”).

to take this administrative shortcut to resolve these matters, notwithstanding, their overall efficiency, because of the way they cut off public input from what should be an open administrative process.

Often these policy decisions in effect command compliance from regulated industries and thus have substantial practical effects on the public, regardless of whether they are framed as mere guidances, interpretations, or tentative policy statements. It would seem inconsistent with both legislative intent and democratic theory to allow agencies to make such decisions without public input whenever they wish (Franklin 2010, p. 305).

The upshot is that Franklin appears to defend the status quo ante by endorsing “current doctrine” under which “the Supreme Court has held that the decision whether to craft policy via rulemaking or case-by-case adjudication lies primarily in the informed discretion of the agency” (*id.* at 306). The one obvious response to this proposal is that it does not explain exactly how the discretion of agencies should be exercised under that case-by-case standard. In response, Professor Mark Seidenfeld has proposed, for example, that agency guidances issued without notice and comment proceedings should be subject to a substantive review under an arbitrary and capricious standard. “Recognizing that ex post monitoring leaves much leeway for agencies to abuse guidance documents by depriving stakeholders of opportunities to participate in their development and of obtaining substantive judicial review of them, the article advocates that nonlegislative rules generally should be subject to arbitrary and capricious review when issued” (Seidenfeld 2011, p. 331).

Manifestly, these approaches properly reflect a deep uneasiness with the current situation, but these modest fixes will resolve the matter. As was intimated above, the Court has to rebuild administrative law from the ground up—by junking *Chevron*. The basic difficulty with interpretive rules came again to a head in the unanimous (in name only) recent decision of the Supreme Court in *Perez v. Mortgage Bankers Ass’n*, 135 S. Ct. 1199 (2015), which addressed the deceptively simple question of whether an administrative agency can change its prior interpretation of a rule by reversing its decision without the benefit of a notice and comment proceeding. The matter had been previously addressed by the D.C. Circuit in *Paralyzed Veterans of America v. D.C. Arena L.P.*, 117 F.3d 579, 588 (1997), which held that any reversal in agency interpretation required a notice and comment hearing. The driving concern behind this rule was the fear of untrammelled agency discretion.

*Perez* involved an interpretation of an exemption from the hours and wages provisions of the Fair Labor Standards Act (FLSA), 29 U.S.C. § 201 et seq., for mortgage loan officers as persons who are “employed in a bona fide executive,

administrative, or professional capacity . . . or in the capacity of outside salesman. . . ” (FLSA § 213(a)(1)). The issue was not new to the Department of Labor, which in 1999 and 2001 had held that these persons were not exempt. That decision was reversed in 2004, but only after a notice and comment proceeding. The original rule was then restored without a notice and comment hearing in 2010. The political implications were these: The 1999 and 2010 decisions were by Democratic administrations (Clinton and Obama); the 2004 variation was by a Republican administration (George W. Bush). It was this last iteration, which once again expanded the category of covered workers, that the Mortgage Bankers challenged.

Justice Sotomayor, writing for the Court, took the correct position that notice and comment hearings were not necessary to these proceedings under section 4 of the APA, 5 U.S.C. §553, on the simple ground that “the notice-and-comment requirement ‘does not apply’ to ‘interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,’” which the agency can issue on its own accord under 5 U.S.C. § 553(b)(A) (*Perez*, 135 S. Ct. at 1204). The notice and comment proceeding therefore may be done, but it is not required, and hence the change in position can be upheld because of the nonbinding nature of the interpretive rule in the first place.

Initially, it seems clear that there is little or no reason to have any notice and comment proceeding at all to ask about the way in which one class of professionals, Mortgage Loan Officers, intersects with some broad category, namely, “employed in a bona fide executive, administrative, or professional capacity . . . or in the capacity of outside salesman. . . ” (FLSA § 213(a)(1)). Here the very title “mortgage loan officers” was not dreamed up as a strategic response to FLSA mandates, but rather reflects the type of administrative work that these loan officers do. This question of classification is a question of law, and an easy one at that. No one would think twice if the matter of interpretation arose outside the scope of administrative law, say in a common law dispute. Resolving this question is one for which the notice and comment proceedings add nothing of value, beyond a simple statement of the standard duties of these officers, which can be easily obtained from job descriptions that the parties can introduce into evidence in litigation.<sup>19</sup>

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19 For the description of the mortgage brokers responsibilities, looks like “a bona fide executive, administrative, or professional capacity . . . or in the capacity of outside salesman.” See, Monster.com, <http://hiring.monster.com/hr/hr-best-practices/recruiting-hiring-advice/job-descriptions/mortgage-loan-officer-job-description-sample.aspx> (The first component reads: “Increases mortgage loan portfolio by developing business contacts; attracting mortgage customers; completing mortgage loan processing and closing; supervising staff.”)

It follows therefore that the only issue is whether the nonbinding nature of the interpretation puts it outside the scope of judicial review. On that issue, the key question is whether the basic command of section 706 of the APA should govern, and the two well-written concurrences by Justices Scalia and Thomas take the affirmative position. The basic issue is whether these administrative interpretations, which govern the activities of the entire agency, should be subject to *de novo* review as a question of law, and if so when that review should come. At this point, it seems clear that the Seidenfeld proposal, which opts for an arbitrary and capricious standard on interpretative rules, is too timid. We are not dealing with how to make general standards more concrete on questions as, for example, how to measure the presence and severity of black lung disease, which cannot be regarded as pure questions of law. Hence the correct approach in all these cases is to see whether these cases fall under mixed questions of fact and law, or whether they are questions of law over which courts can exercise full power.<sup>20</sup>

One additional reason for treating these interpretive disputes as questions of law relates to the stability of expectations under the rule of law. Statutes like the FLSA do not apply intermittently to the parties governed by them. They apply to longstanding practices that firms must follow in order to be in accordance with the law. The decisions in one year often blend with those in another, and the set of contractual expectations that are formed in one year necessarily bleed over into the next. Any legal system that allows for administrators to switch gears without any explanation or notice increases compliance costs for all concerned, and is a fertile source of disagreement in periods of transitions. The mere prospect of a shift thus invites parties to lobby fiercely first for this rule and then for that, which means that interpretation necessarily becomes a political game that can switch radically, especially where there are polarized differences between the two parties. I see no reason whatsoever why the worst features of political factions should receive the implicit blessing of the Supreme Court, when it is possible to adopt the *de novo* approach that only asks courts to work in their own sweet spot—which is, after all, statutory construction. This point is especially true with respect to the Department of Labor and similar administrative agencies, where the purported claims of expertise seem to be overwrought, while the evident danger of political bias by intermediate officials chosen on a party-line basis are very high. Deference is a losing value in cases where agency officials have no skill-set worth deferring to.

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20 On the difficulties with black lung disease, see *American Mining Congress v. Mine Safety and Health Administration*, 995 F.2d 1106 (D.C. Cir. 1993) (finding, incorrectly I believe, that detailed statements about the x-ray findings that were needed to establish eligibility under the black lung disease program were interpretive rules not covered by the APA notice and comment provisions).

A similar dynamic can play out with policy statements. As with other forms of guidance, they can often be highly instructive. Here is one way in which this dynamic plays out in connection with guidances that find their APA home in policy statements, which are also nonbinding under the APA. As with other forms of guidances, these can be a source of immense benefit. One illustration is the recent policy statement issued by the Federal Trade Commission, which stated in so many words that in future litigation the FTC would use its ability to regulate “unfair methods of competition” under section 5 of the FTC Act as a supplement to the antitrust laws.<sup>21</sup> In so doing it signaled a shift away from various consumer protection that often weaken competitive processes. The statement is short and to the point, and it signals a change in direction, without committing the FTC to any result. The statement is of immense benefit just as it is.

