### DOMESTICATING GUIDANCE

BY

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\*Request Abstract.

### I. Introduction

Professor Funk learned much of his administrative law, as I did, through his important responsibilities in the general counsel's office of a government agency. And that has shown particularly in his scholarship about the soft law documents – statements of general policy and interpretive rules – that today one generally finds discussed under the rubric "guidance." These are agency texts of less formality than hard law regulations adopted under the procedures of 5 U.S.C. §553, that inform the public how an agency intends to administer its responsibilities, as a matter of policy or (what may seem just one instance of that) via the interpretation of its governing statutes. The APA is explicit that in adopting these texts, agencies are not required to use the notice-and-comment process ordinarily required for the adoption of regulations having the force of law; but it also signals that, like agency caselaw precedent, guidance may be relied upon to a private party's disadvantage if it has been published or come to its actual notice. Guidance documents, revealing agency policy and perhaps showing the way to safe compliance, can structure the behavior of agency staff and be highly influential for the regulated; but they are not in themselves enforceable against actors in the outside world – hence, soft law.

Documents like these are common world-wide in regulatory contexts. The reason is not far to seek. One can imagine a hierarchy of law-like documents, each characterized by a certain

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<sup>&</sup>lt;sup>1</sup> 5 U.S.C. §552(a)(2). This endorsement of their potential use led me to propose calling guidance instruments "publication rules," Peter Strauss, Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Function, 53 Admin. L. Rev. 803 (2001); in his Primer on Nonlegislative Rules, 53 Admin. L. Rev. 1321 (2001), Professor Funk convincingly suggested that this locution could be misleading, substituting "nonlegislative rules," as others also have. Since then, "guidance" has become the accepted term for describing the universe of interpretive rules and general statements of policy.

level of generality resolving questions unaddressed by its hierarchical superior, yet itself leaving unaddressed questions of greater detail.

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

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

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

means of securing that result. But a necessary result, then, is uncertainty just what technologies will satisfy the regulatory demand.

Guidance may be created by agency bureaus and staff (that is, it need not be issued or approved by the agency head); it takes many forms and is issued in a volume that dwarfs that of agency regulations.<sup>2</sup> One frequent use is to inform the public (the regulated especially) about specific approaches agency staff has determined will meet the standards a regulation has set; since the regulation (not the guidance) sets the obligation, this is "soft law" and one can attempt to show compliance in other ways. Guidance may also inform the public of the interpretation the agency places on a statute or regulation whose language is susceptible of more than one meaning; again, if the agency is using guidance correctly, the legal obligation is that stated by the law or regulation and *not* what the guidance instrument itself may say. Guidance may also set out policy paths the agency intends to take, enforcement priorities it anticipates following, or rules of conduct it expects its staff to follow. None of this is obligatory on the public, although it may provide useful information and, if it has been included in the agency's electronic library, the agency is permitted to give it presumptive force against outside parties who might be

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<sup>&</sup>lt;sup>2</sup> In 1992, "(1) formally adopted regulations of the Internal Revenue Service occup[ied] about a foot of library shelf space, but Revenue Rulings and other similar publications, closer to twenty feet; (2) the rules of the Federal Aviation Administration (FAA), two inches, but the corresponding technical guidance materials, well in excess of forty feet; (3) finally, Part 50 of the Nuclear Regulatory Commission's regulations on nuclear power plant safety, in the looseleaf edition, consume[d] three-sixteenths of an inch, while the supplemental technical guidance manuals and standard reactor plans in the same format stack[ed] up to nine and three-fourths inches." Peter L. Strauss, The Rulemaking Continuum, 41 Duke Law Journal, 1463, 1469 (1992)(citations omitted). The complaints that, increasingly, the obstacles to notice-and-comment rulemaking are increasingly leading agencies to use guidance in situations in which regulations would be more appropriate, cf. Todd Rakoff, The Choice Between Formal and Informal Modes of Administrative Regulation, 52 Admin. L. Rev. 159 (2000), suggest that today (when electronic data bases complicate similar measurements) the contrast would, if anything, be more dramatic. Any suggestion that the use of "guidance" is a product of bad faith agency behaviors seeking affirmatively to evade the requirements of rulemaking have been repudiated, not only in the scholarship of Professor Funk but also in recent empirical work underlying an important set of recommendations by the Administrative Conference of the United States. ACUS Recommendation 2017-5, Agency Guidance Through Policy Statements, 82 Fed. Reg. 61734 (Dec. 29, 2017); Nicholas Parrillo, Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries, 36 Yale J. Reg. 165 (2019); see also Daniel Walters, The Self-Delegation False Alarm: Analyzing Auer Deference's Effect on Agency Rules, 119 Colum. L. Rev. 1 (2019)("agencies did not measurably increase the vagueness of their writing in response to Auer. If anything, rule writing arguably became more specific over time")

disadvantaged by its use.<sup>3</sup> Within the agency, however, the agency leadership and its staff may regard it as internal law: if a regulated party has followed guidance in its actions, then the staff will not (and should not) feel free to accuse it of non-compliance; if a member of staff does not act as agency guidance directs, she might be subject to internal discipline.

Perhaps surprisingly given how common they are, and how important they are in the world of regulation – to the regulated, to regulatory beneficiaries and, perhaps especially, to agency leadership seeking to coordinate the activities of its staff and to assure their predictability, uniformity and regularity – guidance documents are not often the subject of litigation; and when they are, their treatment is contentious and confused. Professor Funk<sup>4</sup> and I,<sup>5</sup> with a few others,<sup>6</sup> are prominent among the scholars who have written at all often on the subject, and others who frequently encountered it from inside government<sup>7</sup> have agreed with our preference that this issue be resolved by what Prof. David Franklin characterized as "the short

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<sup>&</sup>lt;sup>3</sup> 5 U.S.C. 552(a)(2), after requiring that guidance (and other matters not relevant here) be made "available for public inspection in an electronic format," ends with the statement that "A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than an agency only if—

<sup>(</sup>i) it has been indexed and either made available or published as provided by this paragraph; or

<sup>(</sup>ii) the party has actual and timely notice of the terms thereof.

<sup>&</sup>lt;sup>4</sup> Final Agency Action After Hawkes, 11 New York University Journal of Law & Liberty 285 (2017); Make My Day! Dirty Harry and Final Agency Action, 46 Env. L. 313 (2016); Legislating for Non-Legislative Rules, 56 Admin. L. Rev. 1023 (2004); When is a Rule a Regulation? Marking a Clear Line Between Non-Legislative Rules and Legislative Rules, 54 Admin. L. Rev. (2002); A Primer on Non-Legislative Rules, 53 Admin. L. Rev. 1321 (2001).

<sup>&</sup>lt;sup>5</sup> Administrative Justice in the United States 303-05, 352-56, 501-02 (3d ed., Carolina Academic Press 2016); Implications of The Internet For Quasi-Legislative Instruments Of Regulation, 28 Windsor Yearbook of Access to Justice 377 (2010); Publication Rules in the Rulemaking Spectrum: Assuring Proper Respect for an Essential Element, 53 Admin. L. Rev. 803 (2001); The Rulemaking Continuum, 41 Duke Law Journal, 1463 (1992).

<sup>&</sup>lt;sup>6</sup> Notably, Robert A. Anthony, Three Settings In Which Non-Legislative Rules Should Not Bind, 53 Admin. L. Rev. 1313 (2001); A Taxonomy Of Federal Agency Rules, 52 Admin. L. Rev. 1045 (2000); Pro-Ossification: A Harder Look At Agency Policy Statements, 31 Wake Forest L. Rev. 667 (1996); "Interpretive" Rules, "Legislative" Rules and "Spurious" Rules: Lifting the Smog, 8 Admin. L.J. Am. U. 1 (1994); Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like -- Should Federal Agencies Use Them To Bind The Public?, 41 Duke L.J. 1311 (1992); Which Agency Interpretations Should Bind Citizens and the Courts?, 7 Yale J. on Reg. 1 (1991). and Ronald Levin, Rulemaking and the Guidance Exemption, 70 Admin. L. Rev. 263 (2018); Nonlegislative Rules and the Administrative Open Mind, 41 Duke L. J. 1497 (1992).

Cass R. Sunstein, "Practically Binding": General Policy Statements and Notice-and-Comment Rulemaking, 68 Admin.L.Rev. 491 (2016)(formerly Administrator, Office of Information and Regulatory Analysis); E. Donald Elliott, Re-Inventing Rulemaking, 41 Duke L.J. 1490 (1992).

cut," simply asking whether notice and comment procedures had been used and, if not, refusing the guidance the legal effect a regulation would have. The paragraphs that follow are informed by that experience and scholarship, and also by the appearance on the Supreme Court's docket, as this essay was being written, of a case that appears likely to address a question much disputed in recent years: if an agency has used guidance to interpret one of its regulations, must a court reviewing an application of that interpretation accept it, if the regulation's language is susceptible of that interpretation? In Auer v. Robbins 10 the Supreme Court ruled that a court reviewing an agency's interpretation of its own regulations should accept that interpretation so long as it is not "plainly erroneous or inconsistent with the regulation." 11 Critics 12 fear that this lenient attitude encourages agencies to write their regulations loosely, permitting future policy changes via guidance, without the inconvenience and expense of further notice-and-comment proceedings. Proponents argue that the ruling supports the agency's much greater familiarity with the intricacies of its responsibilities overall and its primary incentive to regulate for the current day with as much clarity as its knowledge permits; evidence of the feared encouragement to laxity, they say, is simply missing. Important to note at the outset is what this essay is not - acomprehensive critical review of the literature such as others have essayed. While it has points of considerable tangency with other writings on the subject, <sup>14</sup> it essentially continues to develop

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<sup>&</sup>lt;sup>8</sup> David A. Franklin, Legislative Rules, Nonlegislative Rules, and the Perils of the Shortcut, 120 Yale L.J. 276 (2010).

<sup>&</sup>lt;sup>9</sup> Kisor v. O'Rourke, No. 18-15, certiorari granted sub nom. Kisor v. Wilkie, December 10, 2018.

<sup>&</sup>lt;sup>10</sup> 519 U.S. 452 (1997).

<sup>&</sup>lt;sup>11</sup> At 461.

<sup>&</sup>lt;sup>12</sup> Notably the late Robert Anthony, note 6 above; see Parrillo, note 2 above, 36 Yale J. Reg at pp. 175-76 and their footnotes.

<sup>&</sup>lt;sup>13</sup> E.g., Mark Seidenfeld, Substituting Substantive for Procedural Review of Guidance Documents, 90 Texas L. Rev. 331 (2011).

<sup>&</sup>lt;sup>14</sup> Agreeing, for example, with Prof. Seidenfeld's ultimate conclusion, ibid., that finding a route to substantive review of important guidance to which agencies are seriously committed is far preferable to finding procedural fault with guidance documents not the product of notice-and-comment rulemaking; and with Nina Mendelson, Regulatory Beneficiaries and Informal Agency Policymaking, 92 Cornell L. Rev. 397 (2007) that the importance of guidance to those on whose behalf regulation occurs counsels finding means for permitting their disputing of its merits (as distinct from the procedures by which it is formulated).

the view of the issues my earlier writings have expressed, and which has many points of agreement with Professor Funk's many writings on the subject.

# II. IS "GUIDANCE" A SINGULAR CONCEPT?

The APA does not separately define "general statements of policy" and "interpretative rules" – its definition of "rule" in 5 U.S.C. §551(4) mentions neither while readily encompassing both, but in four places<sup>15</sup> the APA refers to them separately, as if there might be a difference, but in conjunction. Is there a difference between the two types?

This question is at the heart of Ronald Levin's very recent analysis in the pages of the Administrative Law Review, 16 and he persuasively makes the case that "guidance" should be treated as a unitary concept. To be sure, sometimes it is used to convey interpretations of other documents, rules or statutes, with which the public may be concerned, and the impact of those interpretations on the meaning of the law (statute or regulation) being interpreted is a distinct question. Conveying a policy, whether about enforcement or program development, does not speak directly to law's meaning. In that sense these two guidance types are distinct. But in no respect does the APA suggest that the procedures necessary for their development differ from one another. Both are forms of soft law that may influence but cannot in themselves properly control private behavior. For each, it is impermissible for the agency to use it as if it did embody an independent legal obligation, and the agency must be willing to reconsider each if challenged in an appropriate proceeding – showing, however summarily, some reason for maintaining its position in the face of that challenge if it does continue to adhere to it. Procedurally, then, they are identical. And Professor Levin's article strongly argues that separate treatment has been a practical failure, that no manageable standard different from the standard for assessing the procedural adequacy of "statements of general policy" has emerged for "interpretative rules."

<sup>15 &</sup>quot;statements of general policy or interpretations of general applicability," 5 U.S.C. §552(a)(1)(D); "statements of policy and interpretations," §552(a)(2)(B); "A final order, opinion, statement of policy, interpretation, or staff manual or instruction," §522(a)(2)(E); and "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice," §553(b)(3)(A).

<sup>&</sup>lt;sup>16</sup> Rulemaking and the Guidance Exemption, 70 Admin. L. Rev. 263 (2018).

Professor Robert A. Anthony's scholarship, of which Professor Funk has been more accepting than I, forcefully stated a contrary position, sharply distinguishing interpretive rules from general statements of policy.<sup>17</sup> Interpretive rules, he argued, take a legal position on the meaning of a statute (his analysis dealt, almost exclusively, with the interpretation of statutes, and not agency regulations), and he saw no greater reason for the agency to entertain others' views about its interpretation than it would have to consult with them about positions taken in its briefs. Courts might ultimately say whether its interpretation was sustainable or not, but in its own proceedings the agency was entitled to treat those who might be affected by the interpretation as bound by it. It had no obligation, as Professor Levin observed in a contemporary critique, 18 to pretend to open-mindedness on the matter. Levin's contrary view, now fully developed in his recent analysis, was that "[w]hich label the agency uses should have little effect on the public's right to be heard, because roughly the same procedural requirement comes into play either way. That requirement consists in a duty to give fair consideration to challenges that private parties subsequently raise against the determinations contained in the rule." And §552's obligations of publication, and permission to give the soft law presumptive effect against persons outside the agency if published, <sup>20</sup> are identical for each.

Respecting general statements of policy – that is, soft law that did not purport to attach a particular meaning to a text creating legal obligations of possibly uncertain meaning – Professor Anthony's view was strikingly different. Uncontroversially, he observed that for an agency to treat the view contained in its policy statement as hard law, legally binding on a private party and directly enforceable against it, would be a fundamental error; creation of a hard law obligation not itself imposed by statute or regulation, requires use of the notice-and-comment rulemaking procedures of 5 U.S.C. §553. But suppose, instead, soft law documents, *not* directly enforced

<sup>&</sup>lt;sup>17</sup> E.g., Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like -- Should Federal Agencies Use Them To Bind The Public?, 41 Duke L.J. 1311 (1992)

<sup>&</sup>lt;sup>18</sup> Nonlegislative Rules and the Administrative Open Mind, 41 Duke L. J. 1497 (1992).

<sup>&</sup>lt;sup>19</sup> 41 Duke L.J. at 1507.