Yet all policy statements are not so benign. Indeed, often they share the same pathologies as interpretive statements. To be sure these two forms of communication differ because a policy statement is not generally concerned with the explication of difficult statutory terms, but with giving indications as to the processes and objectives that will guide its deliberation. The standard way in which the distinction is put in the cases, however, tends to expand the scope of policy statements beyond its proper domain. Thus it is often said: “A general statement of policy, [in contrast with a rule,] does not establish a ‘binding norm.’ It is not finally determinative of the issues or rights to which it is addressed” (*see, e.g., Pac. Gas & Electric Co. v. Fed. Power Comm’n*, 506 F.2d 33, 39 (D.C. Cir. 1974)). But that is the wrong way to look at the question. It shifts the focus from what it is that the agency would like to learn to the question of what position the agency will assert in future disputes. To be sure, the norm may not be “binding,” but it is a mistake to overlook the systematic risks that are associated with “nonbinding norms,” which immediately force the regulated parties to guess whether and, if so, when the “non” will drop out of the picture, perhaps in the course of some enforcement action. It is one thing for the government to warn you of risks of third-party behavior, which contain no threat component. It is quite another to warn you of its future intentions, in which a threat is often, but not always, implicit.

It is the growing awareness of these risks that helps explain in *Perez* why there is some evidence that Justices Scalia and Thomas have accepted them. Justice

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21 The FTC Press Release reads: “FTC Issues Statement of Principles Regarding Enforcement of FTC ACT as a Competition Statute.” FTC, (August 13, 2015), <https://www.ftc.gov/news-events/press-releases/2015/08/ftc-issues-statement-principles-regarding-enforcement-ftc-act>. For my defense of the move *see* Epstein (2015).

Scalia put the point well when, in his short “concurrency,” he explained the dangers of deference in both guidance and enforcement proceedings:

By supplementing the APA with judge-made doctrines of deference, we have revolutionized the import of interpretive rules’ exemption from notice-and-comment rulemaking. Agencies may now use these rules not just to advise the public, but also to bind them. After all, if an interpretive rule gets deference, the people are bound to obey it on pain of sanction, no less surely than they are bound to obey substantive rules, which are accorded similar deference. Interpretive rules that command deference do have the force of law (*Perez*, 135 S. Ct. at 1211–12).

The word “revolutionized” is well chosen to reinforce the enormous gap between the APA as written and the APA as it has been interpreted by the Supreme Court. The administrative law regime may raise the stakes, and may increase the complexity of the power, but it does not in any real way point to any different division of labor. Appellate courts can still address questions of law at least as well as trial courts and administrative agencies, and should not allow their comparative advantage to be frittered away by doctrines of deference to any or all of the determinations of administrative bodies.

The position that Justice Scalia took in this case was paralleled by his recent criticism of so-called *Auer* deference, pulled from *Auer v. Robbins*, 519 U.S. 452 (1997), in *Decker v. Northwest Environmental Defense Center*, 133 S. Ct. 1326 (2013), which addresses how much discretion should be afforded to an agency in the interpretation, not of a Congressional statute, but of its own regulations. At the height of the New Deal synthesis, the answer was a great deal, which meant that under the 1945 antecedent to *Auer*, the Court will defer to agency determination unless that interpretation is “plainly erroneous or inconsistent with the regulation.” (*Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410 (1945)) (affording deference to the Office of Price Administration under Section 2(a) of the Emergency Price Control Act of 1942, in setting ceiling prices for goods).<sup>22</sup>

Making regulatory programs effective is the purpose of rulemaking, in which the agency uses its “special expertise” to formulate the best rule. But the purpose of interpretation is to determine the fair meaning of the rule — to “say what the law is,” *Marbury v. Madison*, 1 Cranch 137, 177, 2 L.Ed. 60 (1803). Not to make policy, but to determine what policy has been made and promulgated by the agency, to which the public owes obedience (*Decker*, 133 S. Ct. at 1340).

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22 *Seminole Rock* was decided in the run up to the 1946 passage of the APA, as mentioned in *Decker*, 133 S. Ct. at 1339.

What it is not possible to understand is why *Chevron* could survive this critique. To be sure, the agency that interprets a statute is not interpreting its own handiwork, but that of Congress. But what is the precise significance of that difference, given that the same perverse political incentives of administrative aggrandizement or indifference arise as much in the one case as in the other. The critique of *Auer* is therefore a critique of *Chevron*, and of course of Scalia's acceptance of *Chevron* that same year in *City of Arlington v. FCC*, decided just two months later (*Arlington*, 133 S. Ct. 1863 (2013)). This point has been recognized by others (Bednar 2015), who in writing about both *Perez* and *Auer* argue that the proper approach is a return to the less deferential standard of *Skidmore v. Swift & Co.* (323 U.S. 134 (1944)). *Skidmore*, as is well known, is *Chevron*-light under which the decisions of the administrator are "entitled to respect even when they were not forged in adversarial relations."<sup>23</sup> This muddiness should not do. If the administrator has all sorts of comparative advantages in understanding the terms of a statute, he or she should be able to prevail by making those arguments to the court under a standard of *de novo* review, which gives the reviewing court the benefit of that institutional knowledge, but only if it holds up in the crucible of litigation. There is no reason to double the government's inside track advantage by adopting a favorable standard of review. The constant resort to intermediate standard of review does not address the interpretive issues here, or indicate how large a thumb should be placed on the scale. The inveterate problem of administrative law is developing too many standards of review, too many distinctions for its own good, when the best approach is that major questions of statutory interpretation should be decided *de novo* as questions of law, period. Of course, questions of law are sometimes close. Nonetheless, getting rid of *Chevron* root and branch could do away with much of this problem. It would also impose certain limitations on modern guidance practices, to which I now turn.

## 2. MODERN GUIDANCES IN PRACTICE

This extensive background has set the stage for examining the modern use of guidances, which is an amalgam of all the various forms that are commonly

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23 "[T]he Administrator's policies are made in pursuance of official duty, based upon more specialized experience and broader investigations and information than is likely to come to a judge in a particular case. They do determine the policy which will guide applications for enforcement by injunction on behalf of the Government. Good administration of the Act and good judicial administration alike require that the standards of public enforcement and those for determining private rights shall be at variance only where justified by very good reasons. The fact that the Administrator's policies and standards are not reached by trial in adversary form does not mean that they are not entitled to respect." *Skidmore*, 323 U.S. at 139-140.

used under modern administrative procedure law. In analyzing their validity under the APA, it is important not to be seduced by labels. It is perfectly proper for an administrative agency to issue a guidance that complies with all of the elements of a notice and comment proceeding, without calling it such. The substance governs, so long as the applicable process elements are there. It is also equally clear that large numbers of guidances do have the desirable effect of clarifying the current state of the law, at which point they will be welcomed by the parties who receive them, and are not likely to be subject to any resistance through litigation or otherwise. In addition, no agency has any incentive to use the term “guidance” whenever it plans to engage in a notice and comment proceeding.

It follows therefore that the guidance cases that raise the greatest anxiety are those where agencies strategically issue guidances when they want to short-circuit the formal processes in order to gain some tactical advantage to implement some policy scheme. In some cases agencies may use the guidance to impose new requirements in the course of restating old ones. It is all too easy for an agency to play it both ways. First, an agency may insist that its position has no binding effect, but only supplies useful information to private parties. Next, it may muddy the waters by suggesting that additional requirements might be required, which can have a profound, practical effect on how regulated parties, both private and public, operate. In all cases, an agency then relies on a combination of the principles of standing and finality to insulate itself from review if enforcement is undertaken in an individual case or final regulations are issued. This Part addresses possible permutations on how this can proceed.

## **2.1 Examples of Guidances in Use**

### *2.1.1 Drug Regulation*

The FDA has published a statement about its use of guidances:

- (d) Are you or FDA required to follow a guidance document?
  - (1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.
  - (2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.
  - (3) Although guidance documents do not legally bind FDA, they represent the agency’s current thinking. Therefore, FDA

employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

....

- (f) How can you participate in the development and issuance of guidance documents?

....