<sup>&</sup>lt;sup>20</sup> Note 3 above.

against private parties, that agency staff could be expected to treat as internal administrative law constraining their actions, and/or that could strongly influence private conduct. He described such highly influential impacts, that 5 U.S.C. 552(a) appears to endorse so long as the policy statements have been published, as being "binding in practice." He argued that agencies must use §553 procedures for general statements of policy that are "binding in practice," as well as for those it treats as creating, in themselves, legal obligations. Only if the agency stated its general policy in terms indicating that it was not binding on itself or its employees – just a tentative position that its front-line employees need not honor and that was fully open to reconsideration – could the exemption for general policy statements be used. Professor Anthony gave as an example a boilerplate expression that had begun to appear in EPA guidance documents, although expressing understandable doubt about its one-sidedness and sincerity:

NOTICE: The policies set out in this [document] are not final agency action, but are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. EPA officials may decide to follow the guidance provided in this [document] or to act at variance with the guidance, based on an analysis of sitespecific circumstances. The Agency also reserves the right to change this guidance at any time without public notice.<sup>2</sup>

The problems here, fully developed in my earlier writings, 22 are the subject of the following section of these materials.

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

The "binding in practice" idea directly implicates a tension between the internal law of administration, that many scholars credit as a major force in securing the uniformity and predictability of administration, and constraints on uncontrolled exercises of discretion by agency bureaucrats – in a word, the rule of law<sup>23</sup> – and the world of unquestioned hard law. As

<sup>22</sup> Note 5 above.

<sup>&</sup>lt;sup>21</sup> Anthony, note 17 above, 41 Duke L.J. at 1361. Appalachian Power Co. v. EPA, 208 F.3d 1015 (D.C. Cir. 2000) is only one of the occasions on which the D.C. Circuit declined to credit such a disclaimer - finding, instead (and questionably in the author's view, see note 61 below) a hard law action that had required notice-and-comment rulemaking for its adoption.

 $<sup>^{23}</sup>$  Gillian E. Metzger, The Constitutional Duty to Supervise, 124 Yale L.J. 1836 (2015); Gillian E. Metzger & Kevin M. Stack, Internal Administrative Law, 115 Mich. L. Rev. 1239 (2017); Nicholas Parillo, ed., Administrative Law from the Inside Out: Essays on Themes in the Work of Jerry L. Mashaw (2018).

the following graphic and text from in my earliest writing on this subject may illustrate, "binding in practice" as a reason notice-and-comment rulemaking must be used tends to treat as a binary question an issue that has four possible outcomes.

	Gov't bound	Gov't not bound
Regulated party bound	A) Both parties bound	B) Regulated party only bound
Regulated party not bound	C) Government only bound	D) Neither party bound

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

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

"It is hard, on the other hand, to find desirable content to Box B, in which the citizen is bound but the government is not. Pronouncements like the Environmental Protection Agency (EPA) disclaimer Professor Anthony quotes seem the very antithesis of what we think of as the 'rule of law." <sup>24</sup>

One can find a recent example of the Box C phenomenon in the Supreme Court's recent decision in *Encino Motorcars*, *LLC v. Navarro*, <sup>25</sup> in which the Court held that a 1978 agency opinion letter (that is, a guidance document) had created private party reliance interests requiring an

<sup>25</sup> 136 S.Ct. 2117 (2016).

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<sup>&</sup>lt;sup>24</sup> Strauss, note 5 above, 41 Duke L. J. 1464-65 (footnotes omitted).

agency to give a reasoned explanation for change in it made by a subsequently adopted notice-and-comment regulation. Given the seriousness and consistency with which the agency had subsequently adhered to this opinion letter, that is, the agency had bound itself, had created law for itself that its insufficiently explained statement of basis and purpose in its notice-and-comment rulemaking had been ineffective to change.<sup>26</sup>

Encino did not hold that the notice-and-comment rulemaking the agency had in fact used would have been necessary to effect the desired policy change. Just a year earlier, in *Perez v. Mortgage Bankers*,<sup>27</sup> the Court had sharply repudiated a D.C. Circuit holding that change in an agency's interpretation of an existing regulation could only be effected by notice-and-comment rulemaking. The procedures required for the adoption of general statements of policy and interpretive rules are those stated by the APA – only publication, if soft law effects on private parties are in view. In Encino, then, the change of interpretation could have been effected by a new interpretive rule; but that change, too, would have required the kind of explanation the Court found missing, one that sufficiently and persuasively explained the basis for the change. The failure of adequate explanation for a change in the policy by which the agency had effectively bound itself was the fatal flaw in Encino; its use of notice-and-comment rulemaking to effect the change made judicial review uncontroversially available, but was not a necessary element of change. One could say that the two opinions, taken together, confirm Professor Funk's view that guidance documents/non-legislative rules<sup>28</sup> are never procedurally deficient, although they may be ineffective if not properly anchored in hard law documents to which they relate.

Nonetheless, at least in part as a consequence of the obstacles to review on the merits of guidance documents that are addressed in the next section of this essay, courts sustaining

See also Anastasoff v. United States, 253 F.3d 1054 (8<sup>th</sup> Cir. En banc 2000)(government statement of acquiescence in taxpayer-favoring ruling by one circuit required the same outcome in another – the government had bound itself). Professor Parrillo's influential empirical study, note 2 above, and the ACUS Recommendations resulting from it, ibid., recognize both the fact and the desirability of internal agency law of this nature, that operating staff will treat as binding for them, albeit open to waiver or alteration by their superiors on a demonstration of the need for that.

<sup>&</sup>lt;sup>27</sup> 135 U.S. 1199 (2015).

<sup>&</sup>lt;sup>28</sup> See note 1 above

challenges to guidance documents under the "binding in practice" rubric have generally done so on the basis of faulty procedure, holding that notice-and-comment procedures had been necessary. But then, as has been noted, agencies have the choice not to issue guidance, or to pretend to its unreliability, as in the EPA boilerplate Professor Anthony quoted. One readily agrees that statements that are "binding in practice" on the outside world, but ineffective internally – box B in the graphic above – are undesirable, insupportable. Yet forbidding actions fitting box C in the graphic above – internally hard law, but externally only the soft law evoked by "binding in practice" -- would leave to staff discretion (and consequent variation in administration) outcomes that could have been made predictable and uniform. Frequent actual use of notice-and-comment rulemaking for the ends now served by guidance is unlikely, given its significant resource and time costs. Agencies could act through adjudication – again at the considerable cost of abjuring timely notice to the regulated of agency views, since interpretations emerging through agency adjudica-tion, like those emerging through judges' statutory interpretations, are (if linguistically proper) applied retrospectively, to behavior that has already occurred.

If the agency has not made the fundamental error of treating its guidance as hard law for the outside world, then, discouraging its use of soft law would be unfortunate indeed. Requiring the relatively formal procedures of notice and comment rulemaking for advice that is intended to control staff actions and to be reliable for the public creates perverse incentives – either not to give such advice, or to accompany any advice given with prominent notices that it is *not* intended to bind agency personnel and may *not* be relied on by the public. Such notices now do appear frequently. Why one should wish such outcomes is beyond the author's ready understanding. Much better if guidance seriously given and intended (whether publicized instructions to staff about enforcement policies, indications of behaviors the agency will accept as compliance with its regulations, or other "soft law") is treated is open to reconsideration

within the agency,<sup>29</sup> and could be reviewed on the merits by those whose behavior may be seriously affected by it.