- (4) You can, at any time, suggest that FDA revise or withdraw an already existing guidance document. Your suggestion should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.
- (5) Once a year, FDA will publish, both in the Federal Register and on the Internet, a list of possible topics for future guidance document development or revision during the next year. You can comment on this list (e.g., by suggesting alternatives or making recommendations on the topics that FDA is considering).

(21 C.F.R. § 10.115.).

The most obvious point about this meta-guidance, like the substantive guidances issued under it, is that it is hard to know whether it is best viewed as the useful provision of information to outsiders or as an implicit threat to them. The statement in question contains elements of both. On the one hand, it is a positive assistance to individuals who are to go before the FDA to understand its requirements. That information allows them to organize their behavior in ways that reduce potential conflicts, which in turn saves resources both for the applicant and the FDA. Knowing where someone stands is, as a first approximation, a good thing, and there is no question that ordinary private firms in competitive markets provide similar services.

The situation with any government agency, including the FDA, is much more difficult to evaluate because of its monopoly position over the goods and services that it regulates. In this situation, the FDA faces relatively few constraints if its guidances push the legal envelope in some direction it desires. Unlike competitive markets, however, the potential seller of a drug or a medical device cannot go elsewhere if it dislikes the proposed regulation. It has to play by FDA rules or go home, losing its extensive sunk costs. Going home may minimize the private costs to the potential applicant, but at the same time, the FDA's unilateral action could easily have high social costs if its guidance deters desirable new drugs or devices or new applications of either. If the FDA has overreached, the companies that elect to run the gauntlet will face higher costs

with lower rates of return, which again counts as a social loss. The hard inquiry therefore is whether the threat element dominates the informational element, and on that score much depends on how the information is presented.

In this regard, at the opening bell, the guidance announces that neither the FDA nor the applicant is bound to follow it, so that both sides are free to move as they will. But following that general reassurance is the veiled threat that any applicant who does not follow the guidance may fall out of compliance with the applicable statute. Remember that the FDA is not warning about the wrongdoings of a third party, but is rather only telegraphing, as it were, its own punches. At the very least, the government insists that by offering one safe harbor, it is okay to impose arduous demands on various private parties who take some alternative route. The FDA's willingness to discuss matters with private parties carries the clear negative implication that any party that does not talk to the FDA will face an uphill battle in any subsequent enforcement action. The guidance contains a veiled threat absent from simple silence, which is one reason why it is issued.

Point (3) of the guidance drives home this idea by making it clear that the guidance binds inferior personnel inside the FDA, even if it does not bind the FDA itself. Any effort to get around the guidance will require at a minimum some internal appeal to higher officials within the FDA. In principle, this notice could be perfectly innocuous, but in practice, the requirement offers a clear signal that it will prove costly and time-consuming to fight any substantive battle within the agency. Indeed, the right to urge the FDA to switch its position puts the shoe on the wrong foot. The burden of proof facing the supplicant is surely higher in a world in which it is trying to get the FDA to back down from a public position than it is in asking the FDA to switch before it makes any public announcement.

This line-up of incentives is likely to have some serious implications for behavior. Any firm that is inclined to follow its own interpretation of a statute is likely to think twice before doing so. At this point, the following scenario is all too likely to occur. A given firm decides to follow the FDA's position, only to discover down the road that the FDA has been rebuffed in court. At this point, its prior expenditures are largely wasted, but the chances of any financial recoupment are virtually nil. An aggressive guidance can tip the balance in the FDA's favor. The need for an immediate facial challenge should be clear, but as will become evident, it is exceedingly difficult to maintain today given the judicial insistence that no party has standing to challenge a guidance until it has been subject to some enforcement action.

It is perhaps for these reasons that some judicial resistance has developed to the aggressive use of both forms of guidance. In *Professionals and Patients for Customized Care v. Shalala*, the court addressed whether the FDA's 1992

Compliance Policy Guide (CPG) 7132.16 was a substantive rule (56 F.3d 592 (5th Cir. 1995)). That guidance gave extensive instructions on the important question of when local pharmacies could compound drugs for general resale. Downstream fabrication is necessary for those compounds that have a short and useful shelf life. The typical pharmacy fabricates under prescription, so it is a fair question whether a pharmacy should be allowed to open up a more general business without meeting other FDA requirements. On that issue, the FDA wrote: “If a pharmacy compounds finished drugs from bulk active ingredient materials considered to be unapproved new drug substances, as defined in 21 CFR 310.3(g), such activity must be covered by an FDA-sanctioned investigational new drug application (IND) that is in effect in accordance with 21 U.S.C. Section 355(i) and 21 CFR 312” (*id.* at 593–94). After which comes the now explicit punch line: “Pharmacies may not, without losing their status as retail entities, compound, provide, and dispense drugs to third parties for resale to individual patients” (*id.* at 594). This last “nonbinding” sentence is nothing short of an open threat to prosecute, which thus creates exactly the *in terrorem* effect that should not be allowed in administrative law. Who is in a position to say no to a requirement of this sort if the guidance is sustained, which is likely given the standard of deference to administrative agencies? And worse, note that a high level of compliance with a contested rule is achieved even if some hard party decides to challenge the guidance and wins. There is no reason to allow this clever indirect effort to expand jurisdiction. If this statement is a conclusion of law, it should be subject to promptly to *de novo* challenge in court before people get enmeshed in potential enforcement actions. If, which seems doubtful, it is a mixed statement of law and fact, then and only then it should be subject to notice and comment proceedings, which is what the Court in *Customized Care* required.

Nor is it possible to duck this treatment by listing nine relevant factors that the FDA “will consider” in making its determination of whether to pursue any individual party. Those are exactly the same kinds of factors that are contained in all sorts of rules that rely on any form of cost/benefit analysis, including, for example, the definition of product defects.<sup>24</sup> It is a classic instance of how agencies try to play the game both ways. The FDA failed in this effort to fly under the judicial radar on all questions of fact and law. But that outcome should not be reached on a detailed consideration of the facts and circumstances of each individual case. It should be the result of a determined effort

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24 RESTATEMENT (SECOND) OF TORTS § 402A & cmts. h–j. For criticism, see Henderson (1973, p. 1531). For my take, see Epstein (1980, pp. 64–66).

never to give the FDA, or indeed any other agency, untrammelled control of questions of law.

A closely analogous question for PET radiopharmaceuticals arose two years later in the D.C. Circuit in *Syncor International Corp. v. Shalala*, where the FDA sought to extend its regulatory authority to PET. 127 F.3d 90 (D.C. Cir. 1997). The question before the Court was whether these downstream fabrication facilities created drugs that were subject to FDA oversight, chiefly with respect to the FDA's requirements for best manufacturing practices.<sup>25</sup> FDA oversight with these technologies does not raise any constitutional issues, given the close connection to health and safety. But there is the question of how the Food Drug & Cosmetic Act should be construed. On this issue, the FDA had revoked its earlier 1984 rule, which unequivocally had held that these products and/or processes were outside the scope of the Act (*id.* at 92).

It should be apparent that these gatekeeper cases are immensely important because, unlike individual decisions on the merits, they impact every single case within some broad class, which in this instance leads to a huge expansion in FDA power, given the large number of decentralized processors who meet this description. The FDA sought to shoehorn its new directive into a cross between an interpretative rule and a policy statement, but that approach was rightly rejected in favor of a strict requirement of a notice and comment proceeding. But, ironically, it is an open question whether the D.C. Circuit reached the right result. Initially, it is surely clear that this is not a policy statement, which is generally directed toward general announcements of the factors that go into making rules that will govern cases. So the FDA can announce by policy statements, for example, that in deciding whether to subject PET radiopharmaceuticals to the Act, it considers the benefits and burdens of this regulatory objective. The basic announcement could then be broken down into a discussion of the costs of compliance relative to the added safety benefits, which quickly looks like an invitation for rulemaking, at least under the 1947 interpretation of the APA.