# IV. REVIEWING THE MERITS OF GUIDANCE DOCUMENTS

Agency use of guidance is readily reviewed, whether for procedural sufficiency or for its substantive acceptability, when reliance on the guidance has been an element of decision in a matter undeniably final, such as a notice-and-comment rulemaking or an on-the-record adjudication. The issues then concern the force the agency has given the guidance in that proceeding, and the extent (if any) to which courts should respect the judgments it embodies in determining its acceptability. But parties may also seek review of the guidance itself, before any such embodiment, asserting that it is an improper influence on their conduct, or fails responsibly to protect their interests as the agency's statutes require. For the general public that may fear being harmed by resulting private behaviors, as distinct from those regulated, pre-enforcement review may be all that could possibly be available, if the consequence of the guidance will be non-enforcement or an agency action in which they are unable to participate.<sup>30</sup> Here, the absence of a decision creating or formally enforcing hard law raises questions whether the guidance, in itself, has the "finality" and "ripeness" of decision that are requisite for securing review. The paragraphs following treat these issues in turn.

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

Agency interpretations of their constitutive statutes that are first voiced in guidance, and then relied upon in a notice-and-comment regulation or a formal adjudicatory decision are, on judicial review, entitled to review under the two-step process known as *Chevron* deference.<sup>31</sup> That entails, first, an independent judicial determination whether the statute is susceptible of the

<sup>&</sup>lt;sup>29</sup> Professor Parrillo's study and the ACUS recommendation resulting from it, note 2 above, suggest both the importance of and appropriate structures for this.

<sup>&</sup>lt;sup>30</sup> Parrillo, note 2 above, 36 Yale J. Reg. at 183.

<sup>&</sup>lt;sup>31</sup> Chevron, U.S.A., Inc. v. NRDC, 467 U.S. 837 (1984). Note that onb this hypothesis the guidance's interpretation has effectively been adopted by the agency and given the force of law – for itself as well as the outside world. The guidance itself would not be reviewed in the Chevron framework. United States v. Mead Corp., 533 U.S. 218 (2001).

meaning the agency has given it, and, second, a further decision (such as animates review under 5 U.S.C. §706(2)(A)) whether the agency appropriately reasoned to the choice it made, in relation both to the facts before it and to policies it may appropriately pursue.<sup>32</sup> As *Chevron* itself illustrates, and was more recently confirmed by *Perez*,<sup>33</sup> an agency is not permanently wedded to the first interpretation it may adopt; but its reasoning in adopting any interpretation it may make, within the space statutory language permits,<sup>34</sup> is an element of the judicial review of that interpretation.<sup>35</sup>

It is a separate question, one Professor Anthony elided, whether an agency relying on an interpretation voiced in guidance when deciding an adjudication or promulgating a rule must entertain arguments about its reasonableness in general, or in the particular proceeding. That is, may it treat the interpretation, issued informally, as binding upon disadvantaged private parties who later protest it in a subsequent, more formal proceeding? It is impossible to square that position with the language of 5 U.S.C. §552(a), which permits interpretive rules, as well as general statements of policy, to be "relied on, used, or cited as precedent by an agency against a party other than an agency" if they have been published. "Precedent" is inherently subject to reexamination in the proceeding in which it might be relied on, used or cited; it does not constitute "hard law" as constitution, treaty, statute and regulation do, and treating soft law as hard law – whether it is an interpretive rule or a general statement of policy – is a categorical

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<sup>&</sup>lt;sup>32</sup> Peter L. Strauss, A Softer, Simpler View of *Chevron*, 43 Admin & Reg Law News 7 (Summer 2018).

Note 27 above.

<sup>&</sup>lt;sup>34</sup> Peter L. Strauss, "Deference" is too Confusing – Let's Call Them "Chevron Space" and "Skidmore Weight," 112 Colum. L. Rev. 1143 (2012)

<sup>&</sup>lt;sup>35</sup> Note in passing the tension between this flexibility and the increasing tendency of the Supreme Court, when itself engaging in statutory interpretation, to treat statutory meaning as a static matter, determined by the language and expectations of the enacting legislature, and not subject to subsequent variation within the possibilities of contemporary meaning that language (and contemporary legal understandings) may suggest. Epic Systems Corp. v. Lewis, 138 S. Ct. 1612 (2018); See Peter L. Strauss, Resegregating the Worlds of Statute and Common Law, 1994 Supreme Court Review 427 (1995).

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

error. Professor Anthony never turned his attention to this element of the APA. Professor Funk saw this clearly eighteen years ago, when he wrote these words:

There is, I believe, a simple test for whether a rule is legislative rule or a nonlegislative rule: simply whether it has gone through notice and comment rulemaking. Thus, any substantive rule adopted without notice and comment and without a finding of good cause for avoiding notice and comment must of necessity be a nonlegislative rule. It may still be an invalid nonlegislative rule on the merits, such as by interpreting the law erroneously, but it is not invalid procedurally. Moreover, if an agency gives a nonlegislative rule binding, legal effect, then the agency has acted unlawfully, not because the nonlegislative rule was an invalid legislative rule, but because the nonlegislative rule cannot have the legal effect the agency accorded it.<sup>37</sup>

What it means to "give[] a nonlegislative rule binding, legal effect" is a separate question, already addressed. Here, too, there can be a "simple test" – whether the agency has treated a nonlegislative rule as, in itself, the direct source of the legal obligation it is enforcing – and my view that this is the appropriate test, essentially excluding the idea of "binding in practice" for the outside world, would not prevail in the D.C. Circuit or for many scholars. But on the quoted proposition I believe we all agree.

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

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<sup>&</sup>lt;sup>37</sup> William Funk, A Primer on Non-Legislative Rules, 53 Admin. L. Rev. 1321, 1324-25 (2001).

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

Readers will quickly recognize that the question here concerns the controversy over socalled Auer deference, highly controversial in recent years and likely to have been resolved by the Supreme Court in Kisor v. O'Rourke<sup>38</sup> by the time this essay has been published. Auer appears to limit judicial inquiry on the merits of an agency's interpretation not of a statute, but of its own regulation, to the equivalent of *Chevron*'s first step – the question whether the agency's regulation could possibly bear the interpretation the agency has given it. And the Supreme Court's recent decision in *Perez*<sup>39</sup> (which featured several separate opinions questioning *Auer*) makes clear that agencies are not bound by the first interpretation they may give to their regulations, but are free to change those interpretations, within the possibilities that regulatory language permits (and, as Encino<sup>40</sup> holds, with demonstrable reasons for the change). Unsurprisingly, the range of scholarship on Auer and its predecessor Seminole Rock<sup>41</sup> has been great, <sup>42</sup> and its treatment in this essay must be summary. Supporters of *Auer* point to an agency's vastly superior and integral knowledge of its regulations and their bearing on its continuing responsibilities; to the consequence of preferring to have regulations stated as standards to be attained rather than rules to be rigidly adhered to in inviting changes in policy within the framework they establish as social and technical understandings alter; to an agency's incentives to be as clear as possible to those it regulates in the current day; and to the sluggishness of the rulemaking process. Critics fear that Auer's strong deference invites the outcomes Professor Anthony so feared – vacuous regulations structured to permit future interpretations that

S.Ct. --- (2018) (certiorari granted sub nom. Kisor v. Wilkie, Dec. 10, 2018).

Note 33 above.

<sup>&</sup>lt;sup>40</sup> Note 27 above.

<sup>&</sup>lt;sup>41</sup> Bowles v. Seminole Rock & Sand Co., 345 U.S. 410 (1945).

<sup>&</sup>lt;sup>42</sup> Interested readers can get a start into it in an online symposium with 30 contributors, Reflections on *Seminole Rock*: The Past, Present, and Future of Deference to Agency Regulatory Interpretations, available at <a href="https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2847668">https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=2847668</a> (September 2016).

effectively change governing law without the need for notice-and-comment rulemaking.<sup>43</sup> At least when Congress drafts imprecise language it is aware that under *Chevron* it is transferring law-making authority to a body it can at best imperfectly control,<sup>44</sup> giving it an incentive to be as precise as it can be in drafting; agencies drafting regulations that leave their staffs room for future maneuver experience no similar incentive, and for *Auer*'s critics the temptation to avoid the considerable costs of notice-and-comment rulemaking will be high. Professor Funk's experience at the Department of Energy led him to see reality in both sides of this dispute, as more recently has Professor Parrillo<sup>45</sup> – when DoE drafted regulations, providing clarity of obligation for the regulated was its major incentive; but if unforeseen issues subsequently arose that permitted a choice between interpreting an existing regulation and engaging in new rulemaking, the high costs and time dimensions of notice-and-comment rulemaking encouraged interpretation.<sup>46</sup>

Daniel Walters's recent empirical study published in the Columbia Law Review,<sup>47</sup> measuring regulatory slack in a variety of ways, favors *Auer*'s proponents, concluding that *Auer* deference has had no measurable impact on the extent to which agencies are less precise in regulatory drafting than arguably they could be. Although the argument that *Auer* might provide an incentive for capacious drafting has theoretical legs, careful linguistic analysis revealed no

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<sup>&</sup>lt;sup>43</sup> As noted above, note 2, recent empirical work refutes this claim. Daniel Walters, The Self-Delegation False Alarm: Analyzing *Auer* Deference's Effect on Agency Rules, 119 Colum. L. Rev. 1 (2019)("agencies did not measurably increase the vagueness of their writing in response to Auer. If anything, rule writing arguably became more specific over time"); see also Nicholas Parrillo, Federal Agency Guidance and the Power to Bind: An Empirical Study of Agencies and Industries, 36 Yale J. Reg. 165 (2019).

Abbe Gluck & Lisa Bressman, Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation, and the Canons, 65 Stan. L. Rev. 901 (2013) and 66 Stan. L. Rev. 725 (2014).

<sup>&</sup>lt;sup>45</sup> Note 43 above.

William Funk, Why SOPRA is not the Answer, in Symposium. Note 42 above ("Professors Sunstein and Vermeule have in their blog here and in their Chicago Law Review article [The Unbearable Rightness of *Auer*, 84 U. Chi. L. Rev. 297 (2017)] provided their policy reasons for why they believe *Auer* should be retained. I will not add to that debate except to second, on the basis of my experience as a government lawyer writing regulations, their belief that *Auer* does not in fact result in agencies writing vaguer regulations than they otherwise would. ... Unlike the incentive to write ambiguous regulations in order to retain flexibility for later interpretation, for which there is no empirical support for agencies acting on that basis, the incentive to avoid notice-and-comment rulemaking is strong, and there is a wealth of empirical support for the fact that agencies indeed try to cut corners, especially given the number of cases challenging agency interpretive rules as improperly adopted legislative rules.")

<sup>&</sup>lt;sup>47</sup> Note 43 above. Several posts in the Symposium, note 42 above, are to similar effect.

such effect. One might, as he briefly recognizes, think his findings compromised by the data set he relies on for his analysis, the genuinely important (OIRA "significant") rules that face both the most demanding scrutiny within government, under the Executive Order process, and the highest prospect of intense ("hard look") judicial review. This is a setting in which effort and precision are likely to be maximized. Yet other elements of his analysis point in the same direction – that agencies, like other human institutions, will value immediate, short-term outcomes over providing for longer-term uncertainties (uncertainties that might fall into the hands of political opponents). Achieving present regulatory ends will ordinarily conduce to achievable precision.

Nonetheless, as Professor Funk reported experiencing at DoE, resource constraints (and the impossibility of foreseeing all possible future situations) will limit today's rule-drafting efforts in ways that might permit responding with new interpretations, in lieu of fresh rulemaking, in the future. So too, when agencies draft regulations with the often preferred end of setting standards to be achieved rather than specifying particulars in rules. In the statutory context, inquiries into excessive delegation are frustrated by the absence of judicially manageable standards for assessing the adequacy of legislative effort. Yet one might think courts more capable of measuring the adequacy of the regulatory effort that created the potential for subsequent guidance than they are of measuring the adequacy of statutory effort creating the potential for regulations. Courts asking such a question would not face the political issues associated with telling Congress how well or poorly it has done its job; and the intensity of rulemaking review – well known to agencies and a strong incentive to careful drafting – is itself a signal of that. The extensive agency explanations of their reasoning now commonplace in adopting regulations, no longer "concise, general statements of basis and purpose," in themselves

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<sup>&</sup>lt;sup>48</sup> E.g., Mistretta v. United States, 488 U.S. 361, 416 (Scalia, J., dissenting); see Whitman v. American Trucking Ass'ns, Inc., 531 U.S. 437 (2001).

can provide a framework for constraining the range of possible future interpretations, a framework that is simply unavailable in the statutory context.<sup>49</sup>

The extent of overall agency effort was important to the decision in *Shalala v. Guernsey Hospital*, <sup>50</sup> briefly mentioned in Prof. Walters's analysis. There, the Court remarked that the revised interpretation challenged in that case had addressed only one element of a highly complex set of rules, in the formulation of which considerable administrative energy had been spent. Similarly, one could view the controversy involved in *Hoctor v. U.S. Dept. Agriculture*, <sup>51</sup> frequently invoked in Professor Funk's discussions of guidance questions, as having been one element of a highly complex set of rules about structural integrity in animal breeding – reaching many species, and for common ones (cattle, cats, hamsters) in considerable detail; that issues about raising lions, tigers and leopards were less precisely dealt with, in that context, was hardly surprising. <sup>52</sup> The Department, moreover, had made the fundamental mistake of accusing Hoctor of violating its 8-foot standard rather than the regulatory requirement to provide a structurally sound containment, thus treating its guidance as if it were hard law. The department's regulatory requirement could properly have been informed by the guidance, 5 U.S.C. §552(a)(2), but it was an elementary error to rely on the guidance as if it stated a legal obligation. <sup>53</sup>

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

Appropriately in the author's judgment, *Shalala*, note 50 above, suggests that the important consideration here is the extent of the agency's overall effort. Dogs and monkeys are extensively bred commercially, and the court should have accepted the regulations' lacunae for species much less commonly bred. From this perspective, the Department's use of its guidance would have been acceptable, *if* it had used it as soft, and not hard, law.

<sup>&</sup>lt;sup>49</sup> Kevin Stack, Interpreting Regulations, 111 Mich. L. Rev. 355 (2012)

<sup>&</sup>lt;sup>50</sup> 514 U.S. 87 (1995).

<sup>&</sup>lt;sup>51</sup> 82 F.3d 165 (7<sup>th</sup> Cir. 1996).

<sup>&</sup>lt;sup>52</sup> Judge Posner's concluding paragraph in his *Hoctor* opinion notes that

<sup>&</sup>lt;sup>53</sup> In his illuminating discussion of *Hoctor*, Jacon E. Gersen, Legislative Rules Revisited, 74 U.Chi. L. Rev. 1705, 1719 (2007), Prof. Gersen stresses this aspect.

It seems possible, despite Professor Walters's findings and analysis, that the theoretical concern persuasively invoked by the analysis of Harvard Law School's Dean John Manning<sup>54</sup> will lead the Court to reformulate the approach courts should take when presented with an agency's interpretations of its own regulation. One hopes that the Justices, informed by *Perez*,<sup>55</sup> will then avoid any suggestion that the meaning of regulations, once adopted, is necessarily static,<sup>56</sup> or that courts should interpret regulations' meaning wholly independent of agency views. More readily understood would be indications that the possibilities of interpretation are limned not only by the regulation's language, but also by the explanations given in its accompanying statement of basis and purpose;<sup>57</sup> that the agency's responsibilities and awareness of the universe of its governing law entitles it to the respect the Court has accorded administrative views over the whole course of its history<sup>58</sup> – now encapsulated in the formulation Justice Jackson famously stated in *Skidmore v. Swift & Co.*;<sup>59</sup> and, finally, that the reasonableness/acceptability of the present interpretation is to be assessed in relation to the explanation the agency has contemporaneously given for having changed its view of the regulation's meaning and application.<sup>60</sup>

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

Given the requirement of "finality" for merits review of agency action, courts facing challenges to seriously intended guidance have often used "binding in practice" formulations to hold that its adoption had required notice-and-comment rulemaking. This passage from *Appalachian Power Co. v. EPA* <sup>61</sup> reflects reasoning often used:

<sup>&</sup>lt;sup>54</sup> John Manning, Nonlegislative Rules, 72 Geo. Wash. L. Rev. 893 (2003).