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25 *Id.* at 92 (“FDA indicated that it would require PET ‘radiopharmaceutical manufacturers’ to comply with the adulteration provision of § 501(a)(2)(B) of the Act (drugs are considered adulterated unless manufactured in conformance with current good manufacturing practices); the misbranding provision of § 502 of the Act (drugs are considered misbranded if the product labeling is false or misleading, if the drug is dangerous to health when used as suggested in the labeling, or if the labeling fails to include certain required information); the new drug provision of § 505 of the Act (new drugs must be the subject of approved new drug applications or abbreviated new drug applications before marketing); and the registration and listing provisions of § 510 of the Act (drug establishment must register with FDA, and file a list of all drugs that it makes or processes). See Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products, Guidance, Public Workshop, 60 Fed. Reg. 10594, 10595 (1995).”).

This entire project on the coverage of downstream fabricators, therefore, shows a well-nigh complete overlap between the so-called interpretative rule and any ordinary question of statutory construction—normally a question of law that should be decided *de novo* by any court. This interpretive issue is not unlike the question of whether tobacco should be considered a drug under the Pure Food and Drug Act—a claim that the Supreme Court rejected in *FDA v. Brown and Williamson Tobacco Corp.*, 529 U.S. 120 (2000).<sup>26</sup> At this point, the dangers of the *Chevron* doctrine become clear, for if this coverage question is treated as one of law, it is easy for any court to conclude that the disputed issue is ambiguous enough to warrant an agency getting its way, without going through any notice and comment procedures at all. It is as if, in the end, this pure question of law is treated like the interpretive rule and policy judgment that the D.C. Circuit in *Syncor* sought to avoid.

### 2.1.2 *Discrimination and Civil Rights*

The same basic approach is found in other areas as well. For example, the Department of Education’s Office for Civil Rights (OCR) issues extensive guidance documents that bear only the most remote connection to the statutory text, which states simply enough:

(a) Prohibition against discrimination; exceptions

No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance, except. . .

20 U.S.C. § 1681.

The initial text uses the phrase “subjected to discrimination,” which is best read to deal with conscious decisions to exclude persons from programs on grounds of sex. It does not have any clear pedigree to carry over to cases in which neutral rules are thought to be suspect because of their disparate impact. To my knowledge no one has ever claimed that a college engages in

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26 For a parallel issue, see *United States v. Regenerative Sciences, LLC*, 878 F. Supp. 2d 248 (D.C. Cir. 2012), *aff’d*, 741 F.3d 1314 (D.C. Cir. 2014). At issue in this case was whether certain preparations of stem cells that were removed from the body, cleansed, and re-injected for joint treatment counted as drugs that were covered by the FDA statutory procedures. The district court gave “substantial deference” to the FDA on the ground that the FDA has the greatest expertise in the construction of its own regulations. See also *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994), which is yet another variation on the original forms of *Chevron* deference. I have attacked this whole line of reasoning, to no avail, in Epstein (2013b).

discrimination in its admissions process because a larger fraction of male students enroll in math courses than in English courses, or that a larger fraction of women enroll English classes than men. The disparate impact standard on matters of course selection could expose a college or university to serious liabilities based on the voluntary course selection of its own students. So in dealing with the core mission, it is hard to see how the broader interpretation of disparate treatment is sustainable without subjecting every academic program to administrative oversight.

Indeed, the next section of Title IX guards against just that possibility:

- (b) Preferential or disparate treatment because of imbalance in participation or receipt of Federal benefits; statistical evidence of imbalance

Nothing contained in subsection (a) of this section shall be interpreted to require any educational institution to grant preferential or disparate treatment to the members of one sex on account of an imbalance which may exist with respect to the total number or percentage of persons of that sex participating in or receiving the benefits of any federally supported program or activity, in comparison with the total number or percentage of persons of that sex in any community, State, section, or other area: Provided, That this subsection shall not be construed to prevent the consideration in any hearing or proceeding under this chapter of statistical evidence tending to show that such an imbalance exists with respect to the participation in, or receipt of the benefits of, any such program or activity by the members of one sex.

*Id.*

The clear sense of these two provisions is that some form of disparate treatment has to be shown to establish a civil rights violation in all cases of simple statistical imbalance. The offset for that basic norm is the ability to admit statistical evidence of an imbalance as an aid to proving discrimination. Nonetheless, it is quite clear that the current regulations under Title IX that govern participation by sex in intercollegiate athletics has flipped the statute over to impose far more stringent commands on both public and private colleges. The initial stage takes place through regulations that seek to apply the basic system to competitive sports where sex differences have long been engrained. There is nothing in the statute that remotely suggests that contact sports can remain separate but others cannot, but the regulations impose detailed rules on how these differences are to be managed, dealing with every aspect of internal administration of athletic programs—equipment, supplies,

scheduling, travel allowances and the like. 34 C.F.R. § 106.41 (1995).<sup>27</sup> The final stage of the process of statutory expansion is a Policy Interpretation that flies in the face of the basic statute, by imposing these three requirements (44 Fed. Reg. 71,413, 71,418 (December 11, 1979)): (1) have roughly proportionate numbers of male and female students relative to their respective enrollments, (2) show a program of continuing expansion for the “underrepresented” sex (i.e., always women) that is “demonstrably responsive to the developing interests and abilities of the members of that sex, or (3) show a program where “the interests and abilities of the members of [the underrepresented sex] have been fully and effectively accommodated by the present program” (Clarification of Intercollegiate Athletics 1996). No longer is evidence of statistical imbalance allowed as evidence in individual cases. Rather, a *per se* quota-like rule has taken its place, with no effort to explain how the initial statute justifies that result.

The bottom line is that the new rules require massive cross-subsidies of women in college sports that are too costly to achieve if men’s teams are kept at their current size and number. To be sure, there is no explicit mandate that men’s teams be cut. It is in principle always possible to increase the size of women’s teams. But the cost here is prohibitive because to start women’s teams in minor sports always requires substantial scholarships and often new facilities. In the end, it is cheaper by far to shut down an inexpensive male program than to start up, say, a women’s hockey team that is expensive to fund. Football, of course, has to be put to one side, since it generates the revenues that fund other programs. But apart from the tacit acknowledgement that keeps football outside the rules, the revenues derived from different sports are not allowed to influence in any way, shape or form the way in which the money in question should be spent. The ironic result: Title IX, which was supposed to end discrimination, has become the chief tool for its perpetuation. Thus 35 years later, this program has resulted in the massive contraction of, for example, men’s wrestling teams, because of the unmovable need to meet the required quotas (Owoc 2008). And there are all sorts of Division I colleges that don’t have swimming programs for the men who have no interest or ability in football, even though these programs are financially self-sustaining. Again, as a matter of statutory construction, it is impossible to think that the Congress of 1972 passed legislation under which every athletic program in the USA was in abject noncompliance, but the use of an interpretive rule was the last step in achieving that result.

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27 For the endorsement of these regulations, see *Cohen v. Brown University*, 101 F.3d 155 (1st Cir. 1996), *cert. denied*, 520 U.S. 1186 (1997). The denial of certiorari effectively ended all legal challenges to these regulations.

A similar expansion has taken place with respect to sexual harassment. Returning to the original text of Title IX, it is not credible to think that the institution should be responsible for actions of harassment carried out by individual students, or that Title IX in and of itself allows the Department for Civil Rights in the Department of Education to impose responsibilities for that action. Here, the initial question of statutory interpretation is whether sexual harassment of one student by another, and the institutional response thereto, falls within the basic statutory prohibition. There is nothing in the text of the statute or its legislative history that indicates that it does. But the issue is forced to the front with broad social claims, hard to believe, that up to 20 percent of women on campus have been subject to sexual assaults or serious threats thereof (National Sexual Violence Resource Center). In large measure, this startling statistic is a function of definitions, especially when Womenshealth.gov places together wildly different behaviors under the same umbrella when it writes that “sexual assault can be verbal, visual, or anything that forces a person to join in unwanted sexual contact or attention.” In plain English, a nasty stare and a forcible rape fall into the same statistical category (womenshealth.gov 2012).<sup>28</sup> From that highly contested initial baseline, the OCR has issued some detailed guidances (OCR, Dear Colleague Letter) and has posed some “Frequently Asked Questions,” (OCR, Questions and Answers) all of which push the envelope.