<sup>55</sup> Note 33 above.

<sup>&</sup>lt;sup>56</sup> See note 35 above; but cf. Jeffrey A. Pojanowshi, Revisiting *Seminole Rock*, 17 Georgetown J. Lw & Pub. Pol. 87 (2018).

<sup>57</sup> See Stack, n. 49 above.

<sup>&</sup>lt;sup>58</sup> Peter L. Strauss, In Search of Skidmore, 83 Fordham L. Rev. 789 (2014).

<sup>&</sup>lt;sup>59</sup> 323 U.S. 134 (1944).

<sup>&</sup>lt;sup>60</sup> Encino Motorcars, LLC, note 25 above; cf. Jerry L. Mashaw, Reasoned Administration and Democratic Legitimacy (2018).

<sup>&</sup>lt;sup>61</sup> 208 F.3d 1015 (D.C. Cir 2000); see text at note 21 above..

If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes "binding." 62

The understood implication is that notice-and-comment procedures are then required. Yet in the context of Judge Randolph's opinion, this passage was merely dictum. In subsequent passages he properly found both that the EPA guidance at issue in the case had been final agency action<sup>63</sup> – hence reviewable on its merits – and that because, on the merits, the guidance did not reflect a reasonable meaning of the regulation it purported to interpret, it was improper as an interpretive rule.<sup>64</sup> Finding, on the merits, that a regulation cannot support the interpretation given it is wholly appropriate and, as already indicated, insufficient agency effort when adopting the interpreted regulation might be one basis for such a finding. One can understand the quoted passage simply as a means of rejecting the EPA's boilerplate denial of finality,<sup>65</sup> that had been prompted by earlier judicial holdings requiring notice and comment rulemaking in lieu of interpretive rules or general policy statements courts concluded were "binding in practice."

The difficulties arise when, unlike Judge Randolph, courts use the criteria he stated to support finding guidance documents *not* to be final but *nonetheless* "binding in practice," and then conclude that notice-and-comment rulemaking had been required, vacating the agency action without ever reaching the merits.<sup>66</sup> The result is to discourage an agency's formulation of the internal administrative law to be found in box C of the graphic above. To be sure, an agency that "treats the document in the same manner as it treats a legislative rule" clearly errs; soft law

<sup>&</sup>lt;sup>62</sup> At 1021.

<sup>&</sup>lt;sup>63</sup> At 1023 ("The short of the matter is that the Guidance, insofar as relevant here, is final agency action, reflecting a settled agency position which has legal consequences both for State agencies administering their permit programs and for companies like those represented by petitioners who must obtain Title V permits in order to continue operating. Appalachian Power.")

<sup>64</sup> At 1028.

Note 21 above.

<sup>&</sup>lt;sup>66</sup> One can identify a similar difficulty in Professor Franklin's account of Appalachian Power. Op. Cit. n. 8 above, 120 Yale L. J. at 302. CNIRecognizing that Judge Randolph had indeed found the guidance document in that case to have been final, he fails to see this as opening the possibility of review on the *substantive* merits (as Judge Randolph did see it) and like others treats the quoted language as having been us as a test for required procedure rather than finality.

cannot be used as hard law. Yet an agency acting "as if a document issued at headquarters is controlling in the field" is revealing its internal administrative law. 67 So too, is an agency that "bases enforcement actions on the policies or interpretations formulated in the document," or that indicates particular courses of conduct it has determined will satisfy a standard created by a regulation that intentionally defined parameters to be achieved, rather than the manner of achieving them, in order to permit the regulated to create their own means of satisfying the standards if so moved. Having internal administrative law effective and known to all conduces to regularity and predictability in agency action, essential elements of the "rule of law." Knowing an agency's internal administrative law has great value to those it regulates, to those it is responsible to protect, and to the public and political overseers, Congress and President. Given their limited resources, agencies cannot be expected often to engage in notice-and-comment rulemaking to adopt their internal administrative law, and the APA is clear that they are not required to. Thus, the realistic alternatives to having seriously intended guidance documents is leaving discretion unstructured – permitting field agents to reach their own, varying and probably secret understandings of the agency's regulatory requirements; enforcing those requirements for reasons that may be secret and unpredictable; and leaving the regulated on their own to find the means of complying with regulatory standards. All of these impacts reflect departures from the rule of law.

Is lack of finality in guidance documents, whether proclaimed by them or simply inferred as a characteristic of soft law, an insuperable obstacle to merits review? *Appalachian Power* properly discredited that claim in a context in which it was demonstrable that a soft law document represented a firm agency judgment having substantial impacts on the actions of the regulated and of state agencies. And that soft law measures *inherently* lack finality was famously repudiated in Judge Harold Leventhal's decision in *National Automatic Laundry & Cleaning* 

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<sup>&</sup>lt;sup>67</sup> "An agency could properly hope that 'a document issued at headquarters [would be regarded by its staff as] controlling in the field'—that is perhaps the most important reason why guidance documents are issued." Peter L. Strauss, Administrative Justice in the United States 354 (3d Ed., 2016, emphasis in original), remarking that the Supreme Court has recognized this beneficial effect, United States v. Mead, 533 U.S. 218 (2001).

Council v. Schultz.<sup>68</sup> Here, the Department of Labor's bureau responsible for administration of the Fair Labor Standards Act, controlling employers' obligations respecting working hours and overtime pay for certain classes of employees, had responded to a request for advice about the Act's application with an opinion letter. The bureau wrote about 750,000 opinion letters annually, but fewer than 1.5% of them, including the one challenged, were issued over the Administrator's signature. That usage made the letter likely to be profoundly influential on employers' conduct (i.e., binding in practice, but not binding as a matter of law), "presumptively final." The absence from the letter of any indication that the views it expressed were tentative persuaded Judge Leventhal that it was reviewable final action; addressing the merits, he upheld the agency's action.

Professor Funk's very recent scholarship<sup>69</sup> addresses the issues of finality in soft law guidance documents and, like my own,<sup>70</sup> concludes that finding finality in soft law meeting Judge Randolph's *Appalachian Power* tests, followed by review on the merits, is far preferable to the alternative too often used – denying finality and then, without reaching the merits, finding that notice-and-comment rulemaking had been required. The D.C. Circuit has regularly found an obstacle to "finality" in the second leg of a two-part test articulated in the Supreme Court's decision in *Bennett v. Spear*,<sup>71</sup> that agency action must be both "the consummation of the agency's decision-making process" *and* a decision by which "rights or obligations have been determined" or from which "legal consequences will flow."<sup>72</sup> But as Professor Funk's analysis<sup>73</sup> of the Supreme Court's 2016 decision in *U.S. Army Corps of Engineers v. Hawkes*<sup>74</sup> persuasively shows, *Bennett*'s test is a sufficient, but not a necessary test of formality. The Corps judgment

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<sup>&</sup>lt;sup>68</sup> 443 F.2d 689 (D.C. Cir. 1971).