F-6. May every witness at the hearing, including the parties, be cross-examined?

Answer: OCR does not require that a school allow cross-examination of witnesses, including the parties, if they testify at the hearing. But if the school allows one party to cross-examine witnesses, it must do so equally for both parties.

OCR strongly discourages a school from allowing the parties to personally question or cross-examine each other during a hearing on alleged sexual violence. Allowing an alleged perpetrator to question a complainant directly may be traumatic or intimidating, and may perpetuate a hostile environment. A school may choose, instead, to allow the parties to submit questions to a trained third party (e.g., the hearing panel) to ask the questions on their behalf. OCR recommends that the third party screen the questions submitted by the parties and only ask those it deems appropriate and relevant to the case.

*Id.*

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28 The survey data on which this conclusion rests is criticized in Contorno (2014).

It is useful to play out how this section runs. The initial point about the need for parity in cross-examination seems innocuous enough. But the remaining additions are dramatic alterations of the law. These proceedings, which are conducted under federal command, could never be accepted in any judicial proceeding that imposed either civil or criminal sanctions. The right of cross-examination is clearly an important engine of truth, especially when it comes to credibility disputes in a highly charged atmosphere. It may well be that direct cross-examination by the alleged perpetrator is not the proper way to proceed, but to say that it could constitute a potential violation of Title IX presents the exact kind of implicit threat that no government organization should be allowed to make against standard practices in adjudication. Worse still, the alternative that is given is wholly inadequate, for the “recommended” proposal that the questions be first filtered and then asked by some neutral panel is a complete repudiation of the adversary system, especially since any institution fearful of wrath from the OCR can stack any panel with members who share the OCR’s goals. What is missing is any explicit reference to the obvious solution, which allows the lawyer for the “alleged perpetrator” to conduct cross-examination under the standard rules that allow the trier of fact to control for abuse. Instead, the entire tenor of the rules is intended to slant the outcome in favor of the accuser and against the accused. These rules have concrete consequences. Hans Bader of the Competitive Enterprise Institute has compiled strong evidence that colleges, acting under pressure from the OCR, now commonly expel students accused of sexual harassment or assault who are very likely innocent (Bader 2014).

Other rules have the same dangerous effect. Thus the FAQs note: “Any school-imposed restrictions on the ability of lawyers or other advisors to speak or otherwise participate in the proceedings must also apply equally” (OCR, Questions and Answers, 26). This statement carries with it the implication that it is indeed possible to keep individuals charged even from speaking with lawyers, at the time when the accuser may well be receiving advice from the campus officials who conducted, and perhaps instigated, the charges, even months after the events had happened. Yet lost in this shuffle is the asymmetry between the two parties’ interests. The innocent accuser who loses goes home. The innocent accused who is convicted faces expulsion, a raft of lesser sanctions, and a blemish on his transcript that can stay with him for the rest of his personal and professional life. In cases of this sort, the appropriate benchmark is the procedural protections of a criminal trial, not those threadbare procedures recommended by the OCR.

Nonetheless, the OCR continues to push hard on this point by applying its basic guidance norms to dictate the terms of settlement in individual cases. The most recent illustration of its aggressive stance is its interaction with Harvard Law School, no bastion of conservative legal thought. In its own position, the

OCR urged the University to adopt procedures that sharply restricted the rights of persons brought up on charges before the school. The imposition of these procedures brought forth a strongly worded protest by twenty-eight members of the Harvard Law School Faculty, liberals, and conservatives alike, against the ways in which the OCR had extended the scope of Title IX beyond its statutory limits, raising in the process serious constitutional problems.<sup>29</sup> The protest in turn led to some extensive negotiations between the Law School and the OCR, which altered the outcome modestly, but still resulted in outcomes that are wholly without statutory support and subject to serious constitutional challenges.<sup>30</sup> Chief among these outcomes is the OCR's insistence that all these cases be decided on a preponderance of evidence standard, even though the sanctions imposed could involve expulsion from the University.<sup>31</sup> The OCR also takes a

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29 See *Rethink Harvard's Sexual Harassment Policy*, BOSTON GLOBE (October 15, 2014), available at <http://www.bostonglobe.com/opinion/2014/10/14/rethink-harvard-sexual-harassment-policy/HFDDiZN7nU2UwuUuWMnqbM/story.html>:

Among our many concerns are the following:

Harvard has adopted procedures for deciding cases of alleged sexual misconduct which lack the most basic elements of fairness and due process, are overwhelmingly stacked against the accused, and are in no way required by Title IX law or regulation. Here our concerns include but are not limited to the following:

- The absence of any adequate opportunity to discover the facts charged and to confront witnesses and present a defense at an adversary hearing.
- The lodging of the functions of investigation, prosecution, fact-finding, and appellate review in one office, and the fact that that office is itself a Title IX compliance office rather than an entity that could be considered structurally impartial.
- The failure to ensure adequate representation for the accused, particularly for students unable to afford representation.
- Harvard has inappropriately expanded the scope of forbidden conduct, including by:
  - Adopting a definition of sexual harassment that goes significantly beyond Title IX and Title VII law.
  - Adopting rules governing sexual conduct between students both of whom are impaired or incapacitated, rules which are starkly one-sided as between complainants and respondents, and entirely inadequate to address the complex issues in these unfortunate situations involving extreme use and abuse of alcohol and drugs by our students.

30 For a summary of the agreement, see United States Department of Education (2014b). The OCR letter of December 30, 2014 to Dean Martha C. Minow, stating the OCR's view, is available at <http://www2.ed.gov/documents/press-releases/harvard-law-letter.pdf>. The terms of the "Resolution Agreement" are available at <http://www2.ed.gov/documents/press-releases/harvard-law-agreement.pdf>. For criticism of the OCR in these negotiations, see *Harvard Law Pushes Back*, *The Wall Street Journal* (January 30, 2015), available at <http://www.wsj.com/articles/harvard-law-pushes-back-1422663102>.

31 The Resolution Agreement states that Harvard must supply "[a]n explicit statement that the preponderance of the evidence standard will be used for investigating allegations of sexual harassment

very expansive view of what counts as a hostile environment, which includes claims that the Law School is required to take into account off-campus behaviors in organizing its sexual-harassment policy.<sup>32</sup> In addition, it takes the position that “a single instance of rape is sufficiently severe to create a hostile environment” (OCR, Dear Colleague Letter). That assertion is inconsistent with the well-established principle in *Meritor Savings Bank v. Vinson*, 477 U.S. 57 (1986), which provides, in connection with employees, that “[f]or sexual harassment to be actionable, it must be sufficiently severe or pervasive ‘to alter the conditions of [the victim’s] employment and create an abusive working environment’” (*id.* at 67). Recall that the issue in these cases is the question of *workplace* sexual harassment. Presumably the same standard of pervasive behaviors should carry over from Title VII employment discrimination cases to cases of sexual harassment by students. Indeed, if anything, it should be more difficult to make out a case of sexual harassment among students in the university environment where a law school has far less control than an employer. The overreaching in the OCR’s position is evident, but Harvard chose not to go to the mat on this matter, precisely because the rest of the University could not survive the loss of federal funds for its massive university-wide research programs. It is clear that the guidance process is used effectively to leverage settlements in individual cases that go far beyond what existing law under Title IX requires, without ever addressing the serious constitutional challenges like those raised in the letter of the twenty-eight Harvard Law School professors. Once again the obvious need in cases of this sort is to find some way to challenge the exercise of regulatory authority, without depriving private actors of information that enables them to carry out their business in a rational and consistent fashion.

There is a similar pattern of abusive guidance behavior in the OCR’s effort to reshape the rules applicable in K-12 education with respect to disciplinary procedures (Epstein 2014). In this instance, the threat came in the form of a “Dear Colleague” letter on January 8, 2014, issued by the Civil Rights Division of the Department of Justice (DOJ) and the OCR, which addressed the alleged disparate impact of disciplinary action on minority school children. The argument is that a disparate impact claim is established because of the higher incidence of discipline of minority students relative to the white student

or violence.” (Resolution Agreement, 3). The accompanying letter makes no effort to justify this or any other standard.

32 The Resolution Agreement requires that Harvard prepare “[l]anguage clarifying that the University has an obligation to consider the effects of off-campus conduct when evaluating whether there is a hostile environment in a University program or activity.” (*id.* at 2).

baseline. As is typical in these situations, cases of overt, i.e., disparate treatment, are not the source of controversy. Instead the key issue arises “if a policy is neutral on its face—meaning that the policy itself does not mention race—and is administered in an evenhanded manner but has a disparate impact, i.e., a disproportionate and unjustified effect on students of a particular race.”

That view is not supported by either the operative statutory language of Title IV or Title VI of the Civil Rights Act. The former, because it is largely concerned with the process of desegregation by dealing with personnel advice and specialist hiring, seems to have no relevance at all. The latter, Title VI, is couched in the same general language used in Title IX when it states: “No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.”

It is, of course, something of a stretch to say that this position ushers in disparate impact analysis, given that these differences by race are common everywhere. Do grade differentials by race set out a prima facie case of discrimination? In response to matters like this the Supreme Court has hinted that disparate impact analysis is inappropriate here,<sup>33</sup> but it has not so ruled. The disparate impact regime as applied to employment imposes heavy costs by ruling out tests that have a high, but far from perfect, predictive value. The requirements of business necessity, associated with employment testing in *Griggs v. Duke Power Co.* 401 U.S. 424 (1971), sets up too high a bar in the face of these pervasive differences, for it could mean, for example, the elimination of all PSATs and SATs.

The business necessity test was referred to in recent Supreme Court decision *Texas Department of Housing and Community Affairs v. The Inclusive Communities Project*, 135 S. Ct. 2507 (2015), which by a narrow five-to-four vote sustained a disparate impact count under a disparate-impact claim under §§ 804(a) and 805(a) of the Fair Housing Act (FHA), 42 U.S.C. §§ 3604(a), 3605(a). There the majority of the Supreme Court recognized that it had “to give housing authorities and private developers leeway to state and explain the valid interest served by their policies.” *Inclusive Cmty.*, 135 S. Ct. at 2522. How this translates into the educational area is, at least, unclear. But it is worth noting that the majority of the Court remanded the case for a reexamination

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33 See, e.g., *Guardians Ass'n v. Civil Serv. Comm'n of City of New York*, 463 U.S. 582, 613 (1983) (O'Connor, J., concurring) (“If, as five Members of the Court concluded in *Bakke*, the purpose of Title VI is to proscribe only purposeful discrimination . . . , regulations that would proscribe conduct by the recipient having only a discriminatory effect . . . do not simply ‘further’ the purpose of Title VI; they go well beyond that purpose.”).

of the highly burdensome degree that had been entered by the District Court, so that it will probably take time to see how this particular test plays out.

A strong argument can be made that the cautionary words in *Inclusive Communities* could have some real bite, because of the very broad reading given to disparate impact, given that the OCR offers *no* evidence that any of the individual disciplinary determinations made in any school district are themselves the product of some form of discrimination. At this point, the disciplinary rules have no disparate impact whatsoever on any individual student if they impose uniform sanctions for the same types of behavior on all parties, regardless of race. Put otherwise, OCR offers no reason why the higher incidence of punishment should be regarded as “unjustified” when it responds to a higher frequency of improper behavior. The alternatives are surely worse, if it means that minority students should go unpunished for admitted violations, or if white students should be punished for offenses that they did not commit. Clearly this is a form of massive overreach, but it is a brave school district that will not put in place the various procedural devices demanded by the OCR and DOJ, notwithstanding the heavy costs of implementation.

A similar imposition of disparate impact rules through administrative guidance is found in the Equal Employment Opportunity Commission’s (EEOC’s) “Enforcement Guidance Consideration of Arrest and Conviction Records in Employment Decisions Under Title VII.” The rule in question starts from the familiar assumption that there is a disparate impact using arrest or conviction information, which is not justified by any form of business necessity. From that premise, the EEOC concluded that the categorical exclusion of convicted felons from employment could give rise to a disparate impact claim, even though all felons are treated the same, regardless of race. It also thought that it was necessary to conduct a case-by-case, individualized assessment of the criminal record of each potential applicant, even though it is quite likely that EEOC’s recommendations could increase hiring costs, while compromising the health and safety of the clients, often people also in a vulnerable position who come into contact with these employees. Needless to say, the EEOC was not prepared to reimburse any employers who were found vicariously liable for any harms to innocent third parties caused by these protected workers.

### **3. THE OBSTACLES TO *DE NOVO* REVIEW: STANDING, FINALITY, AND RIPENESS**

The question then arises on how best to challenge these guidances in court. The current situation treats all guidances like preliminary activities that take place outside the watchful eye of any court. The basic assumption in this context is

that there will be time enough to mount some form of judicial challenge when a regulation is made final or when an enforcement action is brought against any individuals. But until that time, nothing binding has been done, and therefore there is no reason for courts to want to intervene.

As should be clear from what has been already said, the complex and exhaustive guidances now routinely supplied by government agencies carry a lot of sizzle long before regulations are promulgated or enforcement actions are begun. As to the former, no sensible agency will incur the costs of issuing a final regulation that is subject to attack if it can secure high levels of compliance with its nonbinding approach that only the hardy will disregard. Modern agencies are well aware that the exhaustive directives require various institutions not only to avoid wrongdoing, but also to put into place extensive internal institutional structures and controls to which it can point in the event that some dispute turns sour and ends up in litigation. The internal structures count as a very heavy insurance policy that provides some reduction in sanctions that can otherwise be imposed. It is exceedingly difficult for any General Council or Chief Executive Office to decide against these steps, knowing the consequences that will follow down the road. So by holding back just a bit, an aggressive agency knows that it can secure for itself complete insulation from external scrutiny by backing off from some decisive actions that may prompt judicial review.

Even if an institution tries to challenge an agency in court, the current structure of administrative and constitutional law gives any government agency two powerful tools to fend off litigation. The first of these is the ubiquitous requirement of standing, by which only persons who suffer a separate and disproportionate pocketbook injury are entitled to their day in court. The second is the doctrine of finality, which holds generally under section 704 that judicial challenges are only proper against “final agency action” (5 U.S.C. § 704). The standing doctrine, with its constitutional pedigree, is of broad application and is not limited to cases of final agency orders. Conversely, the want of a final agency order is often taken as conclusive evidence that there is not an individualized grievance that supports a private right of action.

*Standing.* Within the context of administrative law, there is a close connection between the rules of standing and those on agency finality. The nexus is illustrated in a Texas suit to block the EEOC’s enforcement of its disputed guidance. *Texas v. EEOC*, Civil Action No. 5:13-CV-255-C (2014). The guidance was not a final agency action reviewable by a court under the APA. APA § 702. There was therefore no standing to challenge the particular order.

In these cases, the modern interpretation of the standing requirement that dates back to the companion 1923 decisions in *Frothingham v. Mellon* and *Massachusetts v. Mellon*, 262 U.S. 447 (1923) (combined cases), blocks the

one sensible move in this area: a facial challenge to any regulation that anyone thinks lies outside the competence of a commission. But these decisions, which require at the least that a plaintiff show some special injury from government action, only illustrate how the pervasive judicial misunderstanding of the standing rules has thwarted the intelligent administration of the law.