<sup>&</sup>lt;sup>69</sup> Final Agency Action After Hawkes, 11 New York University Journal of Law & Liberty 285 (2017); Make My Day! Dirty Harry and Final Agency Action, 46 Env. L. 313 (2016).

Note 5 above

<sup>&</sup>lt;sup>71</sup> 520 U.S. 154, 177-78 (1997).

<sup>&</sup>lt;sup>72</sup> E.g., Center for Auto Safety v. NHTSA, 452 F.3d 798 (D.C. Cir. 2006); National Mining Ass'n v. McCarthy, 758 F.3d 243, 250-51 (D.C. Cir. 2014).

<sup>73</sup> Note 69 above.

<sup>&</sup>lt;sup>74</sup> 136 S. Ct. 1807 (2016).

sought to be reviewed in *Hawkes* would, if favorable to him, have created a safe harbor from EPA enforcement under the Clean Water Act; denied, as it was in an informal proceeding, it signified only that if Hawkes pursued the course of action he wanted to, EPA might seek to enforce the CWA against it, in a proceeding in which the Act's proper application would have been an issue. Treating the Corps' "denial of the safe harbor" as final, the Court said, "tracks the 'pragmatic' approach we have long taken to finality." Government actions fitting Box C in the preceding graphic, then, as the culmination of an agency's decision-making process, binding the government but not private parties, may be found to be "final." In effect, Judge Leventhal's approach in *National Automatic Laundry & Cleaning Council*<sup>75</sup> has been sustained.

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

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Note 68 above.

<sup>&</sup>lt;sup>6</sup> 387 U.S. 136 (1967)

<sup>&</sup>lt;sup>77</sup> Note 68 above.

serious and disadvantageous behavior by the regulated – the kind of showing that would warrant declaratory judgment in the context of pre-enforcement review of the validity of a statute or regulation –judicial review of its substantive merits, if achievable, would be preferable to requiring procedures that the APA explicitly states that giving influential (and valuable, desirable) public notice of agency interpretations and policies does not require.

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

One of the signal advantages of pre-enforcement review is that it permits review by regulatory beneficiaries claiming that the agency has erred in failing adequately to protect their interest. Consider, for example, the sharply criticized<sup>78</sup> D.C. Circuit opinion in *Community Nutrition Institute v. Young*, <sup>79</sup> that found notice-and-comment rulemaking required for enforcement guidance the FDA had issued to its staff setting a concentration level of aflatoxin in shipped grain that should lead them to seize the shipment. Aflatoxin is a naturally occurring carcinogen inevitably present to some degree in dried grain; like many such substances, no absolutely safe level of presence is known, but its health effects vary with concentration and at very slight levels those costs are overcome by the benefits of having a supply of grain. CNI thought the declared level too high, excessively threatening human health – and perhaps also that

<sup>&</sup>lt;sup>78</sup> Richard Thomas, Prosecutorial Discretion and Agency Self-Regulation, CNI v. Young and the Aflatoxin Dance, 44 Admin. L. Rev. 131 (1992).

<sup>&</sup>lt;sup>79</sup> 818 F.2d 943 (D.C. Cir. 1987).

having a level declared would encourage shippers to mix the bad with the good, to create a level of contamination FDA inspectors would tolerate. Ordinarily, one might think, review of agency enforcement choices would be precluded;<sup>80</sup> and one might also believe public administration the better, not the worse, for letting both the regulated and the public health community know what levels of an unavoidable carcinogen constituent of grain the FDA had told its staff warranted regulatory action. For the D.C. Circuit, this guidance, "binding in practice" given its impact on staff actions, required notice-and-comment rulemaking. FDA could publicly give its staff this guidance only at that significant cost.<sup>81</sup> How much better it would have been to treat its character as internal administrative law as sufficient to make the action "final," permitting merits review if declaratory judgment standards had been met – as for CNI one could believe they had been.<sup>82</sup>

So also for the enforcement directions involved in the challenge to the Department of Homeland Security's guidance respecting the treatment of illegally present immigrants whose lengthy presence in the United States had otherwise been innocent, challenged by Texas in *Texas v. DHS.*<sup>83</sup> The lower courts found notice-and-comment rulemaking to have been required, a result affirmed without opinion by an equally divided Supreme Court. Standing was no issue for Texas, and the circumstances readily met the *Abbott Laboratories* declaratory judgment standards of ripeness. Clearly the program amounted to internal administrative law – and if it had been accepted as "final" for that reason, the merits could have been reached on judicial review, without casting unwarranted procedural doubt on an important tool of administrative action, explicitly recognized in the APA.

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<sup>&</sup>lt;sup>80</sup> Heckler v. Chaney, 470 U.S. 821 (1985).

<sup>&</sup>lt;sup>81</sup> In a concurrence and partial dissent, Judge Kenneth Starr made what many see as the first statement of Professor Funk's (and others') argument that the agency procedural choice controls the force its pronouncement may legally be given in other proceedings. "must the agency merely show that the pronouncement has been violated or must the agency, if its hand is called, show that the pronouncement itself is justified in light of the underlying statute and the facts." At 952.

Treating the guidance as final would have permitted CNI to put the reasonableness of the 20-parts-per-billion enforcement guidance to the test on pre-enforcement review; as Professor Franklin remarks, note 8 above, 120 Yale L. J. at 309, Judge Starr failed to see this consequence, reasoning only that a shipper against whom the FDA had brought an enforcement action could do so.

<sup>83 809</sup> F. 3d 134 (5<sup>th</sup> Cir. 2015) aff'd 136 S.Ct. 2271 (2016).

Meeting those standards is the easier when the regulated have complaints about guidance documents that put them directly in the path of enforcement actions. In Alaska Professional Hunters' Ass'n v. FAA, 84 a case perhaps involving the "one bite" doctrine disapproved in Perez, Under interpretations given by the local FAA office, Alaskan bush pilots had for years been free of FAA regulations applicable to commercial flights. FAA's central office, after considerable discussion with those affected (in effect, a kind of informal notice-and-comment procedure not unlike the FDA's Good Guidance practices), concluded that the regulations (that needed no change in their terms to be so interpreted) did apply. Undoubtedly this constituted internal administrative law, and was final in that perspective; the bush pilots might then have had judicial review of the merits of the change, as in *Encino Motorcars*. Notice, too, that here FAA's central Washington office was correcting what it had determined, after consultation with those affected, to have been an error of judgment in the field; to have required notice-and-comment procedures to do so amounted to finding a measure of estoppel created by subordinates' judgments, a result generally avoided. 85 Hoctor presented similar problems; Hoctor had been advised by a local Department of Agriculture official that a 6-foot fence would suffice to meet the Department's rule about structural integrity for his large cat "farm" (doubtless, in the circumstances, more a protection for local livestock and children outside the fencing than for animals within it). The 8foot guidance from Washington, then, impugned that advice; one would not ordinarily think the Department estopped in his case, albeit it was not entitled to treat "8 feet" rather than "structural integrity" as defining the issue on actual enforcement.

Consider also *U.S. Chamber of Commerce v. Dep't of Labor*, <sup>86</sup> in which the D.C. Circuit found notice-and-comment rulemaking to have been required for the Department's announcement of a program identifying a significant number of employers having demonstrably hazardous workplaces who, on agreeing to cooperate with safety guidance provided to them,

<sup>84 177</sup> F.3d 1030 (D.C. Cir. 1999).

<sup>&</sup>lt;sup>85</sup> Federal Crop Ins. Co. v. Merrill, 332 U.S. 380 (1947); Office of Personnel Management v. Richmond, 496 U.S. 414 (1990)

<sup>&</sup>lt;sup>86</sup> 174 F. 3d 206 (1999).