I have written at length, albeit in vain, on this issue elsewhere,<sup>34</sup> so it is necessary only to sketch the essential points here. The first of these is that the term “standing” nowhere appears in the Constitution, whose applicable provision says that “The judicial power shall extend to all cases, in law and equity, arising under this Constitution, the laws of the United States, and treaties made, or which shall be made, under their authority.” U.S. CONST. art. III, § 2, cl. 1. These words are hardly restrictive. The phrase “all cases” is highly inclusive, and the only thing that it clearly excludes are advisory opinions, which are not at issue when a party seeks to enjoin government action on the grounds that the applicable agency has exceeded its statutory or constitutional authority.<sup>35</sup> The words “in equity” are in fact exactly calibrated to cover these cases because it is common to allow derivative actions in equity to limit the unlawful action of private corporations, charitable organizations, municipal governments and states. These actions impose no excessive burdens on the judicial system because they involve facial challenges that usually can be resolved on the paper record, without having to wade through complex factual issues that have no bearing on the basic legal dispute.

The great advantage of these actions is that they permit a separate resolution of the question of government authority by a party that does not have to put itself at risk of serious government sanctions. It is quite clear that in most cases guidances will not provoke a strong litigation response, for in most instances they provide welcome assistance. But in the cases where they do not, as with the Texas situation, the definitive ruling of the court is necessary to allow people to decide how to organize their behavior before litigation strikes. It is highly doubtful that the OCR could have extracted from Harvard Law School the settlement it did if the OCR’s guidance statements could have been challenged earlier by, not just Harvard, but by *any* interested party who believed that the EEOC went beyond its power. That claim need not be brought by any particular state or private institution, but could be maintained by any umbrella organization, which thus creates a useful defensive buffer zone between the EEOC and

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34 Epstein (2013); Epstein (2002, p. 17); Epstein (2001, p. 1).

35 See *Hayburn’s Case*, 2 U.S. 409 (1792), which was followed shortly by a Letter from the Supreme Court Justices to George Washington (August 8, 1793), <http://founders.archives.gov/documents/Washington/05-13-02-0263> (refusing to comment on the United States’ treaty obligations with Great Britain and France). For further discussion, see Epstein (2013, pp. 103–05).

individual employers. It is also easy enough to open up the proceedings to amicus curiae briefs which can further the information base that a court can draw on to make its decision, or to consolidate multiple challenges to the same guidance. Overcoming the standing obstacle allows for an earlier resolution of any challenges to agency authority, which thus reduces the delays and uncertainties that necessarily arise if the parties subject to guidance must wait until the adoption of final regulations or any immediate enforcement action.

*Finality.* The second obstacle also came into play in the Texas litigation, where the case was not ripe for review. Only if there is finality may an individual aggrieved party seek declaratory relief, whether or not this issue is likely to recur numerous times, given the scope of the guidance and the pervasive nature of the underlying issue. The rules targeted in *Inclusive Communities* of course apply to Texas as a state, many of whose agencies have long had *per se* bans on hiring workers with criminal records, but the issues could not be resolved in advance of any particular dispute in which serious sanctions could be imposed. There is good reason to wait with respect to adjudication if additional facts could help clarify the respective rights. But in this instance, there is little information that can be gained by waiting because the question of whether the *per se* prohibition is authorized under Title VII is one that could, and should, be settled without any case-by-case analysis. Indeed, the case has an added measure of complexity because the EEOC has explicit statutory authorization to issue only procedural regulations, not substantive ones,<sup>36</sup> so that it is an open question whether the EEOC should be able to issue guidances on matters on which it is barred from issuing substantive regulations.

The legal analysis of the finality defense thus traverses in theory the same ground as the standing issue. But the case law development is somewhat different. The initial point of departure in this area is the Supreme Court decision in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), where the question before the Court was whether a drug company could challenge a final regulation of the FDA relating to the labeling of prescription drugs. The regulation question required companies that sold under a “proprietary label” also to list its “established name”—that supplied by the FDA—in type at least half as large as the proprietary name on all labels and other printed materials. The purpose of the regulation was to make physicians aware of the full range of choices for the drug in question. The final regulation required that the established name be used every time that the proprietary name was used, which was argued to be beyond the FDA’s powers.

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36 42 U.S.C. 2000e-12(a) (“The Commission shall have authority from time to time to issue, amend, or rescind suitable procedural regulations to carry out the provisions of this subchapter.”). The subchapter in question is Subchapter VI, dealing with equal employment opportunities.

The Supreme Court sustained the challenge working within the same framework that is still used. For its first point, the Court recognized the presumption in favor of judicial review in the absence of some clear evidence to the contrary in the legislation. That result makes good sense when all the legal issues are set up for judicial resolution without further action by any other parties. There is, in other words, no need to bear the costs of delay when that delay will not supply better information for the decision at hand.

That basic concern informed the narrower question of whether the publication of the regulation counted as a final agency action subject to immediate review. In this instance, it was clear that the regulation was neither temporary nor subject to revision, for it took effect immediately on publication. It was instead a “definitive” statement of the agency position (*id.* at 151). The Court did not want to dispense with finality given its fear that parties might litigate merely “abstract disagreements over administrative policies,” or so that it would be impossible to treat the action as if it were “unripe” for review when nothing was left to be done on the matter (*id.* at 148). It is well known that drug labeling is a complex business that has to be implemented separately for every product line long in advance of actual sales and production, and it is surely the case that “[t]o require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily.” (*id.* at 153). In opposition, the government claimed that allowing for this kind of action “may delay or impede effective enforcement of the Act.” (*id.* at 154). In response, the Court rightly answered that the earlier resolution of these questions could only improve enforcement of the Act. If the government lost, then the unnecessary expense is saved. If the government won, earlier notice will lead to higher levels of compliance and lower administrative costs.

It should be clear that nothing is new in this decision, which only brings into administrative law the usual questions of balancing the errors that is faced by any court of equity asked to decide on the question of injunctive relief. On the timing question, the order can come either too soon or too late. In this instance, the prompt decision does not reduce accuracy, but it does reduce the sum of compliance and administrative costs. Finality therefore is a convenient point to mark the line, and there is nothing about this decision that requires that injunctions be granted, for example, when the regulation is in flux, because at that point the balance of convenience flips over: now it is possible that the usual give and take within an administrative agency could ease the problems before any regulation is published.

The question then arises of what happens when there is no final regulation, but only the publication of the nonbinding guidance subject to all the caveats mentioned above. To be sure, these could be changed at some time in the future, but the probability of change is very slight, and it would indeed be

most unwise to imagine an administrative procedure that allowed individuals to make *ex parte* applications for express exemptions from the rule, which would only distort the competitive balance among rival firms. In this setting, the publication of these often greatly detailed guidances are in practice final, even if the possibility of some modification is held open solely to ward off the prospect of judicial review.

In this new state of affairs, it is necessary to make the same balance of convenience analysis as before. It is surely a somewhat harder case structurally to abandon the bright line rule of the formal regulation. Of course, it is harder to know just how permanent any individual guidance turns out to be. But by the same token, the losses on the other side are still major. To put the point in probabilistic form, suppose that the only uncertainty deals with the potential enforcement of the sanctions set out in the regulation. There is always an argument about the durability of these guidances, but many of the key ones last for long periods of time without any material changes. The FDA guidelines on guidances set out above are the same as they were in 1995. So in most cases they are (near) final in fact, even if they are variable in law.

At this point, the correct analysis asks how much slack is created in the system by making a guidance nonbinding. Let us suppose that its permanence is over 90 percent—a most plausible figure. At this juncture any small change in the level of sanctions can result in the situation where a somewhat increased set of stated sanctions for a guidance has exactly the same consequences—or, given uncertainty, worse—than a lesser set of sanctions that go along with a final regulation. The balance of equities switches therefore, but not by much. As a matter of principle, a change in the APA that allows for all challenges of guidances, confined to major issues, is the correct way in which to deal with strategic government mischief.

The harder question is whether the term “final” could be read as covering cases “final in fact” as opposed to “final in law.” Given the risk of evasion, there is good reason to allow this approach to be taken with respect to a legal confection that was not in anyone’s contemplation on the passage of the APA. The point here is perfectly consistent with basic principles. When private parties engage in conspiracies to commit murder or to violate the antitrust laws, we do not require them to have a binding contract, with offer and acceptance and an intention to create legal relations. We first make these arrangements unenforceable as a matter of common law, and then back that decision up with punishments for entering into nonbinding arrangements under either the criminal law of conspiracy or under the antitrust laws. The cumulative sanctions are thought appropriate to deal with the severity of the problem that these forms of coordinated behavior pose.