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

Finally, consider in this light a pair of D.C. Circuit opinions in seeming tension with one another, such as can animate an administrative law casebook. <sup>87</sup> *General Electric Co. v. EPA* <sup>88</sup> and *Center for Auto Safety v. NHTSA*. <sup>89</sup> In the first, EPA had developed detailed regulations for remedying contamination by polychlorinated biphenyls (PCBs), a potent carcinogen widely used

<sup>&</sup>lt;sup>87</sup> E.g., Peter L. Strauss et al., Gellhorn & Byse's Administrative Law Cases and Comments 365, 368 (12<sup>th</sup> Ed., 2018).

<sup>&</sup>lt;sup>88</sup> 290 F. 3d 377 (D.C. Cir. 2002).

<sup>&</sup>lt;sup>89</sup> 452 F.3d 798 (D.C. Cir. 2006).

before discovery of its toxicity, whose manufacture in the US is now forbidden, and its continued use heavily regulated by the Toxic Substances Control Act. The extensiveness of PCB use, for example in capacitors and electric power transformers, has made contamination of buildings, soil and water common, and the regulations, in general, prescribed acceptable methods for cleanup and disposal both of PCB bulk product waste, and PCB remediation waste. General Electric's extensive use of PCBs in its manufacturing processes and consequent disposal of them as waste had resulted in extensive contamination of the Hudson<sup>90</sup> and Housatonic<sup>91</sup> Rivers, creating expensive clean-up obligations and actions that endured long past this litigation. 92 For GE (and other large industrial users), it could be anticipated that the generic methods prescribed by the regulations would be unsatisfactory, and so a separate section invited applications to use different methods that would demonstrably avoid "unreasonable risk of injury to health or thee environment. Taken as a whole, note, this approach fully reflected a preference for setting standards permitting alternative means of compliance that could be demonstrated to meet them. EPA then published an extensive guidance document indicating its views how such a showing could be made, and alternative measures that in its judgment would permit granting such an application. This was unquestionably a final agency action, in the sense that the agency had bound itself to accept the showings its guidance indicated; GE did not attempt an application, but challenged the guidance as being "binding in practice." That the agency had indicated acceptable means of compliance, and bound itself to accept a demonstration that they had been met, the court held without reaching the merits, required notice-and-comment rulemaking. Confronting final action, why could the merits not be reached?

In *Center for Auto Safety*, NHTSA had issued policy guidelines indicating when it would accept regional recalls for manufacturing defects where the issues prompting the recalls were

 $<sup>^{90}\</sup> http://www.epa.gov/Region2/superfund/npl/0202229c.pdf$ 

<sup>91</sup> http://www.epa.gov/NE/ge/sitehistory.html.

See, e.g., <a href="https://www.timesunion.com/tuplus-local/article/Decades-of-contamination-at-General-Electric-s-8343571.php">https://www.timesunion.com/tuplus-local/article/Decades-of-contamination-at-General-Electric-s-8343571.php</a> (Albany Times-Union, July 7, 2016) and <a href="https://www.nytimes.com/2016/09/09/nyregion/general-electric-pcbs-hudson-river.html">https://www.nytimes.com/2016/09/09/nyregion/general-electric-pcbs-hudson-river.html</a>.

most likely to be presented in some but not all parts of the United States. Examples might be corrosion defects unlikely to occur in states not using road salt to de-ice roads during winter weather, or in states where sustained high humidity would not be present. Its administrators encouraged automakers to comply with the guidelines, and brought no enforcement actions requiring wider recalls in circumstance in which they had been followed. The Center challenged the guidelines as having to be adopted by notice-and-comment rulemaking. Reasoning from *Bennett*, the court reasoned that while the guidelines did mark the end of the agency's decisionmaking process, they neither determined rights or obligations nor resulted in legal consequences – and hence were not final and review of them could not be had. Here, too, the suggested approach would find finality in the high level and importance of the agency's action, then perhaps reaching questions of the Center's standing and the ripeness of its claims – but questions that go to the merits, not procedural requisites.

The two cases, then, reflect a binary approach in which, if review is available it is to determine what procedures were requisite – no review at all for guidance that is not "binding in practice," and procedural rigor if it is. The consequence, again, is to invite boilerplate such as EPA had used in *Appalachian Power* that either rewards agency disingenuousness<sup>93</sup> or results in procedural requirements the APA denies. Treating demonstrably serious, high-level guidance as final because of its effects on agency function, Judge Leventhal's approach apparently sustained in recent Supreme Court actions, permits judgments then about the suitability of declaratory judgment on the merits – aka "ripeness" – an outcome that validates the APA's acceptance of published guidance as permissibly influential on private conduct, and avoid discouraging the use of an administrative technique valuable for its contribution to agency regularity and predictability, and to public knowledge of its policies.

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Professor Franklin reports, Op. Cit. n. 8 above, 120 Yale L.J. at 302 n. 143, that EPA responded to Appalachian Power by adding additional disclaimers to guidance documents, citing Cement Kiln Recycling Coal v. EPA, 493 F.3d 207, 228 (D.C. Cir. 2007).

Were this done, agencies might find in the outcome a reason to invite the public participation in guidance formulation already instinct in FDA Good Guidance practices, OIRA oversight of significant guidance, ACUS recommendations, and thoughtful writing about it.94 Hoctor's 8-foot fence, CNI's 20 parts per billion threshold for aflatoxin contamination, and EPA's definitions of alternative toxicity factors for PCB contamination<sup>95</sup> all set possibly arbitrary cut-off lines between the tolerable and the intolerable – the kinds of lines legislatures set by votes and courts are incapable of themselves providing, 96 relying instead upon demonstrated agency expertise/ration-alization to sustain. Each of these lines, note, could be complained of from either side - area residents might think 8 feet too low to protect their children, shippers 20 parts per billion too high to permit shipments of healthy, nutritious grains, residents of Pittsfield, Massachusetts the permissible toxicity factors too generous to protect their health. Given finality and pre-enforcement review, agencies would understand they might need to defend those judgments on their merits from either side – encouraging, at the least, the development of supporting internal data-bases and explanations based upon them (as well as the necessary willingness to consider alternative showings in the event of resisted enforcement). Where the stakes are high enough, consultation with those affected is to be expected, and one's sense is that, as in Alaska Professional Hunters Ass'n<sup>97</sup> and as since urged by the White House and ACUS, it often occurs. And the agency that has set such levels without using the APA's procedures to do so, absent a clear explanation of its basis for doing so grounded in the information it possesses, might find itself facing an appropriately high level of judicial skepticism. 98 What ought not be faced, however, absent the actual legal effect that can be

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<sup>&</sup>lt;sup>94</sup> E.g., Cass R. Sunstein, note 7 above and David Franklin, note 8 above. Neither author, however, associates the possibility of pre-enforcement review with merits review, as this essay attempts.
<sup>95</sup> 290 F.3d at 378.

<sup>&</sup>lt;sup>96</sup> Cf. Gersen, note 53 above and American Trucking Ass'ns v. EPA, 175 F.3d 1027 (D.C. Cir. 1999), reversed sub nom. Whitman v. American Trucking Ass'ns, Inc., 531 U.S. 457 (2001).
<sup>97</sup> Note 84 above.

<sup>&</sup>lt;sup>98</sup> Consider the impact of the failure to make and explain findings in the highly informal administrative processes involved in Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402 (1971), a 27-day trial on remand, testing the basis for the decision under review.

associated only with regulations, is a demand for notice-and-comment procedures. "There is a reasonable ... argument that the balance of considerations usually argues in favor of allowing a period for notice-and-comment, certainly for significant guidance documents. But as a matter of law, things are much more straightforward. The practically binding test is an unacceptable departure from any plausible reading of the APA."

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<sup>99</sup> Sunstein, note 7 above, 68 Admin. L. Rev. at 516.