It is possible to apply exactly that result here. The most dangerous assumption in administrative law is that all government officials at all times act only to advance some rarified conception of the public good. That optimistic view is true sometimes, but not all times, and the frontal attack on the guidance gives all the right incentives to private actors to sort out the difference. A single strategic step backward by an astute government agency should not give it the breathing room that is accorded under the current case law.

There is here an instructive parallel, moreover, to the cases of direct enforcement against particular parties—*Sackett v. EPA*, 132 S. Ct. 1367 (2012)—an enforcement action that did not involve a general guidance, but which raised many of the issues at stake here. In that case, the Clean Air Act prohibits the discharge of any pollutant by any person into the navigable waters of the USA. In this instance, the Sacketts wished to build on private plot of land two thirds of an acre in size in Bonner County, Idaho. Their building site lay close to Priest Lake, but was separated from it by several other houses, built closer to the lake. To prepare the site for construction, they filled in part of the site with rock and dirt, which elicited a compliance order from the Environmental Protection Agency that carried with it the following warning. When the government prevails in its action, it may recover from private parties a civil penalty of up to \$37,500 for each day of violation. If the government prevails after giving the compliance order, the penalty doubles.

In this particular situation, the government always has the option to issue a compliance order, which imposes the doubling. It is also in position to make some initial findings that some violation has taken place. Under any sensible procedure, the government should allow the private party to challenge the findings, especially in this instance where the merits weigh strongly against the government. Using the general principles of balancing equities, the proper response is to monitor the situation at a distance, and then to impose some (modest) fine on the Sacketts only if clear evidence of lake pollution is found. The dirt in this case is not a nuclear power plant, so one can wait for the harm to occur or be imminent.

The balance of equities for the Sacketts is the exact opposite result from *Abbott Laboratories*. There is no reason to force an early resolution of this dispute by restricting digging and filling on private land that in over 99 percent of cases in which the building will do no harm. Nonetheless, the EPA denied the Sacketts any hearing to discuss the matter, and then resisted the demand for declaratory and injunctive relief prior to any enforcement action undertaken by the EPA, which was denied by the District Court and the Ninth Circuit. *Sackett v. EPA*, 622 F.3d 1139 (2010). The Supreme Court reversed the decision below and treated the compliance order as final, given that there was an order to restore the site to its original condition that required a substantial expenditure

of funds, and hampered any efforts of the Sacketts to obtain a permit from the Army Corp of Engineers (*id.* at 1371–72).

The key point in the case is that the structure of fines leaves the Sacketts no option but to comply. To be sure, they could decide to continue to build, and then resist an enforcement action, just as parties subject to a guidance could continue to work as if the guidance had never been issued. But that course of action is worse than playing with matches. Any appeals process could take years to complete, especially if the agency decides, as it always can, to slow things down. So posit a 99 percent chance of winning a case that carries with it a \$75,000 daily fine. Within one year, the sum owed the government is \$27,375,000 plus any private expenses incurred. In effect the rule in question means that the Sacketts will always choose to pay the lesser sum of clean-up costs incurred at the initial stage of the project, which are likely to be far lower than anticipated fines, even if their challenge is overwhelmingly strong. And if by some miracle the numbers did not work out, simple delay by the government could tighten the noose in ways that could not trigger any expedited review. So long as the EPA has control over the daily fines and the period of uncertainty, it can make it prohibitively expensive for anyone to disobey their rule. And if this result is true for cases in which work has begun, it is even more true for cases where nothing has been done when notice is received. Now costs of clean up are zero, and it is hard to imagine any project that could justify the extraordinary risk that EPA fiat could impose.

Now just vary the situation once more, and assume that the EPA has only issued a nonbinding guidance that it will in extraordinary cases consider a lesser fine. Does that really change the situation? Or does it just create an idle loophole designed to evade the restriction in question? The answer is that it is a strategic retreat that is intended to insulate the guidance from review by stepping back from the finality of its compliance regulation. It would be a travesty if a reduction in the expected probability of penalty by one percent, say, could so transform the legal environment. The logic of *Sackett* reveals the same prospect of abuse for enforcement actions that there is for final regulations. The declaratory judgment should apply to both. In my view, this should be done under current law in order to avoid the constitutional challenges that lurk behind the *Sacketts'* Fifth Amendment Due Process challenge, which is *not* bound by the finality tests built into the APA. No one receives due process if the fines can be set so high that it is always cheaper to comply with an order than to litigate it in any form at any time. What works for the individual case works for the guidance as well, and even more so. *Sackett* is one case, but now suppose that the EPA published a guidance that indicated that anyone who moved dirt with one half mile of Priest Lake might well be found in violation of the Clean Water Act. Is it possible that the *broader* effect of the guidance would exempt it from

constitutional challenges? Is it so much to ask the EPA to give hearings when requested? And if it decides just to impose the restrictions on new developments, at least in frivolous cases, how is this not also a violation of the temporary takings prohibition that was announced (but largely ignored thereafter) in *First English Evangelical Lutheran Church of Glendale v. County of Los Angeles*, 482 U.S. 304 (1987)? Needless to say, none of this scheming would be tolerated in areas where the Supreme Court cares about the outcome. Thus in *Patsy v. Board of Regents*, 457 U.S. 496 (1982), Justice Marshall held that the exhaustion of administrative remedies was not a “prerequisite to an action under 42 U.S.C. § 1983,”<sup>37</sup> which offers all litigants, at least in civil rights cases, a direct shot at the judicial system (*Patsy*, 457 U.S. at 507). In this instance, the simple question is whether the scheme used in *Sackett*, or in any guidance that counts as a “deprivation of any rights, privileges, or immunities secured by the Constitution and laws,” should be neutered because the government reserves some power to back off its enforcement, which it never intends to exercise. The question should answer itself, and declaratory and injunctive relief should be allowed against guidances just as they should be allowed against preliminary orders in enforcement proceedings.

#### 4. CONCLUSION

This extensive analysis shows that modern interpretation of the APA is seriously wanting. Yet even that point is not the source of the opposition to the regulations and guidances that this essay critiques. The basic objection goes to issues of the rule of law. As I have argued elsewhere, that requirement is ubiquitous throughout all legal systems, without regard to their substantive orientation.<sup>38</sup> My objection to modern administrative law is that its use of guidance allows for administrative agencies to enjoy de facto complete and unreviewable discretion on matters of law. Others often share this objection, and recommend that notice and comment hearings be provided to redress the balance, or that various forms of deference be used to soften the blow of arbitrary administrative decisions. But these feeble remedies are no answers to the systematic abuses of public authorities that can take place with guidances just as they can take place in individual enforcement actions. It cannot be right for agencies to determine

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37 “Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress. . . .”

38 See Epstein (2011), building on Fuller (1966).

the extent of their own jurisdiction, to reverse without explanation their prior decisions, to expand the scope given to policy judgments and interpretative rules, and to announce by guidance a set of sanctions so severe that no sensible person will challenge them in court if denied the opportunity for *de novo* review.

The current rules on standing and final judgment too often require individuals to adhere to a system that is nowhere developed in the APA, and they all too often serve as an agency's device to announce onerous legal regimes that have a huge coercive effect on public and private institutions that have no effective way to challenge these ordinances, given the tough rules on standing, ripeness, and finality, unless they are willing to throw themselves under the government's bus. No public official should be allowed to expand the scope of its power through nonbinding actions whose actual impact can be every bit as severe as a final agency action, be it by regulation or enforcement action. Some form of administrative state is absolutely essential in modern society, so that the battle here is not over whether we shall have an EPA, an FDA, and perhaps even an EEOC. But there is no reason why these organizations should be able to avoid direct, *de novo* review of their actions, whether stated in the form of a guidance or a final regulation.

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